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THE ETHICAL CHALLENGE FOR HIPAA'S PRIVACY RULE IN THE GENOMICS ERA  
OF DATA ANALYTICS

A Dissertation

Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

As a partial fulfillment of the requirement for

The degree of Doctor of Philosophy

By

Reem Shinawi, MSc, MA

2020

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Reem Shinawi, MSc, MA

2020

THE ETHICAL CHALLENGE FOR HIPAA'S PRIVACY RULE IN THE GENOMICS ERA  
OF DATA ANALYTICS

By

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Approved November 4, 2020

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## ABSTRACT

# THE ETHICAL CHALLENGE FOR HIPAA'S PRIVACY RULE IN THE GENOMICS ERA OF DATA ANALYTICS

By

Reem Shinawi

December 2020

Dissertation supervised by: Dr. Gerard Magill

The thesis of this dissertation focuses on the Ethical Challenge for HIPAA's Privacy Rule in the Genomics Era of Data Analytics. HIPAA laws are studied within the clinical and research settings. The same form of studies is used to show the contrast in HIPAA's coverage over Genomic Medicine field with the inevitable use of data analytics technologies. The limitations to HIPAA's Privacy Rule will require HIPAA to have a sounder revision to its final rule to focus on the privacy of genetics and its related fields. Moreover, to consider revising its approach to population privacy protection instead of individual privacy protection.

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## **Chapter 1 Introduction**

The thesis of this dissertation focuses on the Ethical Challenge for HIPAA's Privacy Rule in the Genomics Era of Data Analytics. The discussion deals with treatments and research in Genomic Medicine that requires Data Analytics across populations. The thesis is explained in Chapter One that introduces the analysis. The direction of the analysis is to explain the ethical significance of HIPAA's Privacy Rule regarding consent, both in clinical ethics and in research ethics (chapters two, three and four). Having established the ethical bedrock of privacy based on HIPAA's requirements, the final chapter discusses the ethical challenge for HIPAA with regards to privacy insofar as Genomic medicine requires Data Analytics to be used across populations. Each of these can be explained in a little more detail to explain the chapter sequence.

Chapter two explores the relationship between privacy and consent. First, this relation is explained by examining the correlation between consent and law from a multi-cultural perspective. Second, the relation is furtherly described through debating the connection between consent and substituted judgment. The conclusions of the chapter summarize the core issues that emerge in relation to Privacy regarding HIPAA's focus on this topic. Chapter three studies privacy in two different settings. On the one hand, it tackles privacy issues on abortion; on the other hand, it studies privacy related to mandatory vaccination under the umbrella of Public Health. The outcome of the arguments sums up the privacy issues in the clinical field while examining HIPAA's privacy rules regarding those issues. Chapter four explores privacy within the Research arena. The chapter begins the discussion on research with children. Then it continues through understanding the issues related to the sharing of benefits with research participants. Finally, chapter five shifts the focus from the current emphasis on individual privacy in HIPAA to the emerging focus upon populations in Genomic Medicine that uses data

Analytics. Several points are explored. First, privacy matters are examined within the practice of pre-implantation genetic diagnosis (PGD) for selecting Savior Siblings – this example is used to demonstrate the breakthrough capabilities of Genomic Medicine. Second, this relation is explored through understanding the privacy issues within Genetic databases and genetic biobanks. Finally, the examination moves forward through investigating the privacy issues related to the application of Data Analytics in the genetics era. The outcome is to consider what changes might be ethically appropriate regarding HIPAA's Privacy Rule in the genetics era of Genomic Medicine and Data Analytics.

There is a significant change occurring in medicine that is focusing on Genomic Medicine where treatments are adopted based on discoveries in the human genome. These discoveries promise more and better treatments for previously incurable diseases. The new genetics era is the outcome of many years of basic, clinical, and translational research in multiple fields of science including biology, chemistry, mathematics, engineering and bioinformatics. A crucial characteristic of the genetics era is the use of data analytics.

Data analytics helped with the sequencing of the lists of the four letters that make up the different human traits and suitability to diseases. The storage and management of the data was an important thing to figure out since the amount of information was overwhelming for traditional avenues of research tracking. There are almost three billion base pairs of the haploid human genome. This amount of information corresponds to about 725 megabytes of data. While the human body has around ten trillion cells, the storage of the sequenced genetic information unquestionably required the aid of new technologies. Hence, Knowledge Discovery and Data mining made use of data analytics (referred to in the media as Big Data) to store and analyze all the data that resulted from the gene sequencing of billions of individuals. Genomic Medicine

wasn't the first to use Data Analytics, which is used almost everywhere whether it was on social media, advertising, fraud detecting or location tracking. Data Analytics enables Genomic Medicine to treat individuals and plan treatments across populations by tracking different traits, bipolar disorder as an example. The advancements of biotechnologies and the use of knowledge discovery and data mining to sequence, store, analyze and understand human genetics contributed to the emergence of Genomic Medicine. This understanding is lifesaving as it assists with finding treatments, cure and eradicate diseases. However, a core ethics challenge has resulted from these breakthroughs, the meaning of patient privacy in the genetics era where Data Analytics requires information of populations. Data Analytics in Genomic Medicine challenges the previously recognized centrality of an individual right to privacy. A balance is needed between the previous centrality of individual privacy and the need for population information to make breakthroughs in Genomic Medicine using Data Analytics. Such a problem demands regulatory solutions. And such solutions require the collaboration of policy makers, bioethicists, researchers, technology experts, and medical professionals.

The Healthcare Insurance Portability and Accountability Act (HIPAA) emphasizes the Protection of Privacy of the individual. It is the recognized gold standard for medical practice in the US. However, genetic privacy does not seem to be explicitly covered by the law. The law needs to develop a new perspective that balances its traditional focus on individual privacy with the emergence of Genomic Medicine that relies on Data Analytics using information across populations. This dissertation aims to address the Ethical dilemma that HIPAA's Privacy Rule raises related to Genomic Medicine. Since 1996 and until 2013, updates and additional rules were added to improve privacy protection and fill the gaps that existed in earlier laws. The aim was to safeguard the privacy and safekeeping of the patients' data and information whether it

was physical or electronic data. HIPAA managed not only healthcare settings but also other areas where patients' information were in use such as research, marketing, and fundraising.

The Healthcare Insurance Portability and Accountability Act is a landmark bill that was shaped to improve the portability and accountability of health insurance coverage. It allowed individuals to keep their health insurance between jobs. Moreover, HIPAA limited the restrictions that were enforced by healthcare insurance companies on pre-existing conditions. That meant that individuals with a pre-existing condition could not be excluded as long as the patient has continued coverage. In regards to patients' health data, HIPAA safeguarded the confidentiality and safekeeping of the patients' data and information. It had a massive difference over the methods and protections used for storing, handling and transmitting healthcare data whether it was physical or electronic records. Not only individuals benefit from HIPAA, entities complying with HIPAA inspire trust and confidence while also reassuring the public. This requires an enormous amount of resources and investment with some expected burdens. Therefore, benefits might not be immediately apparent to the organizations.

### **The HIPAA Privacy Rule:**

The HIPAA Privacy rule came into effect by the 14th of April 2003. It defines Protected Health Information as of any information held by a covered entity which concerns health status, the provision of healthcare or payment for healthcare that can be linked to an individual.<sup>1</sup> HIPAA explained how Protected Health Information could be disclosed and under which circumstances. It also placed restrictions on the use of the Protected Health Information in cases of research, marketing, and fundraising. Then the Security Rule dealt explicitly with the electronically stored Protected Health Information and specified three security safeguards to comply with HIPAA; the Administrative, the Physical and the technical protection. The Administrative safeguard was to

create policies and procedures that were designed by each entity to clarify how it will comply with the Healthcare Insurance Portability and Accountability Act. Then the Physical safeguard that was meant to protect against any inappropriate physical access to areas of data storage while controlling any privileged access. Last was the Technical safeguard that protects Protected Health Information when communicated and transmitted electronically over open networks.<sup>2</sup>

When it comes to research; HIPAA defines research as: “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Under the Privacy Rule, HIPAA shaped the conditions that protect health information that is used and disclosed during research. HIPAA requires covered entities to use proper de-indentation methods when dealing with disclosed participants’ information. It also covers how participants would be informed about the use and disclosure of their medical information. Moreover, it explains the participants’ right to access information that is related to them at covered entities.<sup>3</sup>

The Privacy Rule primary goal is to protect the privacy of the research participants’ identifiable information. However, this rule allows the medical researchers to have proper access to the information needed to conduct the research. Most of the current research that involves human subjects follow both or either the Common Rule, the Food and Drug Administration’s human subject protection regulations and the most recent ‘The Final Rule’ that came into effect on 19<sup>th</sup> Jan 2018.<sup>4</sup> These rules and regulations have some provisions that are similar to, yet separate from, the Privacy Rule’s provisions for research. The Privacy Rule protection shaped itself to be covering both the Common Rule and the FDA’s human subject protection regulations. Therefore; it creates same standards of privacy protection for research whether it was or wasn’t governed by the existing Federal human subject regulations.<sup>5</sup>

The Enforcement Rule came into effect in March 2006, when several covered entities failed to comply with both the Privacy and Security Rules. This rule enabled the Department's Office for Civil Rights to press criminal charges on an entity that fails to introduce corrective measures within 30 days. Moreover, patients gained the right to push civil charges whenever their personal healthcare information is disclosed without the permission of the individual.<sup>6</sup>

In 2009 came the Health Information Technology for Economic and Clinical Health Act (HITECH). Its goals were to compel all covered entities to use Electronic Health Records (EHRs) plus to become a part of the Meaningful Use incentive program.<sup>7</sup> The incentive program also came to extend and include third party suppliers to the healthcare industry and Business Associates. Along with HITECH came the Breach Notification Rule. It mainly specified that individuals must report any breach within 60 days of the service.<sup>8</sup>

Later the Omnibus Final Rule showed the criteria for reporting breaches of ePHI in 2013. The Omnibus Final Rule did not introduce any new legislation. However, it filled the gaps that weren't existing in both HIPAA and HITECH. Furthermore, it covered the scenarios which weren't anticipated in 1996 such as the uses of technological advances, specifically, the use of mobile devices.<sup>9</sup> Besides, both Privacy and Security Rules were edited to have the patient health information to be detained indefinitely instead of 50 years. The failure to apply the new amendments would result in implementing the new penalties that are stated in the HITECH rule.<sup>10</sup>

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<sup>1</sup> "HIPAA Privacy Rule." *HIPAA Journal*, 2017, 7-9.

<sup>2</sup> "The HIPAA Security Rule." *HIPAA Journal*, 2017, 18-29.

<sup>3</sup> Secretary, HHS Office of the, and Office for Civil Rights (OCR). "Research." HHS.gov. January 23, 2018. Accessed March 13, 2018. <https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html>.



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<sup>4</sup> Code of Federal Regulations TITLE 45 PUBLIC WELFARE DEPARTMENT OF HEALTH AND HUMAN SERVICES PART 46 PROTECTION OF HUMAN SUBJECTS, 45 CFR 46 § Subpart A. Basic HHS Policy for Protection of Human Research Subjects (2009).

<sup>5</sup> Summary of the HIPAA Privacy Rule." *Health Information Privacy*, U.S. Department of Health & Human Services, [www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html](http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html).

<sup>6</sup> The HIPAA Enforcement Rule - How Is HIPAA-Compliance Enforced?" *HIPAA Journal*, 2017, 37-45.

<sup>7</sup> HIPAA Administrative Simplification: Enforcement, 74 45 CFR § 160 (2009).

<sup>8</sup> "HIPAA Compliance Guide." *HIPAA Journal*, 2017, 5-6.

<sup>9</sup> Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule, 78 45 CFR § 160,164 *et seq.* (2013).

<sup>10</sup> Muller, Lynn S. "Integrity and Accountability The Omnibus Final Rule." *Professional Case Management* 18, no. 4 (2013): 204-7

## **Chapter 2: Consent, Law & Multiculturalism**

### **A. Consent & Law**

This Chapter explores the relationship between privacy and consent. First, this relation is explained through discussing the correlation between consent and law from a multi-cultural perception. Second, this relation is furtherly described through debating the connection between consent and substituted judgment. Conclusions of the chapter summarize the core issues that emerge related to Privacy regarding HIPAA's focus on this topic.

### **1. Introduction**

Ever since the evolution of humankind, there has been a pressing need to formulate and execute law and order to control the situations involving anarchy, chaos, and disputes. The law serves as a complete framework consisting commands and instructions that must be followed for maintaining a peaceful community.<sup>1</sup> Similarly, ethics allows the people to differentiate between right and wrong. Ethics incorporates social dimensions; it is concerned with justice, rights, respect for human dignity, the autonomy of the individual along with respect to the community.<sup>2</sup> A parallel relationship exists between law and ethics as both intends to purify the society from evil and unfair practices. Afterward, ethical values and morality, these are interchangeable terms. Understanding the interplay between law, ethics, and medical practice; is critical since a modern society functions with amalgamations and consensus of different disciplines.<sup>3</sup>

The dimension of morality is inevitable in describing the law. Law and morality both serve as standards for the optimal working of the society. Despite overlapping relationship among ethics and morality, there exists a significant difference between them. Law provides essential rules for regulating the bioethical concerns. Thus, the ethical practices and implications are now governed by more thorough principles.<sup>4</sup> In the medical profession, the lines seem blurred continuously between what is moral and what is not, so a physician is continually placed

in legal and ethical context. Moreover, and with the advancement of technology, the relationship is getting more complicated and intense.<sup>5</sup>

There is an unusual amount of interdependency among the areas of law, medicine, and ethics. The ethical codes are necessary and evident from the prehistoric times stated with the code of Hammurabi till now. Legal regulations and code of conducts in the medical field are also vital to control the working of the physicians, nurses and the whole medical team. Issues like euthanasia, advance directives, DNR orders and abortion are ethically and legally intertwined.<sup>6</sup> These subjects are dealt only when both the principles of ethics and the rules and regulations of laws are obeyed. Such procedures require statues and acts to regulate a smooth running of their operations. The history of these matters showed the impact of one field over the others. Medicine requires the law for dealing with patients, procedures and the use of technology and need ethical considerations to do the right thing which doesn't burden their conscious. Whereas law is dependent on the ethical and moral canons, and standards of the society and the morality of the person is based on the inner virtues.<sup>7</sup> These fields progressed thorough history changes in one area, brought alterations in the other. As advances in the field occurred, so did their ethical dilemmas which were being catered though different legislation, acts and considerations. Thus, although these fields are distinctive, possess the separate knowledge, require discrete areas of expertise and subdivide into unique domains; law, ethics, and medicine are interdependent and intertwined significantly.<sup>8</sup> This can be clearly observed in HIPAA regulations, even though not all aspects of HIPAA are based in ethical practices, the general thrust of the HIPAA's regulations is coherent with the ethical practice of medicine.<sup>9</sup>

## **2. The Conceptual Framework**

### **2.1 Ethics**

Ethics is an academic discipline dealing with the moral values of the society. It resolves differences in beliefs through moral arguments and distinguishes between the right and wrong of acts performed via describing ethical terms, logically representing ethical discourse and exploring generalizable principles.<sup>10</sup> The field of ethics evolved significantly over the years. The classical approaches of Socrates, Plato and Aristotle focused on reaching the full potential of oneself for the betterment of both the society and the self, the classical theories were of the notion that moderation was the key to become a virtuous person.<sup>11</sup> Whereas the modern ethical theories go beyond moderation and usually fall under two school of thoughts, consequentialism and deontological thought. The former states that, if the result is positive it will justify the ethical act, while the latter is of the view that the intent of the person matters while performing the act responsibly and with moral obligations.<sup>12</sup>

Other approaches to ethics are normative and non-normative, normative further divides into general normative ethics, which describes the general norms acceptable for every day conduct and, practical ethics or applied ethics, which is concerned with the application of the norms in professional fields. Non-normative ethics also subdivides into two types, descriptive ethics which is the factual examination of moral demeanors and believes, and metaethics, involved in analysis of methods of reasoning, language and description of ethical terms.<sup>13</sup>

Applied ethics disintegrate into various field, one of them being the medical ethics, these are the moral doctrines guiding the medical professionals regarding their course of action in practice and the moral obligations towards their patients and other members of the field.<sup>14</sup> Medical ethics is relatively an old discipline of ethics initiating from the code of Hammurabi about 2200 BC., then came the Hippocratic Oath, formulated by the Greek physician Hippocrates

in 4<sup>th</sup> century. This statement is fundamental to the ethical practice and is among the best and famous statement regarding medical ethics.<sup>15</sup> Evolving through modification, the code of medical ethics was then formulated after the Second World War by the American Medical Association, and is known as the declaration of Geneva which is based on Thomas Percival's work and is still used today, withstanding amendments. While medical ethics deals with "the role of values in relationship of doctors with patients, colleagues and other members of the society. Bioethics is a much broader term it includes the domain of medical ethics.<sup>16</sup> The field of Bioethics emerged in the early 1970s, as a discipline that arose to combat moral dilemmas occurring due to medical discoveries, technological advances and improvements in clinical procedures and to incorporate exploitations of humans as a research subject. It is a multidisciplinary term, enriched with the legal, philosophical, ethical and clinical knowledge.<sup>17</sup> The foundation of bioethics; the Belmont principles were drafted by an 11-member committee in 1974. These were, respect for persons, justice, and beneficence, these principles till date are called the Belmont principles which later developed the Principlism approach.<sup>18</sup>

## **2.2 Law**

Ever since the existence of human beings, anarchy and chaos have been prevalent in the world. To bring sense and structure into the troubled society, the field of law and order came into being. Plato and Aristotle gave the natural law theory that stated law is everything that drives the behavior of the person that is what the conscious indicates to perform. Law is the instructions and guidelines and the tool to measure the extent of deeds in which individuals and groups are prompted to act or are compelled not to act.<sup>19</sup> The naturalists supported the theory of what the law ought to be rather than what it is. Then the "command theory" stating that it is an organization of rules and regulations, which are obligated by an autonomous authority.<sup>20</sup> These

were of the view that there is an absolute relationship with morality and the law. The opposite of the naturalists' theory came up with the legal positivism, a theory of law which points out that laws are the commands and instructions of the people. Law is what is ought to be.<sup>21</sup>

As time passed, modifications of the theory of law appeared, as per legal realism, law society are in a constant state of change, and courts of law resolve the matters according to the stated laws, thus moral values and principles have no take in law.<sup>22</sup> Law is said to have three important features, that law is, normative, meaning that law is made to guide and to serve as a guide to direct the human behavior. It is institutionalized, i.e. its applied, modified, and regulated by establishments and institutions. Lastly law is coercive in the manner that obedience to it is guaranteed using force, ultimately.<sup>23</sup>

Moral acts ensure that people won't be treated as mere objects, where that is a universal law.<sup>24</sup> The relation between law and ethics is parallel. Moral and legal obligations are interconnected, every legal obligation is established from a moral value Law and ethics, both can be described as standards and principles governing behavior and proposing what acts to perform and prohibit.<sup>25</sup> Law and morals differ in a way that, law is a legal rule possessing three important characteristics, first it should be definite and understandable, second it must be recognized in advance and lastly it should be enforced by the courts.<sup>26</sup>

The amalgamation of law and ethics can be seen in the field of medicine more prominently, life and death situations, surrogacy arrangements, decision of abortion are all governed by law and by morals.<sup>27</sup> Both criminal law and civil law affect the healthcare industry. The violation of these type can be, Medicare and Medicaid fraud. Specific acts oversee the ethical dilemmas is medicine and law, which is the body of rule safeguards the sound functioning

of the systems in medicine and healthcare. In this context; Law would be regarded as per its lexical definition as set of rules and conducts.<sup>28</sup>

### **2.3 Medicine**

The term medicine in the *medical dictionary* is defined as the art of curing and the science of preventing diseases of all kinds. Medical history is rich and profound it dates to prehistoric times. People have been practicing medicine millions of years ago.<sup>29</sup> The Mesopotamian civilization which flourished around 4000 to 5000 years ago inscribed the first written rules, although the language is undecipherable now, but in inscriptions indicate that medicine was practiced by the priests because it was thought to be a divine order.<sup>30</sup> Among the oldest written medical documents, the Egyptian papyri (a medical inscription), relates to the Egyptian empire, containing information regarding the then used treatments. It was devoid of the earlier concepts related to magic and supernatural powers and was one of the first texts to explain ailments, cures of that time and dates back to 2000 BC.<sup>31</sup>

The Greek era of medicine was significantly the most related to modern medicine. Hippocrates and Glen were famous representatives of that age.<sup>32</sup> Hippocrates was also known as the father of modern medicine. Indian medicinal practices particularly known as Ayurveda, dealt with ancient herbs and mixed religion into curing the patients.<sup>33</sup> The Islamic age of medicine is marked with great evaluation, contributions in anatomy and physiology took place by great physicians such as, Abu al-Qasim (Abulcasis), Ibn-Sina (Avicenna) and Al-Razi (Rhazes). Similarly, medicine evolved through different civilizations, improving and exploring the human body and its contents. Modern medicine has developed around 18<sup>th</sup> and 19<sup>th</sup> century. Treatment of scurvy, vaccination for small pox were the inventions of 17<sup>th</sup> and 18<sup>th</sup> century. Since the prehistoric times till now medicine has gone under numerous changes and involved breakthrough

inventions, discoveries and technologies. These advancements such as cloning, surrogacy, artificial development of organs and other life and death matters require ethical considerations, hence bioethics came into existence.<sup>34</sup>

### **3.Theoretical Aspects:**

#### **3.1 How Ethics and Law Meet**

Though the terms ethics and morality overlap, but there exists a significant difference between the two expressions. Ethics has a much broader scope, according to Aristotelian ethical logic, it reflects the ability to distinguish the right from wrong.<sup>35</sup> Whereas law has a much narrow scope dealing with the guarantee that the society has legal standards for its smooth governance. As the German philosopher Jellinek described that law is the minimum ethics.<sup>36</sup>

The relationship between law and ethics is intertwined, on some aspects they overlap and on others they are mutually exclusive. Ethics is active and dynamic which means we often refer to it as doing ethics.<sup>37</sup> Clinical ethics or bioethics is a type of action-oriented ethics in which relevancy of the situation is greatly important. As described earlier ethics in this paper are regarded as bioethics or medical ethics. Bioethics can be used in the broader term including the legal as well as ethical aspects, sometimes referred to as bio law or biomedical law as well in a narrow one, bioethics is basically part of the ethics.<sup>38</sup>

Bioethics and law have a long standing relationship. The development of the medical field brought forward ethical dilemmas which required legal attention for resolution of matters. Development of this field changes the dynamics of doctor-patient relationship and moved beyond the realm of traditional ethical issues into a new territory. Organ transplantation, reproductive biology, genetic mutation, and cloning are some key areas involving legal and ethical issues.<sup>39</sup> The field of bioethics opened doorways for freedom of choice, which created ethical concerns. The choice related to beginning and end of life decisions. It was not as simple



as bringing a new life into the world but rather how the embryos will be created, the surrogacy procedures and the fertilization process itself this clearly indicates that regulating ethical choices in medicine is difficult and hence requires certain acts and legislations to control and regulate bioethical practices.<sup>40</sup>

Bioethics has been involved in legal issues since its inception some of the international standards of legal and ethical issues are regarded as soft law, this means they are legally not binding and lack enforceability.<sup>41</sup> The UNESCO declarations regarding ethics are non-binding but they do have a binding effect in the long run. Soft law makes it easier to understand the acceptable standards (especially in bioethics) internationally because it gradually increases acceptability and makes it easier for converting such standards into enforceable laws.<sup>42</sup>

Other instruments for maintaining professional conduct regarding ethical and legal concerns in United States include, Bills, legislations, code of professional ethics, standards of professional conduct. These all govern the ethical and legal implications of practice.<sup>43</sup> The moment a professional medical practitioner encounters patients, the ethical and legal situation emerging from this is inevitable.<sup>44</sup> Ethical codes have the underlying principles of philosophical norms and professional notions that govern human conduct these include autonomy, beneficence, confidentiality, fidelity, privacy non-maleficence and truthfulness i.e. veracity.<sup>45</sup> In medical ethico-legal settings the respect of autonomy is created via the law of informed consent. The link between autonomy and consent that, the autonomy of a person and the respect of such autonomy morally require others not to interfere in their decision without their consent.<sup>46</sup>

Ethics and law, though overlap but have distinctive vigor concerning enforceability and protection level which is variable. Law is fundamental in regulating bioethical matters.<sup>47</sup> The ultimate sanction for ethical disturbance is expulsion from the group and guilty conscious

whereas law has defined sanctions and legislations for Ethics and morals are external to law. What is deemed unethical may not be unlawful. Hence, they are complexly intertwined.<sup>48</sup>

### **3.2 How Ethics Changed Medicine**

Ethics deals with morality and social concerns of a person while medicine is the science of healing others. Ethics has deep roots in the field of medicine. The earliest ethical code for medical practices was Hippocratic Oath, which declared the relationship of physicians to patients and peers and become central to the medical field. The Hippocratic Oath is a standard code that provides moral guidelines to professionals and physicians.<sup>49</sup>

The physicians and professionals in the medical field constantly face ethical and legal dilemmas. The medical profession has gone under substantial fluctuations regarding the conduct of physicians and the use of treatments and technologies. Thus, the ethical practices and implications are now governed with more thorough principles. In the medical profession, physicians are constantly placed in legal and ethical context. Hence, medical ethics provide a way to keep in check the moral predicaments.<sup>50</sup>

Ethical theories and principles examine human conduct and provide a logical framework for the resolution of conflicting matters. Number of ethical documents and codes of ethical conducts emerged related to the field of medicine. The most prominent among them were the declaration of Geneva and the code of medical ethics adopted by the American Medical Association. Ethical guidelines in WHO serve as a standard for the medical practitioners. WHO pays special attention to the ethical dilemmas arising from issues like, euthanasia, organ donation, AIDS, surrogacy abortion and other related matters.<sup>51</sup>

The advancement of medical field concerned many, the ethical quandaries arose from innovations in the field such as, genetic mutation, nanomedicine, cloning and matters of life and

death decision. These improvements in medicine thus gave birth to the discipline of bioethics. This field was formed in late 1960s and it broadened the horizon of medical ethics and changed the brains and face of traditional ethics.<sup>52</sup> Bioethics is defined as a movement that arose due to reforms in the moral judgements due to changes in medicine and technology. It is an interdisciplinary field where the theological and philosophical aspects of ethics shaped the field of bioethics.<sup>53</sup> It goes beyond the doctor patient relationship and covers wide area of technological uses in medicine and human research matters.<sup>54</sup>

The clinical research or human subject matters are an important area of the medical field. The ethical principles guiding the clinical research include autonomy and informed consent.<sup>55</sup> Though these form the basis of an ethical decision but these are not sufficient for the clinical research. Other issues regarding, placebo effect, involvement of children and medical research in the developing countries initiate questions concerning ethical decisions. Thus, other principles should be regarded when dealing with such issues such as value, validity of research, fair selection of subjects and others such doctrines which determine whether the medical research is ethical or not.<sup>56</sup>

The life sciences discipline has experienced a radical shift from single molecule, small scale research to large scale big-data research models in which thousands of genes and biodata can be studied simultaneously.<sup>57</sup> Yet the ethical and moral implication on such type of sharing and research practices has increased as well. Unauthorized sharing of information of such data is controlled by controlled access policies which somewhat ensure that the human subjects participating in the study have privacy which is both ethical and professional duty of the medical/clinical researcher. The ethicists and developers are working together to create software that can process and diagnose diseases while considering moral and ethical implications of the

data shared.<sup>58</sup> The medical field involves ethical codes of conduct between dealing with specific issues of medical advancements and technologies and everyday simple decisions. Medical practices are incomplete without the implications of ethical considerations.<sup>59</sup>

### **3.3 How Law Controls Medicine**

When doctors meet patients, they are exposed to ethical, medical and legal context simultaneously. Similarly, this applies to patients and their relative.<sup>60</sup> During life, almost every person encounters the medical field. At least in the matters of birth and death that are inevitable and require medical assistance.<sup>61</sup> Thus, legal and ethical issues arise, and are handled and regulated through codes, laws, legislations and acts. This makes the laws governing medical issues significantly important. Hence, this is the area where HIPAA fits. HIPAA's regulations, are considered as laws that are based on an ethical foundation. Although not all aspects of HIPAA are based in ethical practices, the general thrust of the HIPAA's regulations is coherent with the ethical practice of medicine.<sup>62</sup>

The relationship between medicine and law is centuries old. In prehistoric times the priest performed the functions of the jurists as well as the physician, religious and social doctrines were mixed with the legal and ethical ones.<sup>63</sup> The earliest of codes in medical and ethical context, dates to the civilization of Mesopotamia when their king inscribed the code of Hammurabi around 2200 B.C.<sup>64</sup> This code emphasized legal liabilities for medical malpractices set rules and penalties for medical misconducts. These punishments ranged from monetary compensations to cutting the arm of the mistreating physician. It was also considered as the first declaration of human rights in the world. Then the Hippocratic Oath gained much attention as the ethical document for medical practices.<sup>65</sup> He distinguished the physician from an untrained healer. He also set moral obligations for the medical professionals to fulfill which bound them to perform

certain norms and virtues.<sup>66</sup> Similarly, in all other civilization as the medicine providing technique changed so did the laws surrounding it. Till the time, it was inevitable to create the separate field of medical law. The legality of the medical field is crucial to understand and study and is significantly important for creation of a law-abiding society.<sup>67</sup>

The health care field is one of the most regulated field.<sup>68</sup> This discipline is affected by criminal laws, which are the acts defined as illegal by the court, these can be related to medical fraud. Civil law also has roots in medical law, it relates to the wrong doings of the medical professional. Torts are category of civil law, negligence and malpractices of medical practitioners are included in this. The intentional category of tort laws includes, invasion of privacy, such as misuse of the information and case history of the patient, assault and battery which concerns with the law of informed consent. If the surgeon performs an operation without consent of the patient he is convicted of assault and battery charge. The medical professionals are obliged to assist and guide the patient in making treatment choices, protecting patients' rights and performing his own duties.<sup>69</sup>

The government of every country has a set of rights defined by the law which originated from the universal declaration of human rights in 1948.<sup>70</sup> The rights are fundamental to the medical law. They translate into legal legislations and acts. Autonomy, negligence, confidentiality and the need for consent are some of the vital areas of medical law. The treatment of the patient becomes unlawful if the patient does not consent to the treatment. The requisite for consent is legal representation of the right to autonomy and the principles of self-determination. The law of negligence provide protection against the medical malpractices. When the medical practitioners fail to deliver ordinary care and the patient is injured in that process. The professional is not liable for this law on poor quality of the service but only liable when an act of

medical malpractice has been conducted. This falls under the civil law domain of medical law. Misdemeanors are offences less serious than malpractices and are punishable by imposing certain fines.<sup>71</sup>

Medical jurisprudence is that area of medicine that applies medical knowledge in assisting justice.<sup>72</sup> This area of medicine helps in providing case evidence regarding criminal trails which was later named forensic medicine.<sup>73</sup> The term forensic is used as an adjective to categorize area of specialties that deal with legally admissible evidences. The legal medicine deals with the discipline of medicine which collection of materials and substances to apply medical knowledge in administration of justice. Different methods are applied for diagnosis and prognosis which than helps in gathering evidence to be presented in the court of law.<sup>74</sup>

With advances in technology spurting up in 1960s, and with the advent life support technology. The incurably ill patients that used to die before could survive.<sup>75</sup> This bought up the advance directives act. Which provided the patients with “living wills” this meant an appointed surrogate could take the decisions on behalf of the patient.<sup>76</sup> This ensured that the patient has a say in his medical treatment even after brain damage. Thus, the medical specialists incur legal issues regarding advance directives. Which require the practice of law and medicine to avoid any law suits. The advance directives though a promising phenomenon in getting consent and respecting autonomy of the person but raises questions regarding the appropriate and ethical use of making such surrogate decisions.<sup>77</sup>

The right of life as discussed is extended to every individual even the unborn fetus. The abortion act made the abortion legal. It does have certain moral and legal repercussions but this medical procedure is made legal by the law. Thus, the field of medicine and law are assisting and

facilitating in every possible way. Law assists from legal documentation to act of euthanasia whereas medicine assists in providing evidence.

#### 4. Evaluation

Ethics is something we do regularly as it is concerned with our morality and our inner values.<sup>78</sup> These values are formed by the inner beliefs, characteristics of individuals and judgments made by the society. These values then form the standards of the society which guide the behaviors of the people. Law as opposed to morality, guides and conducts the behaviors and acts through imposing some sanctions either monetary compensations or other punishments.<sup>79</sup> Physicians and health professionals need ethical and legal guidelines and rules to perform at optimal level and prove beneficial for the society. When they take the oath they profess their duty to work virtuously for the public whereas when they come in contact with the patients their legal oath as well as moral obligation comes into play and they must act ethically.<sup>80</sup>

The study conducted clearly demonstrates the interdependency of law, medicine and ethics. Medical ethics, law are dynamic fields.<sup>81</sup> They are constantly changing as technological advances arise with *in vitro* fertilization, embryo replacement, organ transplantation and genetic mutation.<sup>82</sup> These advances brought serious concerns regarding the ethical acts and legal directives for administering these. The three fields interconnect on various aspects. Medicine ethics and law develop separate divisions which operate by intermixing the concepts of all these fields. The ethical principles of non-maleficence, autonomy, justice and beneficence apply in the medical field as well in the discipline of law. The principle of autonomy translates into the right of freedom and the law of consent. Many of the issues arising in the medicine field are based on morality and are dealt legally.<sup>83</sup> But morality starts where law ends, and requires moral knowledge for the decision making regarding the subject matter. Hence in dealing medical issues

ethical principles are equally important as the legislation of law.<sup>84</sup> A modern society functions with amalgamations and consensus of different disciplines.<sup>85</sup> Ethics is more demanding than law. There are differences in the extent to which these fields overlap, nonetheless it is provided through the study that law, medicine and ethics overlap countless times in the life of a medical professionals or even in the time span of a lay person.<sup>86</sup>

## 5. Conclusion

The study conducted proved that there is interdependency among the areas of law, medicine and ethics. The ethical codes are necessary and evident from the prehistoric times stated with the code of Hammurabi till now. Legal regulations and code of conducts in the medical field are also vital to control the working of the physicians, nurses and the whole medical team. Medical issues such as euthanasia, advance directives, DNR orders and abortion are ethically and legally intertwined. These issues are resolved when both the principles of ethics and the rules and regulations of laws are applied. These types of procedures require statutes and acts to regulate the smooth running of operations. The history of these fields showed clearly the impact of one field on the other medicine, requires law for dealing with patients, procedures and the use of technology and need ethical considerations to do the right thing which doesn't burden their conscious, whereas law is dependent on the ethical and moral canons and standards of the society and the morality of the person is based on the inner virtues. These fields progressed thorough history, changes in one field brought alterations in the other. And as advancements occurred, so did their ethical dilemmas that required accommodation through new, different or updated legislations, acts and considerations. Thus, even though these fields are distinctive and possess separate knowledge and require separate areas of expertise and subdivide into completely unique areas, law ethics and medicine are interdependent and intertwined



significantly. HIPAA is the paramount illustration that express such relation between Ethics, Law and Medicine.

Privacy is a very broad notion. Within biomedical ethics, it has different forms which include; Informational Privacy, Physical Privacy, Associational Privacy, Proprietary Privacy and Decisional Privacy. These forms of privacy control and enable ethical medical practices and clinical research and are philosophically agreed on. However, the disagreement appears on the level and degree of autonomy and the limits of personal choice in different contexts.<sup>87</sup> HIPAA's Privacy Laws enable autonomy and authority through consenting and following other laws. That ensures privacy, confidentiality and civil rights.

Starting with Informational Privacy. It usually refers to confidentiality that involves the confidentiality of patient-physician encounters along with secrecy and security of the information in patients' records. The information shall not be disclosed to any other party without the confider's authorization. It promotes humans' medical autonomy while preventing harm, injustice, criticism and interference with decision making. In healthcare, it is an ethical duty to keep medical information private. This is required by law, professional codes and policies.<sup>88</sup> Mostly, philosophers, ethicists and bioethicists correspond that respecting humans' confidentiality; benefits both the patients and the public. Confidentiality is debated by the need for dignity, virtue, utility and fairness.<sup>89</sup> Moreover, it can be justified based on the consequence-based argument and/or the autonomy and privacy rights argument. The difference between right to privacy and the right to confidentiality can only appear when the institute/person handling the information; fails to protect it. However, the right to practice autonomy and protect privacy are joined by the right to confidentiality.<sup>90</sup> This form of privacy becomes a serious demand when utilizing bio-banks and genetics data bases. That's not all, such form of privacy is required with

every medical or research encounter such as in abortion, results of research and both physical and electronic records.<sup>91</sup>

Secondly is the Physical Privacy which focuses on patients' bodies and their personal space. It outlooks the rights to modesty, solitude and bodily integrity.<sup>92</sup> This kind of privacy is viewed differently by different cultures and norms. Some patients require time alone to think and make decisions while others require the gathering of family and loved ones.<sup>93</sup> Moreover, body exposure is part of examination, testing and treatment of the sick. Patients need this form of privacy to ensure religious and moral virtues.<sup>94</sup>

Third is the Proprietary Privacy that highlights the property interest in the human person and the rights of self-ownership and the ownership of parts and products of their bodies.<sup>95</sup> It includes both physical-self and the non-physical-self. This includes the right to consent to both treatment and to research. It also pertains to the issues related to women's right to their bodies.<sup>96</sup> Proprietary Privacy is important when discussing samples and genetic data kept in biobanks.<sup>97</sup>

Then the Associational Privacy which is the form of privacy that includes relatives, families and intimate relations. Humans tend to share moments and/or decisions with such relatives, while others tend to keep that information away. This right regulates issues related to pregnancy, abortion and STDs. It is also important in the field of genetics, genetic testing and results sharing.<sup>98</sup> Finally, the Decisional Privacy that refers to the personal choices of a human. It indicates both liberty and autonomy of the patients' decisions made related to their health. This includes women's right to their bodies in cases of abortion. More, it covers the right of parents to vaccinate or not vaccinate their children without the interference of other authorities. Decisional Privacy is also a right when it comes to using different reproductive technologies as IVF & PGD.

Consent related to HIPAA can be viewed as two types. Consent is meant to protect either rights to make a personal decision or on behalf of someone else. It could also be used to protect personal information when linked to HIPAA. The first type of consent is meant for treatment or research which is usually referred to as informed consent. Without this type of consent, a caregiver or a researcher cannot administer a treatment, nor perform a procedure. The other form of consent is used for authorization which is also known as HIPAA consent. It is a written permission that permits healthcare providers to obtain patient's health records from other caregivers to provide a basis for treatment. Further, it allows healthcare plans to get patients' information to review claims and set plan premiums based on the patient's needs and history. This is usually renewed on an annual basis.

## **B Consent and Multiculturalism**

### **1. Introduction**

Ethics principles are developed by theorists who attempt to codify their moral insights. Eventually, this results in the development of what is known as rules, prima facie duties or norms. Regardless how these morals are widely shared and are appreciated by many people and professionals worldwide, it remains hard to apply them in many cultures around the world. That has resulted in a moral norm conflict due to the distinct differences in prioritization and interpretation of such principles in different cultures, religions, and societies.<sup>100</sup> Mostly, the contributors to the process of the ethical principles formation share enough Western philosophical and religious premises that they share the same biases. This has created a massive issue for healthcare providers treating non-Western patients in both Western and Eastern countries.<sup>101</sup> The problem was extended to reach bioethicists since they were taught and trained to handle the principle of patient autonomy to resolve ethical issues in healthcare. Western bioethics showed that respecting a patient's autonomy meant giving the patient his personal

space to decide for himself the course of treatment. Eventually, bioethicists argued and divided over the principle.<sup>102</sup>

For a long time, clinicians and bioethicists have believed that the autonomy principle is the basis for a common moral discourse that can regulate the relationship between patients and their healthcare providers.<sup>103</sup> In Eastern countries, healthcare providers were not able to apply these principles to their practices, since it was never applicable to their cultures or religions. While Western healthcare providers did benefit out of these principles in their practice, it wasn't the same deal when they dealt with patients who held different values from western cultures. Hence, healthcare givers found that this has been affecting their relationships with their patients from different cultures. While aiming to be moral and professional, issues arose and troubled both parties, leaving them questioning their trust in the principle of autonomy. Therefore, it was crucial to re-examine the application of the principle of autonomy in bioethics especially when cultures are becoming more racially and ethnically diverse.<sup>104</sup> One important intervention in the history of bioethics were The Health Insurance Portability and Accountability Act rules. HIPAA pursued to protect the fundamental right to privacy and autonomy of all patients whether they were Americans or citizens. The adoption of HIPAA rules has exceeded the borders of America as it has established its usefulness in the medical field. Such legislation is necessary to ensure the best quality health care, patient control, security, accountability, and other rights. Nevertheless, the adoption of HIPAA in other societies requires bioethicists and policy makers to make similar regulations that protects privacy with the respect for the culture definition of autonomy and consent.<sup>105</sup>

With time, principles and specially Autonomy proved its benefits and accomplishments, yet it also showed its limitations and pitfalls in multicultural societies as a normative principle.

This has resulted in many arguments between writers, philosophers, and bioethicists on the applicability and the universality of autonomy as a normative principal used in healthcare settings. Consequently, another set of discussions took place around consent in the clinical encounter; as informed consent was the clinical application of autonomy.<sup>106</sup>

Western healthcare providers confronted evident issues while having their patients from different cultures and ethnicities go through the consent process, compared to their experience with western patients. That had pointed several disparities when dealing with none Western patients. Among those disparities arose the issues of language access and the patients' level of health literacy. With that being discovered, it was crucial to consider having a system of patient-centered care while providing healthcare givers with cultural competency training to overcome those disparities.<sup>107</sup>

Autonomy along with the other moral principles was entirely applicable in the Western countries as ethicists from there have developed them. The same exact principles especially autonomy is not as functional in Eastern, African and Middle Eastern countries as well in West while dealing with multicultural societies. Respecting the patient's autonomy must include the possibility of challenging and even rejecting medical advice. Nevertheless, the principle should be viewed in a broader perspective, where the person's choice is motivated by some external or internal constraints such as the patients' relationship to their communities, religions, and cultures. There is no easy clear-cut solution to close the health care disparities gap when it comes to the continuing process of consenting to treatment for patients from different races and ethnicities.<sup>108</sup> Still, it is a moral imperative that appropriate resources be brought to bear to address these differences. That can be achieved through developing access to quality care to

minorities and remodeling the health care delivery system. It can be facilitated by improving cultural and linguistic understanding, further by diversifying the health care workforce.<sup>109</sup>

There is a considerable need to adjust the inequities in the social influences of health while treating minorities in a multicultural society. This promises to improve the health of the entire community dramatically. It could start by having the patient understand what he refuses or agrees on when treated. This enables the patient to sense that he has control over his health and treatment. Furthermore, each society could benefit out of having public discussions to set and articulate the fundamental norms of their culture. The ideal way to address the applicability of any moral principles is to have both laypeople, and healthcare providers jointly set and discuss its fit for their society.<sup>110</sup>

## **2. Critical Assessment of Autonomy**

Autonomy has been proposed and defined several times as a moral principle in bioethics. However, the most famous widely used definition belongs to Beauchamp and Childress in their Principles of biomedical ethics book. Many medical schools and healthcare givers adhere to their Principlism and therefore, the arguments below will be focused around and compared to autonomy definition according to Beauchamp and Childress's definition.

### **2.1 Arguments proposing the definition of autonomy according to Beauchamp and Childress**

Autonomy is deviously easy to state and notoriously difficult to explain. As it is known, autonomy is understood as the individuals' capacity and opportunity to exercise rational self-determination over the content and general course of their own lives. To be autonomous, the person needs to at least possess the cognitive ability to rationally deliberate upon the objects of one's will. Bioethicists who positively propose patients' autonomy, usually trace the origins of their understanding of the ideal to the deontological theory.<sup>111</sup>

John Stewart Gordon believes that the four-principle approach that is presented by

Beauchamp and Childress is good enough for global bioethics by virtue of its ability to mediate successfully between universal demands and cultural diversity. Therefore, he claims that the principle of autonomy that also represents the idea of patient's informed consent; does not need any revision to make it compatible with other alternatives such as family- or community-informed consent.<sup>112</sup>

Some argue that some individuals might be supported by their religious or collective groups, they are mostly obliged to follow that religion or group's commands, which might just be contrary to their personal choices and autonomy. Moller Okin criticizes multiculturalism as he sees it ignoring the vulnerability of more fragile individuals while it only defends the cultural or religious rights. He gives women as example in cultures where men get to decide on behalf of their wives. The term "family autonomy" seems to only mean that the men decide for women and not vice versa. Moller Okin recommends not to only recognize the rights of different cultures but also the individuals within those cultures. He argues that if only the rights of the culture were recognized, then by that we legitimize cultures that coerce their single members as they do not acknowledge the individuals' rights to distance themselves from their culture and their right to reject it, if they wanted to. Michael Fetters used the story of a Japanese woman afflicted with cancer, who chose to stay in the United States as she felt more comfortable with the approach used in the United States than the one in her own country during her cancer treatment. He states that this is a clear case of willingness to distance oneself from a cultural pattern, where the patient felt that her wishes were not respected by the culture. Hence, Fetters believes that the healthcare giver should always distance himself from the culture of the patient by resisting the assumption that a patient will anticipate a model of family autonomy or paternalism just because that the patient's culture is known not to exercise respect for his or her autonomy. Fetters sees

that cultures do not possess autonomy, it's the individuals who do. Any individual who belongs to any culture or group, have rights and among those rights is the right to renounce individual autonomy in favor of other important values, which is known as liberal multiculturalism.<sup>113</sup>

Regardless of the main argument around all the issues with autonomy, with no biases, it must be clear that autonomy had many accomplishments for many other cultures such as the North American communities. The principle of autonomy provided a well established avenue for these cultures where the beliefs and commitments of patients impact directly upon medical treatment. The principle of autonomy was more related to the cultures and religion of such communities came perfectly in line with it. Therefore, patient's culture and religion were both respected through autonomy.<sup>114</sup> Observing different cultures made it clear by now that the patients religious and cultural beliefs does affect the patients' ability to accept or withhold consent to a specific form of treatment. Healthcare givers are supposed to understand that and respect the wishes of the patient beside his culture, religion and background. Therefore, some bioethicists debated that the principle of autonomy is the most reasonable ethical principle that maintains a common moral discourse, which has the ability of regulating the relationship between healthcare givers and their patients. This principle helps patients refuse treatments that are not acceptable by their religion or cultural groups.<sup>115</sup>

“Moral strangers” was the term that Engelhardt used to describe the situation when people of different moral backgrounds meet. This represents the situation between patients and their healthcare givers who come from different cultures holding different principles. To him, the conflict arises from the fragmentation of a common fundamental moral discourse into diverse and, radically conflicting normative conceptions of the moral values between the healthcare provider and the patient. Therefore, health care professionals and their patients are seen as moral



strangers when they do not share the same commitment to the ethos of biomedicine.<sup>116</sup>

Having different views regarding morality or any topic related to it and having no common moral or philosophical framework that enables an ethical, rational resolution of the controversial bioethical issue, is what creates moral strangers. Engelhardt believes that most complex societies that are made multicultural and lack the basis for re-establishing some substantive conception of the good capable of comprehensively regulating relations between public authorities and the individuals subject to them.<sup>117</sup> Engelhardt claims that such relations could only be regulated through the formation of neutral principles that are independent of any particular substantively normative conception of the good. He sees the principle of patient autonomy as the means to this end. He believes that autonomy has the ability to provide the basis for a philosophically justifiable foundation for bioethics that can be shared by all persons. To Engelhardt, autonomy is a defining property to every person and that it is acquired independently of his or her cultural beliefs and commitments. Hence, he links autonomy with personhood. Engelhardt obviously supports autonomy as a secularly neutral ideal the legitimacy of which all persons, by the virtue of being a person, are considered bound to accept. Consequently, this makes healthcare providers and patients meet as moral strangers while still having a free and informed consent as a language to use while deciding and agreeing on treatments.<sup>118</sup>

In a healthcare setting, the commitment to the principle autonomy is presented as having ability to regulating relations between clinicians and patients when the normative commitments of the respective parties are fundamentally incommensurable. Therefore, Engelhardt offered autonomy as a normatively minimalist ideal capable of regulating the relationship between clinicians and patients within multicultural societies.

## **2.2 Arguments opposing the definition of autonomy according to Beachamp and Childress**

Anyone who works with bioethics cannot escape the bioethical theories that exist yet still conflict with each other. Many bioethical concepts are made by their theorist according to his or her own norms and concepts. Some philosophers have opposed how deontology proposes the principles of autonomy personhood while it unduly abstracts people from their personal characters. They argue that individuals are ontologically embedded within a form of culture or social structure. Personhood must be understood and recognized by bioethicists and healthcare givers according to the patients believes and personal identities. Healthcare givers have experienced how patients respond to deciding on medical advice drawing upon elements such as their ethnic, cultural, and religious backgrounds. By recognizing the importance of the social context of personal agency has profound implications for defending a general conception of autonomy. Therefore, a commitment to a deontological account of autonomy that tends to incorporate ethnic, cultural, and religious factors within an account of personal agency will, will lead to the conclusion that not all persons can be described as capable of acting autonomously. The autonomy principle in its known definition in the west, is not applicable for multicultural societies. Charles Taylor and Joseph Raz both argue that the human identity is represented through his culturally embedded relationships and practices. Humans have at least one membership to a cultural community and their identities are related and acquired through these communities. Correspondingly, the make-up of the personal identities is constituted through the identification with the varying culturally determined and constituted beliefs, values, and practices that surround the person. Charles Taylor states that humans become full agents capable of understanding themselves, and henceforth of defining their own identity, through the attainment of rich human languages of expression. In addition, Raz gives an example by explaining that it is only possible to pursue a medical career within societies that both recognize

the existence of such a specific profession and within which there exists the institutional infrastructure to support such a practice. Both Taylor and Raz argue that the very objects of even the most significant choices are themselves culturally dependent.<sup>119</sup>

Robert Veatch was never pleased with the idea of limiting respect of persons to the principle of autonomy such as the one presented in Beauchamp and Childress's work. Veatch expanded the notion of respecting autonomy beyond the conception of autonomy. He differentiates the concept of respect for persons into four component principles which are fidelity, autonomy, veracity, and avoidance of killing. Veatch believes that the proper understanding of autonomy and human freedom suggests giving space for both religious and cultural practices. He believes that as long as this does not conflict with the rights and freedoms expressed in the broader universal statements, then these imperatives should not be a problem. The convergence of religious and secular moral systems constrained by the awareness of human finitude, allows the patient and the healthcare provider the autonomy to practice their own understanding of what morality needs. Veatch states that patients of the world will no longer be patients; they will claim their place as full and equal active partners in the process of formulating an ethic for their relations with professionals. Therefore, common moral vision is fallible and subject to revision and Veatch suggests a solution, which shows that religious and secular ethics share a common morality sufficient to articulate a medical ethic.<sup>120</sup>

The family plays a major role in the patient's medical decisions in many cultures in Asia, Africa and the Middle East. It does not matter whether the patient is elderly or young, the family will usually have an input in the mode of treatment that the patient will take. In many Muslim countries, the head of the family will have the last decision, while in many African societies; the elders of the tribe will decide in the matters of health and death, consequently, the western

attitude of individualism is not applicable in those societies. Even in the west itself, different minorities have their own individualistic patterns such as the Chinese, Indians, and Pakistanis cultures that differ from the Western liberal culture.<sup>121</sup> Health care providers in the United States find themselves faced with these different cultures with the need to respect the role of the family in the patient's health as the patients themselves agree to this role. Hence, healthcare providers in the US need to understand that not all societies give autonomy the same priority it has in the West.<sup>122</sup>

Many medical sociologists and anthropologists have confirmed that there is a strong relationship between the organization and general complexion of medical systems and the social, political, and moral values of the societies in which they are located. Correspondingly, critics have argued that biomedicine do ignore the culture element. However, autonomy provides a well-established base in the biomedicine field, even though it does not show how this could be worked out when dealing with different cultures. It must be made clear in bioethics that the cultural and religious beliefs of patients have come to affect medical treatment directly through the inclusion of the principle of respect for patient autonomy in the provision of health care.<sup>123</sup> Therefore, the patient's autonomy cannot be respected without identifying his or her culture and religion and respecting it too. Both religious and cultural beliefs may influence the patient's granting or withholding consent to treatment, and healthcare providers are expected to respect the patient's own or familial decision. Healthcare givers should know this as a fundamental fact in their profession when dealing with patients from other cultures, in order to act both ethically and professionally.<sup>124</sup>

People have a relationship with their values, beliefs and ideals that must be respected. Every community has opportunities for autonomous deliberation and action even if constraints do

apply. Following a cultural or a religious community would prevent some individuals from pursuing alternative courses of action, in other words; due to their respect to their culture and community, they could have not acted in any other way.<sup>125</sup> However, this is usually their own accepted choice, and by that they are acting autonomously. It is important to them to be accepted as part of that community or group. Hence, it is important to expand the notion of autonomy in bioethics for it to be applicable globally within other cultures and while treating different cultures in the West. In a clinical context, informed consent is the actual way to apply autonomy in a medical context. Due to the existence of different cultures in the west, the consent process and autonomy seems different when dealing with non-Caucasian patients. Hence, healthcare givers need to distinguish and understand how different cultures perceive autonomy.<sup>126</sup>

### **3. The Consent in the Clinical Encounter:**

Informed consent is a process that is not limited to gaining a patient's signature on a consent form. It is a process that's done throughout the patient's treatment that involves the perspective of the patient's agreement or refusal to receive the treatment throughout an illness. This process needs a lot of personal and environmental factors to achieve the needed trust and bond between the patient and the healthcare giver. However, when the cultural background of the patient and the physician differs, several obstacles arise and hinder the ability of both to accomplish that required informed consent thought the treatment of the patient. This can occur due to the different views of both parties towards the concept of autonomy, making decisions and informed consent.<sup>127</sup>

#### **3.1 Within the Same Ethnicity in the West**

All western biomedical ethicists promote that, as autonomous moral agents, all competent adult patients should be respected regarding their right to medical decision making even if it was against the medical professional recommendation. As being developed in the west;

informed consent is a process that occurs throughout the course of relationship between the healthcare giver and the patient. It also assumes the ethical imperative of giving patients comprehensive information and allowing them to make independent choices.<sup>128</sup>

According to the principle of autonomy, which underlines the notion of informed consent, it states that patients must have sufficient knowledge about their condition, treatment and alternatives. They also need to be mentally competent, free from any form of constraints to be responsible and take their own decisions, only then the process of informed consent would be considered legal and morally ethical. Self-determination is another principle that is tied to notion of informed consent. Self-determination must be respected by the professional authority. This principle seems to be applicable in the west but not in other cultures. The intended purpose of the informed consent is to provide the patient with his right to participate in the medical decisions along with his healthcare givers to safeguard the patient's wellbeing and to prevent harm from occurring to him.<sup>129</sup>

Patients can provide an informed consent only after they have received sufficient and accurate information on a specific medical intervention on which they can make a decision about. This means that veracity is another ethical principle that is needed to obtain an informed consent. The healthcare provider is supposed to give sufficient information including the benefits, risks and the alternative treatments for the patient to decide on and consent.<sup>130</sup>

A subtler concern is when the patient does not seem to understand the treatment, the side effects, or the alternatives of the treatment he or she is consenting about. Therefore, it's the healthcare providers' responsibility to be conscious and aware of the patients right in such an ongoing process, whether the patient was from a different or the same culture and background, whether he or she spoke the same language or not. This means that healthcare givers should not

only care about obtaining the signature on the medical consent form. They are supposed to be caring about the patients' right throughout the entire process.<sup>131</sup>

### **3.2 Within Multicultural Ethnicities in the West**

Healthcare givers are expected to pay extra care when their patients come from other different cultures and backgrounds. Both healthcare givers and multicultural patients have addressed special concerns while obtaining informed consent. Therefore, in an increasingly multicultural population, informed consent and other bioethical practices are now being considered in the context of culture.<sup>132</sup> Many bioethicists believe that ethical principles are not universal; instead they are unique and specific to each single culture. Therefore, cultural sensitivity requires taking a patient's culture into account in bioethical decisions. This makes it hard for healthcare providers when trying to seek an informed consent and explain procedures, their risks and alternatives to a patient who does not speak the same language. This requires continues training to the healthcare givers besides allocating recourses in order to achieve such a goal. However, it seems that not everybody agrees on that, the President's Commission for the Study of Ethical Problems reported that a desire for information, choice and respectful communication appears to be common to all cultural groups.<sup>133</sup>

The debate remains whether ethical principles are seen universal and therefore should be applied to all people or should be applied differently to each culture, being relative to each particular culture and must be applied individually. However, the struggle that the healthcare providers and the multicultural patients goes through, gives enough evidence that those ethics principles are not universal.<sup>134</sup>

Several empirical studies were conducted on patients from various cultures and their ethical decision making. Blackhall et al have shown that there are some cultures such as Korean

and Mexican-Americans were significantly more likely to promote a family centered medical decision-making than African- or European-Americans. They were also significantly less inclined to believe that patients should make their own decisions about life-support measures.<sup>135</sup>

Even when healthcare givers realize that they should understand autonomy differently when they deal with different cultures, they are still faced with several issues when dealing with their multicultural patients. Above many different disparities come the issues of language access and health literacy. These seem to be the most basic issues that need to be solved in order to deal with the other disparities.<sup>136</sup>

#### **4. Disparities that affects consenting in a multicultural society**

##### **4.1 Language access**

There are more than 300 languages that are being spoken at the United States, which means that almost a quarter of the United States citizens speak another language other than English at home, Spanish is one of the most common ones besides English.<sup>137</sup> When treating a patient, treatment would usually include consenting formally or verbally, this is usually done in the hospital's or healthcare giver's language. It should be clear that Informed consent is not limited to acquiring the patient's signature on a consent form. It includes all patient's agreement or refusal to receive treatment throughout an illness. To obtain a proper informed consent, there must be open, frequent communication between the patient and the healthcare giver. When the physician and the patient do not share the same first language, an immediate barrier seems to be built between them that would prevent the physician from informing the patient of his or her clinical situation, treatments options and other conversations that are supposed to take place between a patient and his physician.<sup>138</sup>



It is critical to note that communication is an important factor that influences the physician-patient relationship. With a linguistic barrier, it becomes harder for both parties to establish that connection and the required trust. In addition, all the physician's recommendations, explanations and treatments will also be harder to fulfill. An informed consent is a process for getting permission before conducting a healthcare intervention on a person. The healthcare provider would ask the patient to consent in order to receive a form of therapy before providing it. Correspondingly, a clinical researcher might ask a research participant for his consent before having him enrolled in the clinical trial.<sup>139</sup> Therefore, the consent process is considered one of the most sensitive processes that necessitate good language access between the patient and the healthcare provider to fulfill its ethical and legal requirements.<sup>140</sup>

It has been agreed on that patients with limited English proficiency, tend to receive health care with lesser quality than patients with fluent English. Several studies have shown that Limited English proficiency patients are less likely to use the preventive and primary care services due to the communication issues they are faced with. Studies also showed that Limited English proficiency patients are more often diagnosed with severe psychopathology when seeking psychiatric care and are more likely to disregard medical advice and leave the hospital prior to discharge.<sup>141</sup>

A study showed that seventy percent of the physicians believe that their LEP patients have trouble understanding the basic health information needed for their proper treatment compared to fluent speakers. This means that the problem is aggravated when a procedure is in need for the patient where explanations of the procedure, its complications, and alternatives take place at the physician office beside the need for providing an informed consent.<sup>142</sup>

Communication barriers between healthcare providers and their multicultural patients are serious issues that make those patients more vulnerable than other patients. One survey showed that 63% of hospitals and 54% of internal medicine physicians reported treating LEP patients at least weekly while 84% of federally qualified health centers treated LEP patients daily. Almost 95% of the treatments required the patient's consent in which it needed extensive explanation and clear communication between both parties.<sup>143</sup>

On one survey, physicians have reported that they see LEP patients with around 80 dialects and languages. In 2002 the IMO produced the report of Unequal Treatment. It showed that the communication problems between physicians and LEP patients were worse among some groups. The IMO made some recommendations, which included having the use of interpreters and translation services as this could improve the communication between physicians and LEP patients. Even though federal and state laws tried to ensure the access to such services but yet the gaps in medical services persisted as the laws were insufficiently enforced. Surveys still showed huge numbers of departments that lacked interpreters and translation services while they were in need to it. These services do require recruiting language specialized people which means allocating resources in another direction.<sup>144</sup>

During the consent process, it is also important for healthcare providers to be extra cautious when having a family member or a friend of the patient acting as an interpreter for them. This could lead to other issues such as forcing the patient into the family member's wishes, which might interfere with the patient's autonomy. Another point to care for is when the interpreter is a child of the patient, this could place the child in a huge amount of stress due to the responsibility and the type of information conveyed as the situation might be beyond their maturity level to handle.<sup>145</sup>

## **4.2 Health literacy**

This is another disparity that may sound similar to the language access however the difference is that the patient may communicate perfectly in English while this issue would still persist where he would not understand health related recommendations conveyed by health care professionals. Health literacy is known as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Therefore, even if the language barrier did not exist between the healthcare giver and the patient for a different culture, there is another form of gap. This issue could even occur with patient and health care givers from the same culture.<sup>146</sup> The IMO has reported that almost half of the Americans have problems while trying to understand medical information such as drug labels, prescriptions and insurance forms. The IMO also found that patients with limited health literacy are more likely to be hospitalized than those with adequate literacy. Patients with low health literacy and chronic disease are less likely to adhere to disease management regimens. This all could occur, as the patient did not understand the needed information when consenting to a treatment.<sup>147</sup>

This issue is more common between some racial and ethnic minorities than others. It is also found to be most common among older adults, individuals with low education levels, and LEP patients. However, it was found that when healthcare givers tried to use illustrations, plain language, and had patients restate the consent and treatment information in their own words, communication was greatly improved.<sup>148</sup>

## **5. Solutions to overcome disparities that affect the consenting process in a multicultural society**

Patient centered care fosters the alertness of healthcare to the patient's values and preferences. The impression of culturally competent care might seem closely related to the concept of patient centered care however it focuses more on the healthcare provider's skills. The

potential complexity of interaction with patients from an ethnic minority group, due to the existence of cultural difference, a language barriers, or the influence of personal bias requires distinct care provider qualities additional to general competencies in the healthcare provider and the healthcare system.<sup>149</sup>

### **5.1 Patient centered care**

Patients from different ethnic and cultural backgrounds seem to have less access to preventive care and even regular resources of care. This mean that their chronic and acute conditions are less likely to be properly treated, leading to hospitalizations. Those patients are found to have lesser access to ambulatory care. Therefore, Minorities lack sufficient access to preventive care, such as diagnostic screenings and vaccinations than white Americans.<sup>150</sup> Hence it is recommended to place more emphasis on prevention and patient-centered care rather than reactive care. Patient-centered care is seen to improve the bond between doctor and patient, strengthening trust, communication, understanding, and health outcomes. Healthcare systems should redesign their health care financing and delivery systems to emphasize prevention, care coordination and quality.<sup>151</sup>

It is found that having a diverse health care workforce that is more representative of those who serve, as it promotes respecting, understanding and absorbing of different cultures. This has been effective among health providers and patients while it also promoted quality care, and equity in the health care system.<sup>152</sup> Another suggested solution was to educate the minority students when it comes to specific fields such as math and science, to create a larger pool of qualified minority applicants for medical school. Therefore, it is recommended that medical and other healthcare professional schools revitalize efforts to improve enrollment and graduation rates of minority students. Some policies encourage institutions of higher education to consider a person's race

and ethnicity as one factor in determining admissions.<sup>153</sup> This has been required to counter the impact of current discriminatory practices and the legacy of past discrimination practices.

Another recommendation is for medical schools to increase efforts to recruit and retain minority faculty. In general, governments need to put effort to foster minorities in leadership positions in all fields of the health care workforce. Hence, funding should be steadily maintained to increase the number of physicians and other health care professionals in minority communities.<sup>154</sup>

## **5.2 Cultural competency training**

Cultural competency is known as the combination of knowledge, attitudes and skills necessary for care providers to effectively interact with culturally and ethnically diverse patient populations.<sup>155</sup> Therefore, healthcare givers should have the knowledge of the processes that influence health and healthcare of minority patients such as what is the ethnic composition of the population so they could be aware of the possible ethnic inequalities that might face them.<sup>156</sup> They should be also knowledgeable about the diverse health values, beliefs, and behaviors of their patients in order to adopt the proper attitudes and to have the ability to reflect that on their own sociocultural background and personal biases, this would lessen their predisposition to stereotyping. All healthcare providers who work with patients from multiculturalism must master the communication skills that enable them to interact with patients with low health literacy.<sup>157</sup>

There are six steps that can help healthcare givers achieve cultural competency. First is to encourage attitudes that associated with excellent transcultural care. Secondly is by developing awareness towards the impact of different cultures on patients beliefs, values which eventually affects clinicians' practices. Later, is by teaching healthcare givers ways on how to obtain background information about their patients' cultures. Healthcare givers also need to perform a cultural assessment that is related to the patients they are treating. This will eventually help them

create a plan their way towards culturally sensitive care using a preserve accommodate restructure framework. Finally, they healthcare givers are expected to avoid defensiveness and recover from cultural mistakes.<sup>158</sup>

The respect of the patients' autonomy involves respecting their values, cultural believes and practices. All healthcare givers need to abandon any tendency to believe biomedical solutions are the only way to maintain and regain health.<sup>159</sup> Optimal health outcomes can be achieved by understanding the patients' culture and values, and by not imposing the healthcare givers' values on the patients. This would help develop a mutually agreeable care plan between the patient and his family beside the healthcare giver.<sup>160</sup> According to Campinha-Bacote & Narayan, healthcare givers who approach their cross-cultural patients with humility; tend to be the most effective when it comes to the care and satisfaction of their patients of diverse cultures. They are experts about the cultural norms of their patients and their families.<sup>161</sup>

## **6. The Application of the Patient Centered Care Model related to issues of autonomy in a Multicultural society:**

### **6.1 Decisions at the End of life of terminally ill patients**

Recently, both healthcare givers and bioethicists have started using autonomy as a central principle for patients' decision making. Healthcare providers need to note that not all patients value autonomy equally. There are many factors that affect their perception to autonomy. The most obvious factor would be their culture, background or religion. This has become a greater issue when dealing with incapacitated patients and chronically ill patients who are near to their end of their lives. Many studies showed that elderly patients from other cultures tend to be delegators when it comes to their desire for decision-making control. Therefore, researchers have found that patients from non-western cultures tend to express heterogeneous attitudes toward autonomy as a decision-making priority.<sup>162</sup>

In many cultures, patients do not wish to discuss their preferences for specific decisions such as cardiopulmonary resuscitation and DNR. When it is the last days for patients, some tend to reflect a “one day at a time” perspective, as they would rather not envision future health states. In some cultures, patients believe that discussing possible illnesses or expectations will lead to that result or illness. While some patients at their end of life prefer that their families and healthcare givers do not comply with their previously expressed wishes and expressed decisions. That was the same result given by a study of patient with end-stage renal disease. One third of the patients responded that they wanted their families and loved ones to have “complete leeway” and over ride their living wills.<sup>163</sup>

It is important too that healthcare givers understand that patients of other culture express and prioritize autonomy and the end of life care differently than patients who are originally from the west. Most of these multicultural patients do not recognize advance directives, like other patients do, therefore healthcare givers need to approach those patients differently when discussing end of life decisions and not trouble them with definitions and explanations about advance directives that they most probably won’t benefit from.<sup>164</sup>

The traditional definition of autonomy cannot incorporate effects on families and that troubles healthcare givers when treating patients from different cultures where the family’s decision is important. In such cultures, patients consider the effect of a decision not only on themselves but also on their families and loved ones. Especially when those patients are near to their end of life, they express potentially conflicting goals, as they wish not to burden their loved ones. Yet, the same patient tends to relay on their families to take care of all their medical decisions if they became incapacitated. However, healthcare decision making standards still do not endorse much consideration to the family burden notwithstanding its importance to

patients.<sup>165</sup>

Most end of life decisions affect patients who lack decision-making capacity and therefore the family and healthcare givers end up making those decisions instead of the patient. This has created concerns regarding the quality of healthcare givers-family communication. Physicians and families frequently report conflicts or disagreements when making end of life decisions or discussing treatment goals. It is recommended that healthcare givers improve the communication with families.<sup>166</sup> The need for quality physician-family communication will increase, as the population of patients with dementia will expand during the next 50 years.<sup>167</sup> This is a critical issue with all patients in general, but it becomes a massive one when dealing with multicultural families. The basic solution is better communication and the openness to understanding cultures and different values other than the person's own values.<sup>168</sup>

## **6.2 Consenting for Research Purposes**

There are two important conditions for autonomy: liberty, which means that a person is independent from controlling influences, and agency that refers to having the capacity to intentional action.<sup>169</sup> Both conditions vary when dealing with multicultural patients according to their level of understanding and their English language proficiency. To respect the autonomy of a subject is to recognize his right to make a choice, hold his own views to take an action according to his own values and beliefs. Therefore, consent is considered an important part of the consenting process when having humans participate in research studies. Individuals' choices must be respected when they are selected to be potential subjects in research.<sup>170</sup> Consenting process needs extra attention and care when dealing with multicultural patients to ensure that they avoid issues such as language access and health literacy. The purpose of using consent is to treat all patients -whether they were from the same culture or a different one- as autonomous



agents as they supposed to be while they are helping in servings the community with their participation in uncomfortable risky procedures.<sup>171</sup> Dealing with multicultural patient demands healthcare givers several requirements that reflects their respect to the patients' autonomy. Health care givers need to make sure that the patients level of understanding and decision-making ability are sufficient to decide whether they would like to participate in an activity that might or might not offer a direct benefit to them.<sup>172</sup>

Influence can come in many shapes and forms some of which are controlling and some are not. Coercion, persuasion and manipulation are all forms of influence. Coercion is when a person uses a sever threat of harm and force to control another person intentionally. Coercion would only occur if the force of threat changed the person's self-directed actions meaning it changed his will and turned him into a non-autonomous person.<sup>173</sup> Persuasion is when a person must come to believe through the merit of reasons given by another person; it usually has to do with playing on the person's emotions. Manipulation is another way of swaying a person to what the manipulator wants. These types of influence are incompatible with making an autonomous choice. Manipulation is usually found the most in the medical field such as in the informational manipulation to motivate the patient into what the healthcare giver wants him to do or choose. Even if that was to provide beneficence and maximum benefit of the patient; manipulation and other ways of influence should not come in the way of the patient's autonomy and make him feel uncomfortable.<sup>174</sup>

Consenting requires researchers to treat patients with dignity and respect regardless their culture, religion or background. Respecting patients as moral agents requires a respect for their choices, values and their understanding of autonomy –whether it was individual of familial- in order for them to exercise autonomy. When healthcare givers use simple, lap person language,

most people who speak English as a second language have the capacity to understand what they are being asked to do in the setting of non-beneficial research and to understand that their participation is not something they must do.<sup>175</sup> Altruism might be the reason for many patients to accept participating, as it is something ideal and multicultural patients must understand it when participating in a research with no direct benefit to them.<sup>176</sup> It would be disrespectful and illegal to attempt to involve patients without first discussing the procedure and securing their permission and that's the reason behind the compulsory use of medical consent. Every adult person should be owed this level of respect in order to be considered a fully autonomous individual.<sup>177</sup>

The relation between patients and the investigators is viewed as a partnership. When patients participate in research with no direct benefit they become the real partners and they should be accorded an appropriate degree of respect.<sup>178</sup> Informed consent reminds researchers that participating patients are persons with interests not mere vessels to serve in a research, therefore, they are supposed to be recognized as partners in the research. This will result in a more respectful relation between the participant and the investigator and avoids the danger of using the patient as a mere end especially when the patient belongs to a vulnerable group.<sup>179</sup>

## **7. Conclusion**

Cultures are becoming more racially and ethnically diverse with time and that could be one of the factors that create disparities in the consenting process. It's important that health care professionals become more aware about their patients' cultures, religions, informational and linguistic needs.<sup>180</sup> Therefore, it is crucial to re-examine the application of the principle of autonomy in bioethics especially when north American and European physician are daily confronted with issues related to the application of this principle on patients from diverse cultures, ethnicities and religious backgrounds.<sup>181</sup> On the other hand, other non-Western societies

must consider the adoption of HIPAA according to their societies needs. Consequently, this requires the bioethicists and policy makers of each society to make similar regulations that protects privacy with the respect for the culture definition of autonomy and consent.<sup>182</sup>

Healthcare givers found that this is affecting their relationships with their multicultural patients. For a long time of period, clinicians and bioethicists have believed that the autonomy principle is the basis for a common moral discourse that can regulate the relationship between patients and their healthcare providers. However, that seemed to be totally mistaken and the proof was all the issues that arose and have troubled both parties through those years.<sup>183</sup> Bioethicists are used to use the principle of patient autonomy to resolve many ethical issues that appear between the patients and their healthcare providers. Respecting the patient's autonomy means giving the patient his own personal space to decide for him or herself the course of treatment. As much as this is agreed on by many bioethicists, however, that is not the case for others.<sup>184</sup> Autonomy and the rest of the moral principles were perfectly applicable in the Western countries as they were developed by ethicists from there. The same exact principles especially autonomy is not functional in Eastern, African and Middle Eastern countries as well in West while dealing with multicultural societies. Respecting the patient's autonomy must include the possibility of challenging and even rejecting medical advice. Nevertheless, the principle should be viewed in a larger perspective, where the person's choice is motivated by some external or internal constraints such as the patients' relationship to their communities, religions and cultures.<sup>185</sup>

There is no easy clear-cut solution to close the health care disparities gap when it comes to the continuing process of consenting to treatment for patients from different races and ethnicities but it is a moral imperative that appropriate resources be brought to bear to address these differences. This can be achieved through improving access to quality care to minorities, remodeling the

health care delivery system.<sup>186</sup> It can also be accomplished by improving cultural and linguistic understanding, and diversifying the health care workforce. There is a huge need to improve the inequities in the social influences of health while treating minorities in a multicultural society. This will dramatically improve the health of the entire society and all of that could start by simply having the patient understand what he is agreeing on or refusing to be treated for meaning that the patient has control over his own health and treatment.<sup>187</sup> Eventually, the ideal way to create medical ethics is to have a public discussion to set and articulate the basic norms for a society then have both laypeople and healthcare providers jointly set the applicable principles for that society or culture.<sup>188</sup>

Privacy is a very broad notion. Within biomedical ethics, it has different forms which include; Informational Privacy, Physical Privacy, Associational Privacy, Proprietary Privacy and Decisional Privacy. These forms of privacy control and enable ethical medical practices and clinical research and are philosophically agreed on. However, the disagreement appears on the level and degree of autonomy and the limits of personal choice in different contexts. HIPAA's Privacy Laws enable autonomy and authority through consenting and following other laws. That ensures privacy, confidentiality and civil rights.<sup>189</sup>

Starting with Informational Privacy. It usually refers to confidentiality that involves the confidentiality of patient-physician encounters along with secrecy and security of the information in patients' records. The information shall not be disclosed to any other party without the confider's authorization. It promotes humans' medical autonomy while preventing harm, injustice, criticism and interference with decision making. In healthcare, it is an ethical duty to keep medical information private. This is required by law, professional codes and policies. Mostly, philosophers, ethicists and bioethicists correspond that respecting humans'

confidentiality; benefits both the patients and the public. Confidentiality is debated by the need for dignity, virtue, utility and fairness.<sup>190</sup> Moreover, it can be justified based on the consequence-based argument and/or the autonomy and privacy rights argument. The difference between right to privacy and the right to confidentiality can only appear when the institute/person handling the information; fails to protect it. However, the right to practice autonomy and protect privacy are joined by the right to confidentiality.<sup>191</sup> This form of privacy becomes a serious demand when utilizing bio-banks and genetics data bases. That's not all, such form of privacy is required with every medical or research encounter such as in abortion, results of research and both physical and electronic records.<sup>192</sup>

Secondly is the Physical Privacy which focuses on patients' bodies and their personal space. It outlooks the rights to modesty, solitude and bodily integrity.<sup>193</sup> This kind of privacy is viewed differently by different cultures and norms. Some patients require time alone to think and make decisions while others require the gathering of family and loved ones.<sup>194</sup> Moreover, body exposure is part of examination, testing and treatment of the sick. Patients need this form of privacy to ensure religious and moral virtues.<sup>195</sup>

Third is the Proprietary Privacy that highlights the property interest in the human person and the rights of self-ownership and the ownership of parts and products of their bodies.<sup>196</sup> It includes both physical-self and the non-physical-self. This includes the right to consent to both treatment and to research. It also pertains to the issues related to women's right their bodies.<sup>197</sup> Proprietary Privacy is important when discussing samples and genetic data kept in biobanks.<sup>198</sup>

Then the Associational Privacy which is the form of privacy that includes relatives, families and intimate relations. Humans tend to share moments and/or decisions with such relatives, while others tend to keep that information away. This right regulates issues related to

pregnancy, abortion and STDs. It is also important in the field of genetics, genetic testing and results sharing.<sup>199</sup>

Finally, the Decisional Privacy that refers to the personal choices of a human. It indicates both liberty and autonomy of the patients' decisions made related to their health. This includes women's right to their bodies in cases of abortion. More, it covers the right of parents to vaccinate or not vaccinate their children without the interference of other authorities. Decisional Privacy is also a right when it comes to using different reproductive technologies as IVF & PGD.<sup>200</sup>

Consent related to HIPAA can be viewed as two types. Consent is meant to protect either rights to make a personal decision or on behalf of someone else. It could also be used to protect personal information when linked to HIPAA. The first type of consent is meant for treatment or research which is usually referred to as informed consent. Without this type of consent, a caregiver or a researcher cannot administer a treatment, nor perform a procedure. The other form of consent is used for authorization which is also known as HIPAA consent. It is a written permission that permits healthcare providers to obtain patient's health records from other caregivers to provide a basis for treatment. Further, it allows healthcare plans to get patients' information to review claims and set plan premiums based on the patient's needs and history. This is usually renewed on an annual basis.

## **C. Consent and Substituted Judgment**

### **1 Substitute Judgment**

#### **1.1 Introduction**

Incapacitated patients might be unconscious or uncommunicative or both. There's a wide range of diseases that would lead to that such as a mental illness, a chronic illness, or a disability. Medico-legal ethics is directed towards the rights of patients such as privacy and autonomy. Patients have the right to make decisions related to their healthcare. However, as part of some

illnesses, some patients lose capacity or their ability to make decisions. In other occasions, the patients' decisions contradict with their best interest.<sup>201</sup> Decision-making ability falls along a continuum, with no natural threshold for adequate decision-making capacity. When such a thing happens, someone else should take over the decision-making process.<sup>202</sup> Nevertheless, privacy and the best interest of the incapacitated patient must be maintained while undertaking that process. Hence, a health care power of attorney for an individual, can get access to that patient's medical record to take medical decisions. This is covered and permitted by the HIPAA Privacy Rule at 45 CFR 164.524.<sup>203</sup>

It is ethically and legally known that Informed consent can often lead to a better doctor-patient relationship if it was done correctly. It could also help in having the patient adhere to the treatment plan which will lead to a better understanding of the disease on the healthcare provider's side. Informed consent can improve communication besides the decision-making process between; however, it will not enable autonomous choices when patients are incompetent. This is not an excuse to ignore the patient's right to autonomy; there should also be substantial considerations. This means that assent is to be obtained to interventions decided on by a surrogate or court.<sup>204</sup>

Decision making for an incapacitated patient can be extremely problematic. However, there are some ways to get an idea around the patient's preference by looking for any left advance directives then by searching for the proper surrogate decision maker. This process is guided by the standards of substitute judgment and best interest. However, even these solutions have their limitations that leave healthcare providers with lingering dilemmas around the decision-making process for incompetent patients.<sup>205</sup>

Even with the availability of advance directives and the help of a proxy or a surrogate. Every single factor has its issues and limitations. Advance directives can be general and include vague terms.<sup>206</sup> They can also be not very well informed when patients do not know what interventions they are asking for. One more essential limitation to advance directives is that patients usually can't predict their prognosis or can change their minds before having the chance to change the advance directive. Besides, a substitute judgment made by a proxy or a surrogate can be bias or lead to a conflict of interest. Too much care and love towards the patient can make the surrogate mislead the healthcare givers. On the other hand, conflict of interest can result due to considering the interest of a third party while ignoring the patient's best interest. By that, it shows that both advance directives and substitute judgments could both conflict with the patient's best interest.<sup>207</sup> Weighing a decision through using the ethical principles of autonomy, beneficence, non-maleficence, and justice could be helpful. Obtaining the help of an ethics consultant in these situations can help guide both healthcare givers and surrogates be assured that their decision is not an idiosyncratic reflection of their personal views. Finally, if these measures weren't useful in solving the problem, the court will give the final decision that might become a precedent.<sup>208</sup>

## **1.2 Methods for Decision-Making for Incapacitated Patients**

### **1.2.1 Informed consent embedded in Advance Directive**

According to the Patient Self-Determination Act of 1990, all hospitals are required to provide written information to their patients regarding their rights under state law to make medical decisions and execute advance directives. Every patient's record must have a document that shows whether they have an advance directive or not. The most formal type of advance directives are the written ones. They can be in the form of a living will, medical advance directive or even a health proxy. These are legally witnessed or certified forms that the



competent patient fills.<sup>209</sup> From a legal point of view, most states honor other state's forms, as laws differ from a state to another. All fifty states allow living wills; however, each state has specific laws to deal with them. Healthcare givers grant immunity when applying the documented wishes of the patient from other state. They become free from civil and criminal liability and professional disciplinary actions. However, healthcare providers must not practice any discrimination act against any patient based on whether he does or doesn't have an advance directive. They are also expected to be familiar with the state's law and health institute's policy regarding advance directives.<sup>210</sup> Patients are recommended to fill their advance directives as they are more reliable in courts, thereby, patients think more seriously while filling them. Yet only 25% of the patients fill these forms.<sup>211</sup>

Nevertheless, it seems that the most common type of advance directives is the oral conversations that the patient has with family or friends. However, it was found that in many cases, the family express their own wishes towards the treatment of their beloved patient while hiding the patient's wishes. This is what happened in the famous Quinlan case, where the patient has expressed her wishes earlier that she wouldn't want to be kept alive with extraordinary measures. The second form of oral advance directives is the oral statements expressed by the patient to the healthcare givers. They are not considered as casual statements that are expressed to family or friend. In some states; these statements are only legally binding to the time of the illness or the hospital stay.<sup>212</sup>

The main reason to have patients prepare their advance directives is to respect their wishes when it comes to making important decisions when they reach end of life care or become incompetent. Advance directives are a mean to express the patients' informed choices that accordingly help surrogates make the rest of the decisions when needed. Yet, it seems hard to

give full trust into advance directives when they seem to have limitations. Healthcare givers and surrogates must weight how much valuable is the advance directive to the situation the patient is in and it should be followed carefully if it was applicable to the patient's situation. Advance directives are seen as more trustworthy than surrogate decisions that is based on an earlier discussion. As much as it is recommended to have patients have their advanced directives made; it seems that these forms have their own limitations. On one study, it was found that only 33% of patients who knew that patients on ventilators can't talk. Half of them thought that ventilators were oxygen tanks only. Regarding CPR –which is an important decision when it comes to end of life care- one fourth of the patients didn't know that it involved assisted breathing and chest compressions. This means that patient might be expressing strong preferences towards treatments that they don't even know. Based on that; advanced directives might not always be informed. It seems that the advance directive's statements might not be anticipated to guide care. It guides people to states views towards their future care without directing them to think deeply about it.<sup>213</sup>

Another issue that weakens advance directives is that generally most patients cannot predict how they'd react to future interventions. Moreover, it is hard to estimate their own survival rate, as many conditions would control that. Patients' choices differ when they are healthier than when their condition deteriorates. Many patients do not have a premade decision towards their life-prolonging interventions until they are faced with the real situation. The mind changing can be explained but sometimes patients decline healthcare interventions with unexplained reasons. This is also one more reason to make advance directives hard to apprehend. It seems like a matter of time when patients choose to accept potentially life-sustaining therapy that is highly burdensome or would result in a severely disabled condition, and then they change their minds.<sup>214</sup>

A third reason that shows the limitation of advance directives is the vagueness of the terms used in it such as heroic or extraordinary care. It is better to refuse performing an intervention when the burdens outweigh the benefits of care. But with such vague terms showing in the advance directive, how can the physician decide on what the patient means while weighing that with the principle of best interest. This can be solved somehow with the help of the patient's surrogates. But in this case, how much leeway surrogates should have? One study showed that 39% of patients wanted their surrogates to follow the advance directives literally while 31% of patients gave the surrogate the permission to override their wishes if it was for the patients' best interest.<sup>215</sup>

Having an advanced directive does not mean that the patient has complete control over their healthcare decisions when they lose the ability to make decisions. This is one misunderstanding that leads to unrealistic expectations. The simple reason behind that is that no one can predict what specific clinical decisions will be needed to be made in the future or how the patient's condition might change.<sup>216</sup>

Another issue is that patients write their advance directives according to implicit assumptions about their prognosis that might not be accurate. To be more specific, when patients become incompetent; they might have changed a lot since writing the advance directive therefore any earlier statements might not be relevant any more.<sup>217</sup>

### **1.2.2 Other Decision Makers**

This could describe the power of attorney, healthcare proxy or a healthcare representative which is also known as the surrogate. However, there's a difference, the durable power of attorney is a document that deliberates another person appointed by the patient and documented legally in advance directives. This allows that person to make legal and healthcare decisions on

behalf of the patient. In some states the agent has the power and authority to admit or remove the patient from a health care facility. The power of attorney may be both durable or non-durable. The power of attorney expires when the principal –the patient- dies, or revokes it. On the other hand, the healthcare proxy is limited to medical decisions only.<sup>218</sup> The patient can control the form of interventions and under what circumstances, so the healthcare proxy is limited with the amount of authority he has. In some states this is called executing a durable power of attorney for health care while in others it is called a healthcare proxy. Limitations may be placed on what decisions agent can make; agent may be given full discretion depending on the state' law.<sup>219</sup>

A healthcare representative or a surrogate is appointed when the patient didn't appoint any healthcare proxy and lost the ability to make decisions. A surrogate might be a friend or a relative. However, there is a legal hierarchy of consideration. The surrogate must also have ability to make decisions besides the relationship level and level of concern. If no relative or friend was found, surrogate can be a healthcare giver. The main issue is that the surrogate is making decisions for the patient based on the patient's best interest with no advance directives available. This could lead to personal bias and conflict of interest. Therefore, some states exclude healthcare givers from being the patient's surrogates.<sup>220</sup>

### **1.3 Standards of Substitute Decision Making for incompetent patient**

#### **1.3.1 Substitute judgment**

Substitute judgment is when the surrogate relies on preferences of the patient's when making medical decisions on behalf of the patient. Substitute judgment can be used in two situations; when the patient had previously expressed his preferences explicitly. The other case is when the surrogate can assume the patient's preferences from past conversations, actions or statements.<sup>221</sup>

Most patients write general advance directives which leave the surrogates with no indication or clear preference. With the absence of a clearly specified advance directive; surrogates are

expected to decide on behalf of the patient under the circumstance, considering all what they know about that person's preferences. Imagining and reconstructing the patient's medical choices is ethically acceptable when the patient can't make his own decisions as long as it respects the patient's individuality. The surrogate is expected to honor the coherence, integrity and authenticity of the patient as a being.<sup>222</sup>

However, there seems to be problems with the substitute judgment. Even when people act in faith, they still do disagree over what the patient might choose as a medical decision. Therefore, neither family nor healthcare givers can give accurate choice of a competent patient when it comes to future life sustaining treatments. Studies showed that surrogates and proxies' statements about what the patients' preferences are actually their own preferences and not the patients'. About one third of the surrogates choose incorrect medical decisions that do not match the patients' preferences. There were attempts to facilitate the discussions between patients and their proxies or surrogates; nevertheless, these attempts failed to improve the level of agreement. The issues arise from the care and love that the surrogate would usually have towards the patient. While the patient might not want to become a burden, wants to spare the financial expenses and stress or even would want to die with dignity when he can't gain the wanted quality of life he is used to have. The surrogate is expected to adhere to these wishes and consider the factors that the patient himself has considered. An ethical issue can also arise when the surrogate would consider these factors while the patient did not give them importance. This would lead to a huge conflict of interest. Having a general advance directive or no advance directive at all would usually lead to unavoidable speculation substituted judgments.<sup>223</sup>

The substitute judgment might conflict sometimes with the patient's best interest as much as an advance directive can conflict with the patient's best interest. This would lead to unwanted

decisions by the patient if he'd had the ability to communicate later. In some cases, it would be appropriate to withhold a treatment regimen on the bases of a clear advance directive even if it's obvious that such a treatment would save the patient with a good level of functionality. The same could happen when the surrogate states the patient's wishes that contradict the best interest from a medical point of view. Still it would be extremely problematic to decline a simple medical intervention that grants a good quality of function just based on a substitute judgment. This yet leave the healthcare providers in a dilemma regarding the decision making. Despite the shown limitation of substitute judgments, they are still ethically preferred as they show respect to the patient's individuality and his unique values and preferences but with the focus that surrogates would help find what the patient would want, not what they might want for themselves. Two famous cases where the court's help was needed for the decisions to be taken were the Nancy Cruzan case 1990 and the Terri Schiavo case in 2005. These two cases illustrate the importance of both surrogate decision making and substitute judgment while still facing the limitations of both.<sup>224</sup>

### **1.3.2 Best interest**

Best interest is considered when the patient's own preferences are not known to the surrogate. This would require the surrogate to promote the patient's welfare. Patient's welfare is defined as making choices that relief suffering, preserve and restore function and extend and sustain the quality of life of the patient. These choices should be similar to a reasonable person's choices in the same circumstance. The surrogate's decision making should be attempted with the view through the patient's eyes rather than his own. This is ethically challenging and requires an ethical evaluation to exclude prejudice, stereotyping, discrimination or misinformation. Therefore, the general presumption must be made according to the individual case and best

interest must be designated from the point of view of the person who's the judgment is made for.<sup>225</sup>

When the patient does not give any advance directive, substitute judgment may be so hypothetical therefore it would be more honest for the surrogate and physician to base the medical decision on best interest of the patient. The healthcare givers are expected to use the principle of beneficence to weight the benefits and the burdens of a medical intervention which will lead to acting in best interest but from a medical point of view. A surrogate whom knows the patient preferences can help with personalizing such a medical decision. Regardless, the medical point of view of best interest, the best interest of a particular person must be determined in the light of the available options under specific circumstances. Best interest does not mean that the patient's life must be extended as medically possible. It must be a combination of what a reasonable competent person would choose in his best interest however personalized to that individual patient's preference. The issue occurs when the surrogates take decisions based on their own values or when they consider the best interest of a third party other than the patient. As humans; family members are not expected to ignore their own interests and needs but to hold up to the standards of a trusted surrogates. On the other hand, dilemmas could occur due to requiring burdening life prolonging treatments that are only based on the surrogate's needs to keep the patient alive much longer. Patients who believe that illnesses have spiritual purposes, tend to refuse such interventions. While healthcare providers refrain from such interventions based on the ethical principle of non-maleficence. Advance directives can sometimes conflict with the patient's best interest. Therefore, physicians and surrogates might suffer with the patient's advance directive when it does not meet his current situation's best interest. In some situations, there might be a need to override the refusal to care stated in the advance directive as

a short-term intervention can restore the patient's health. On the other hand, the patient's wishes to receive an intervention might become impractical or unbeneficial if his condition deteriorates. A unique situation tends to occur when an incompetent patient has no advance directive yet has no surrogates available. Some healthcare givers believe in providing all life sustaining treatments to such a case unless it is futile. However, this could still be burdening leading to a patient who is a prisoner of technology. An ethics consultant would advise the physician on choosing what's in the patient's best interest.<sup>226</sup>

#### **1.4 Conclusion**

Decision making for incapacitated patient can be extremely problematic. Even with the availability of an advance directives and the help of a proxy or a surrogate. Each single factor has its own issues and limitations. Advance directives can be general and include vague terms.<sup>227</sup> They can also be not very well informed when patients do not know what interventions they are asking for. One more basic limitation to advance directives is that patients usually can't predict their prognosis or can change their minds before having the chance to change the advance directive. In addition, the substitute judgment made by a proxy or a surrogate can be bias or lead to a conflict of interest. Too much care and love towards the patient can make the surrogate mislead the healthcare givers. On the other hand, conflict of interest can result due to considering the interest of a third party while ignoring the patient's best interest. By that, it shows that both advance directives and substitute judgments could both conflict with the patient's best interest. Using the ethics principles of autonomy, beneficence, non-maleficence and justice could be helpful. Obtaining the help of an ethics consultant in these situations can help guide both healthcare givers and surrogates be assured that their decision is not an idiosyncratic reflection of their own personal views. Finally, if these measures weren't effective in solving the problem, the



court will be give the final decision that might become a precedent.<sup>228</sup>

## **2. Decision Making**

### **2.1 Introduction**

A significant portion of Clinical ethics is directed towards the autonomy of patients and their rights. Patients have the right to make decisions related to their healthcare. Thus, clinical ethics created several goals that must be met when treating patients. Informed consent is one step towards achieving these goals. However, as part of some illnesses, some patients lose capacity and the ability to consent. Decision-making ability falls along a continuum, with no natural threshold for adequate decision-making capacity. When such a thing happens, someone else should take over the decision-making process.<sup>229</sup>

Incapacitated patients might be unconscious or uncommunicative or both. However, that should never be a reason to neglect the patient's right to autonomy; there should also be substantial considerations. This means that assent is to be obtained to interventions decided on by a surrogate or court.<sup>230</sup> According to HIPAA Privacy Rule at 45 CFR 164.510(b), this is not considered a violation of privacy. Whenever a patient is incapacitated, a health care provider can share the patient's information with a surrogate or a designated power of attorney. This is permitted by law if the health care provider determines, based on professional judgment, that it is in the best interest of the patient.<sup>231</sup>

There are several methods to get an idea around the patient's preference by looking for any left advance directives then by searching for the proper surrogate decision maker. This process is guided by the standards of substitute judgment and best interest.<sup>232</sup>

Nevertheless, the standard approach for substitute decision making that is being practiced beside several other suggested approaches by contributors all seems to have issues when applied

to practice. These solutions have their limitations that leave healthcare providers lingering with dilemmas around the process of decision-making for an incompetent patient.<sup>233</sup>

Moreover, they leave surrogates worried, troubled, carrying guilt and sometimes unsatisfied with the decision. Even with the availability of an advance directive and the help of a proxy or a surrogate, dilemmas still do exist. Every single factor has its issues and limitations. Advance directives and substitute judgments could both conflict with the patient's best interest. Hence, the existing standard used approach and several suggested approaches remain unhelpful. Therefore, it's necessary to gather the advantages of those approaches in one single approach while using the concept of shared decision making. The suggested approach is called the modified reasonable person approach. This approach determines on the substitute decision maker to focus on the clinical picture only beside omitting the idea that this is a decision taken for an incompetent person.<sup>234</sup> With the help of healthcare professionals, this can be achieved using many tools that measure the quality-of-life changes. Then the comparative quality of quality-of-life coefficient for each treatment option can be compared to each other numerically. This has to be also combined with the patient's know preferences and values that are either stated in the advance directive or expressed to the surrogate.<sup>235</sup> And although numbers cannot measure the life of humans; using technology and numbers to measure the quality of life might have a significant impact when deciding on an end of life treatment for an incapacitated patient.<sup>236</sup> Hence, this approach enables surrogates to make a better substitute decision that follows the six ethical goals, the principles of the Universal Declaration of Human Rights and ensures the medical appropriateness of the treatment.<sup>237</sup>

## **2.2 Ethics of decision making**

### **2.2.1 Autonomy and Informed consent**

Autonomy is understood as the individuals' capacity and opportunity to exercise rational

self-determination over the content and general course of their own lives.<sup>238</sup> Both healthcare givers and bioethicists use autonomy as a central principle for patients' decision making. There are many factors that affect their perception to autonomy. The most obvious factor would be their competency, level of understanding and consciousness. This has become a greater issue when dealing with incapacitated patients and chronically ill patients who are near to their end of their lives. Many studies showed that elderly and terminally patients tend to have delegators when it comes to their desire for decision-making control.<sup>239</sup>

Many ethicists support autonomy as a secularly neutral ideal of legitimacy of which all persons, by virtue of being a person, are considered bound to accept. Consequently, this makes healthcare providers and patients meet as moral strangers while still having a free and informed consent as a language to use while deciding and agreeing on treatments.<sup>240</sup>

There are two important conditions for autonomy: liberty, which means that a person is independent from controlling influences, and agency that refers to having the capacity to intentional action.<sup>241</sup> Both conditions vary in patients according to their diseases, level of capacity and consciousness. To respect the autonomy of a subject is to recognize his right to make a choice, hold his own views to take an action according to his own values and beliefs. Therefore, advance directives are considered as important documents that could substitute the consenting process when patients lose capacity. Patients' wishes have to be respected when they lose capacity to make medical decisions but have expressed those earlier either verbally or on formal forms.<sup>242</sup>

According to the principle of autonomy, which underlines the notion of informed consent, it states that patients must have sufficient knowledge about their condition, treatment and alternatives. They also need to be mentally competent, free from any form of constrains to

be responsible and take their own decisions, only then the process of informed consent would be considered legal and morally ethical.<sup>243</sup> Self-determination is another principle that is tied to notion of informed consent. Self-determination must be respected by the professional authority. The intended purpose of the informed consent is to provide the patient with his right to participate in the medical decisions along with his healthcare givers in order to safeguard the patient's wellbeing and to prevent harm from occurring to him. Incompetent patients lack these abilities, therefore can't consent to treatment.<sup>244</sup>

The right to informed consent is grounded in the principles of autonomy and respect for persons. It is not a political or legal artifact.<sup>245</sup> It is a general principle that applies to every person has a right to self-determination limited only by the equal and competing rights of others. Many would assume that the patient needs to have decision-making capacity to exercise that right. However, the right to autonomy applies even when the person lacks capacity.<sup>246</sup>

Most end of life decisions affect patients who lack decision-making capacity and therefore the family and healthcare givers end up making those decisions instead of the patient. This has created concerns regarding the substitute decision making for incapacitated patients. Physicians and families frequently report conflicts or disagreements when making end of life decisions or discussing treatment goals. It is recommended that healthcare givers improve the communication with families.<sup>247</sup> The need for quality physician-family communication will increase, as the population of patients with dementia will expand during the next 50 years.<sup>248</sup> This is a critical issue that faces doctors and healthcare providers on a daily basis. Several approaches were introduced to determine the best substitute decision making process that cares for the patient's best interest and holds the person's own values.<sup>249</sup>

### **2.2.2 Ethical Goals for Treating Patients**

There are six ethical goals that should be all considered when treating patients with capacity or taking a medical decision on behalf of an incapacitated patient. These goals help in deciding on which approach should be adopted when dealing with the decision making process. First, it is always important to remember to promote respect for the patients, their families and loved ones. Therefore, decision making should promote the patient's clinical interests. A shared decision between patients and their physicians promote the well-being of the patient. Physicians have the relevant medical facts while patients are the best judges to their own interests. Together; they can identify treatments for times of incapacity.<sup>250</sup>

Secondly by enabling the patient's control on how he or she is treated as much as possible. This goal is fundamental in order to respect the patient's autonomy regardless whether their choices promote their best interest or not. Through that patients can determine their lives during periods of incapacity through advance directives whether they were oral or written. Third goal is achieved by providing the treatment that is consistent with the patient's preferences and values. Patients' well-being is highly influenced when their values and preferences are consistent with their treatment. In addition, it promotes respecting their autonomy.<sup>251</sup>

Fourth goal promotes respecting the patient's preferences for how treatment decisions are made. Respecting the patient's preferences when it comes to their treatments when they become incapacitated is a form of respecting their autonomy. Another way of respecting patient's autonomy is through allowing their designated surrogate to make their medical choices. It is a way for the patient to control his treatment indirectly. The fifth goal calls for respecting and helping the patient's family and loved ones. Medical decisions have implications not only on the patients but even his family and loved ones. Additionally, medical decisions for incapacitated patients have a greater emotional and sometimes a financial impact on the families. Healthcare

givers happen to respect their patients' wishes and values through respecting and helping the families of the patients. Finally, it is important to promote a timely decision making. Making decisions takes time and that time is critical sometimes to some patients. Taking so much time can result in unwanted clinical outcomes that would harm the patient or results against his values and wishes.<sup>252</sup>

Autonomy, informed consent and the six ethical goals of treatment might seem related to competent patients at the first glance. However, these rights do apply also to incompetent patients when receiving treatments and deciding on their behalf. It is important to keep these goals and right in mind while discussing the standard approach used for substitute decision making for the incompetent patients.<sup>253</sup>

## **2.3 Issues with Several Approaches for Substitute Decision Making for Incapacitated patients**

### **2.3.1 Existing approaches**

Society has developed a very general mechanism to compensate the lack of decision making capacity when patients become incompetent and unable to provide their own decisions. Regardless being incompetent, all patients have the right to choose their medical decisions; this right must be exercised by their substitute decision makers when they can't choose for themselves. This force two fundamental issues; who should be the substitute decision maker and what values should be used for these decisions for every single different patient. In the case where the patient has been previously competent, the substitute decision makers is expected to use the values that the patient used to hold when he was competent. The patient might have his wishes written or have stated it orally only. In case the substitute decision maker used values other than those that the patient used to believe in, then he would be forcing the incompetent patient's life to another direction that the patient would have rejected if he had a choice.<sup>254</sup>

Such an act would violate the ethics of substitute decision making, beside not respecting the patient's autonomy, it would be violating the patient's rights to justice and equality. The incompetent patient would not be treated fairly as other persons are simply because of his disability.<sup>255</sup>

Thereby, a surrogate should only be a person who will take the responsibility of making healthcare decisions on behalf of the patient but based on the patient's values and wishes. The surrogate is seen as giving effect to decisions the patient would have made for himself; not as making new decisions instead of the patient. According to the practiced approach, the ideal situation suggests that the now-incompetent patient had already prearranged a substitute decision maker through his signed and witnessed advance directive. Through advance directives; patients clearly state what they want and what they don't want to be done to them beside identifying who they believe to be the trustworthy person to respect their wishes and take decisions. On the bases of the principle of autonomy and equality; surrogates are expected to honor the wishes of the patients whether he/she was the next of kin or not.<sup>256</sup>

Being the next of kin doesn't guarantee that person would have the patient's best interest at heart nor that he shares the same values as the patient. It is only a rebuttable presumption that the next of kin is highly likely to care and share the same values as the patient.<sup>257</sup>

The situation becomes tougher when the now-incompetent patient hasn't appointed a specific substitute decision maker or has not previously specified values. The standard presumption suggests that those who stand in a close personal relationship to the incompetent patient are more likely to hold the incompetent person's best interests at heart and are more aware of his values.<sup>258</sup>

In our societies, family members have traditionally been identified as the closest kind of relationships to know the patient. Therefore, law has identified a specific hierarchy to follow if the patient hadn't appointed a surrogate. The substitute decision makers in descending order of priority as follows: spouse, child, parent, sibling, and anyone else related by birth or adoption. Nevertheless, this order can be overruled by the court if there were any grounds that suggests that this substitute decision maker would not follow the patient's best interest, or depart from the patient's values and wishes.<sup>259</sup>

There were several suggested approaches by commentators where some were even applied at some institutions. One approach was to have the physicians take the decisions for their incapacitated patients. This would result in a timely decision that's also medically accurate however it would fail other ethical goals and fail to respect the role of the surrogates and their role in the patients' lives.<sup>260</sup>

Others suggested to have the ethics committees or judges do all the decision making for the incapacitated patients. Such decisions would be considered ethically accurate; data showed that strangers have the ability to predict patient's preferences more accurate than family members can do for their loved ones. However, both ethics committees and courts require a considerable amount of time to be familiar with a case and take a decision. This would conflict with the goal of having a timely decision-making besides distancing surrogates from their role. A third form of decision making that was highly suggested and applied was the to base treatment decision for incapacitated patients on the surveyed preferences of patients in the same community the patients come from. This approach could promote timely decision making if the required data was already collected earlier. However, basing a treatment on other's views would not be likely to follow that patient's wishes and values. This community based approach also



does distance the surrogates from their duty. With all the previously mentioned approaches, there seems to be issues in every single one of them. Therefore, it's hard to rely on a specific approach for decision making for incompetent patients. Yet it seems that every single approach has some form of validity while still having some limitations.<sup>261</sup>

### **2.3.2 Issues with current practices.**

The main criticism on the standard approach is that it fails to keep up to the six ethical goals. For a beginning, it is always an issue for healthcare givers to determine the best course of treatment that would also be following the individualized interest of each patient. This often occurs when clinical experts are unclear about which treatments are clinically indicated. Sometimes, even the current practice –while still developing for a new disease- is unable to determine if it is the best treatment that would promote the patient's clinical interest. This becomes a bigger dilemma when the patient has no input.

Second, the current practice tends to solve this issue by having the patients prepare their advance directives prospectively. Patients are encouraged to document their preferences preparing for times of incapacity. Most patients do not fill their advance directives, even if they did it sometimes doesn't specify their exact preferences or values.

Third, when the patient has left no advance directives and its not clear which treatment is best to suit his interest when he is incapacitated; the standard practice seeks to look for the surrogate. The surrogate holds the responsibility of making the medical decision that is the most consistent with the patient's preferences and values. Studies in social psychology and behavior showed that individuals are unable to predict the preferences and values of loved ones.<sup>262</sup> This supports the fact that the two most widely discussed methods for improving surrogate accuracy by having appointing one's own surrogate and discussing one's treatment preferences and values

with the surrogate are ineffective.<sup>263</sup>

Fourth, systemic reviews showed that patients want their beloved ones and families to make their substitute medical decisions. However, there are no studies that show how patients would want treatment decisions to be made if they knew that surrogates were unable to predict accurately their preferred treatment decisions.<sup>264</sup>

Fifth, there doesn't seem to be any studies the time frame that is taken to make decisions for incapacitated patients. However, it is known that disagreements -between family members and families and healthcare givers- over treatments are frequent and cause delay at least in one third of the cases. Therefore, relying on surrogates may compromise timely decision making.<sup>265</sup>

Finally, a systemic review had shown that having to make decisions on behalf of beloved ones cause at least one third of the surrogates an enormous amount of emotional stress and burden. A study showed that the levels of stress were as high as the posttraumatic stress disorder.<sup>266</sup> On another study, two thirds of the surrogates suffered from symptoms of depression and anxiety.<sup>267</sup> This is against the goal of helping and benefiting the patients' families and loved ones. Informed patients who knew about the amount of surrogate burden, did not want their families and loved ones to make decisions for them when they lose capacity.<sup>268</sup>

Psychological studies showed several issues that the surrogates suffer from. Besides the high levels of anxiety, surrogates state their discomfort with the surrogate role.<sup>269</sup> Predicting the patient's preference makes them feel responsible for the outcomes. Some studies showed that surrogates would often respond by choosing whichever treatment option minimizes their sense of responsibility.<sup>270</sup>

After viewing the general limitations in those approaches, there's a need to dig deeper in the limitations that are embedded in the current approach. The basic elements of substitute advance

directives seem to have extreme limitations to them, causing the obstacles in the current practiced approach in substitute decision making for incapacitated patients.

## **2.4 Some Limitations to Substitute Decision-Making Process**

### **2.4.1 Limitations of advance directives**

The most formal type of advance directives are the written ones. They can be in the form of a living will, medical advance directive or even a health proxy. These are legally witnessed or certified forms that the competent patient fills. From a legal point of view, most states honor other state's forms, as laws differ from a states to another. This gives immunity to healthcare givers when applying the documented wishes of the patient from civil and criminal liability and professional disciplinary actions. Patients are recommended to fill their advance directives as they are more reliable in courts, thereby, patients think more seriously while filling them. Yet only 25% of the patients fill these forms.<sup>271</sup>

Nevertheless, it seems that the most common type of advance directives is the oral conversations that the patient has with family or friends. However, it was found that in many cases, the family express their own wishes towards the treatment of their beloved patient while hiding the patient's wishes. The second form of oral advance directives is the oral statements expressed by the patient to the healthcare givers. They are not considered as casual statements that are expressed to family or friend. In some states; these statements are only legally binding to the time of the illness or the hospital stay.<sup>272</sup>

The main reason to have patients prepare their advance directives is to respect their wishes when it comes to making important decisions when they reach end of life care or become incompetent. Advance directives are a mean to express the patients' informed choices that accordingly help surrogates make the rest of the decisions when needed. Yet, it seems hard to give full trust into advance directives when they seem to have limitations. Healthcare givers and

surrogates must weight how much valuable is the advance directive to the situation the patient is in and it should be followed carefully if it was applicable to the patient's situation. Advance directives are seen as more trustworthy than surrogate decisions that is based on an earlier discussion. As much as it is recommended to have patients have their advanced directives made; it seems that these forms have their own limitations. On one study, it was found that only 33% of patients who knew that patients on ventilators can't talk. Half of them thought that ventilators were oxygen tanks only. Regarding CPR –which is an important decision when it comes to end of life care- one fourth of the patients didn't know that it involved assisted breathing and chest compressions. This means that patient might be expressing strong preferences towards treatments that they don't even know. Based on that; advanced directives might not always be informed. It seems that the advance directive's statements might not be anticipated to guide care. It guides people to states views towards their future care without directing them to think deeply about it.<sup>273</sup>

Another issue that weakens advance directives is that generally most patients cannot predict how they'd react to future interventions. Moreover, it is hard to estimate their own survival rate, as many conditions would control that. Patients' choices differ when they are healthier than when their condition deteriorates. Many patients do not have a premade decision towards their life-prolonging interventions until they are faced with the real situation.<sup>274</sup> The mind changing can be explained but sometimes patients decline healthcare interventions with unexplained reasons. This is also one more reason to make advance directives hard to apprehend. It seems like a matter of time when patients choose to accept potentially life-sustaining therapy that is highly burdensome or would result in a severely disabled condition, and then they change their minds.<sup>275</sup>

A third reason that shows the limitation of advance directives is the vagueness of the

terms used in it such as heroic or extraordinary care. It is better to refuse performing an intervention when the burdens outweigh the benefits of care. But with such vague terms showing in the advance directive, how can the physician decide on what the patient means while weighing that with the principle of best interest. This can be solved somehow with the help of the patient's surrogates. But in this case, how much leeway surrogates should have? One study showed that 39% of patients wanted their surrogates to follow the advance directives literally while 31% of patients gave the surrogate the permission to override their wishes if it was for the patients' best interest.<sup>276\</sup>

Having an advanced directive does not mean that the patient has complete control over their healthcare decisions when they lose the ability to make decisions. This is one misunderstanding that leads to unrealistic expectations. The simple reason behind that is that no one can predict what specific clinical decisions will be needed to be made in the future or how the patient's condition might change.<sup>277</sup>

Another issue is that patients write their advance directives according to implicit assumptions about their prognosis that might not be accurate. To be more specific, when patients become incompetent; they might have changed a lot since writing the advance directive therefore any earlier statements might not be relevant any more.<sup>278</sup>

#### **2.4.2 Conflicts between Advance Directives and Best Interest**

Advance directives can sometimes conflict with the patient's best interest. Therefore, physicians and surrogates might suffer with the patient's advance directive when it does not meet his current situation's best interest. In some situations, there might be a need to override the refusal to care stated in the advance directive as a short-term intervention can restore the patient's health. On the other hand, the patient's wishes to receive an intervention might become

impractical or unbeneficial if his condition deteriorates. A unique situation tends to occur when an incompetent patient has no advance directive yet has no surrogates available. Some healthcare givers believe in providing all life sustaining treatments to such a case unless it is futile.

However, this could still be burdening leading to a patient who is a prisoner of technology. An ethics consultant would advise the physician on choosing what's in the patient's best interest.<sup>279</sup>

This could describe the durable power of attorney or surrogates. However, there's a difference, the power of attorney is appointed by the patient and documented legally in advance directives. This allows that person to make decisions on behalf of the patient when he loses decision-making capacity. It can control the forms of interventions and under what circumstances, so the healthcare proxy is limited with the amount of authority he has. In some states this is called executing a durable power of attorney for health care while in others it is called a healthcare proxy.<sup>280</sup>

Part of the advance directives include mentioning a surrogate. A healthcare representative or a surrogate is appointed when the patient didn't appoint any healthcare proxy and lost the ability to make decisions. A surrogate might be a friend or a relative. However, there is a legal hierarchy of consideration. The surrogate must also have ability to make decisions besides the relationship level and level of concern. If no relative or friend was found, surrogate can be a healthcare giver. The main issue is that the surrogate is making decisions for the patient based on the patient's best interest with no advance directives available. This could lead to personal bias and conflict of interest. Therefore, some healthcare givers are excluded from being the patient's surrogates.<sup>281</sup>

## **2.5 Application of the New Suggested Approach**

### **2.5.1 New suggested approach**

Competent patients always consider the quality of life factor when taking a medical decision.

Therefore, it is suggested to include this implication when taking a substitute decision as form of equality and justice. This is called the modified reasonable person approach. This approach determines on the substitute decision maker to focus on the clinical picture only beside omitting the idea that this is a decision taken for an incompetent person.<sup>282</sup> The next step is to help the surrogate develop a quality-of-life rating considering a Capacitated patient with a similar clinical profile similar to the incapacitated patient's profile. Through this step, the surrogate identifies the different treatment options that are available and appropriate then projects the quality of life that results from each course of treatment. All subjective expression of satisfaction with life, psychosocial impact and other evaluative parameters are relevant and must be factored into the equation. With the help of healthcare professionals, this can be achieved through the use of many tools that measure the quality-of-life changes.<sup>283</sup> Then the comparative quality of quality-of-life coefficient for each treatment option can be compared to each other numerically. Its obvious that a normal competent patient would opt for treatment under these conditions.

After having a more or less clear picture on the options, the surrogate applies the same clinical standards and develops corresponding comparative quality-of-life coefficient ranges for the incompetent person on each interventional option. Then the subjective expression of satisfaction with life, psychosocial impact, and other evaluative parameters relative to the incompetent patient will be factored into the equations.<sup>284</sup>

A shared decision between the healthcare giver and surrogate must result from taking into account the results of the quality of quality-of-life coefficient for the incompetent patient that falls within the range that is acceptable to the competent patient with a similar medical profile. This has to be also combined with the patient's know preferences and values that are either stated in the advance directive or expressed to the surrogate.<sup>285</sup>

This approach satisfies the principle of equality and justice as well as dignity and respect for persons. Equality and justice are satisfied procedurally through the use of the quality of life tools and comparing the treatment to a competent patient's treatment and quality of life. The principle of dignity and respect for persons is satisfied through respecting the patient's wishes and values. Respect of persons is also addressed in having the surrogate's role applied.<sup>286</sup> Furthermore, it respects the HIPAA Privacy Rule at 45 CFR 164.510(b), hence there is no violation of privacy.<sup>287</sup>

The principle of beneficence is applied through having the physicians share their input regarding the appropriateness of the treatments. Sharing the decision with physicians allows surrogates to gain the benefit of the physicians' medical expertise while being involved in decisions about the care of their loved ones and protecting them from abuse. This is also expected to reduce the surrogates' level of anxiety while promoting a timely decision making.<sup>288</sup>

Two steps can be followed to make sure that the Substitute decision making is ethical. First, the values used by the surrogate must all be compatible with the principles of equality and respect for persons. These are the principles stated in the Universal Declaration of Human Rights. If the used values do not meet those two principles, then they won't be considered ethical. Regardless how well-entrenched these values may be seen in the culture of the incompetent patient.<sup>289</sup> Secondly, the decision must not deprive the incompetent person of an opportunity that interferes with the patient's development as a person in the society. The decision should treat the incompetent patient like any other person with equality and fairness. It is important to note that while society does allow a competent person to take decision for themselves that might not follow the principles of equality and justice, and these decisions should not affect others. However, ethically it is not possible to take decision that hold deviant



values on behalf of an incompetent person who haven't asked for such a decision. Autonomy is a must when Deviant values are used.<sup>290</sup>

These two principles provide the main framework for all healthcare decision making for both competent and incompetent patients. Justice and equality strip substitute decision making to their bare ethical and logical structure while providing so much flexibility for substituted judgment. They help surrogates avoid any form of bias.<sup>291</sup>

This approach combines the advantages of several approaches mentioned earlier. Having a shared decision between the surrogates and physicians while still including the advance directive's wishes and using the available quality of life measurements, can improve the substitute decision making process dramatically.

### **2.5.2 Case and its Analysis**

This was a case that I encountered during one of the clinical rotations at Mercy Hospital. Mr. M is a 52 years old male. He is married and has three children. He was admitted to Mercy Hospital for the treatment of sepsis. In the past, he had multiple brainstem strokes, which required him to do rehabilitation for some time. Later he could perform some of his daily activities. However, he had a sever pneumonia that required him to be admitted to a long-term facility. There he developed bed ulcers. The worst one was a deep open coccyx ulcer. The patient ended up with sepsis and a huge coccyx ulcer therefore, his wife had him transferred to Mercy Hospital. After the several strokes, he had his wife became his surrogate according to ACT 169 in Pennsylvania State. The surgery team decided upon his situation that the patient had to perform two operations which were debridement of the ulcer and having a colostomy opening. The urgent need for the colostomy was because the ulcer was being badly affected by each bowel movement the patient had. The ethical problem that the team faces was that the patient's wife

was against having the colostomy opening. She was concerned that this will affect her husband's dignity especially that such an operation might not be reversible. The team described the wife as being emotional because she had many family losses during the last year. Her eldest son survived a gun shooting but was badly disabled; however, being a Christian, she believes in miracles. The medical team was faced with a dilemma on how to balance an incapacitated patient's medical best interest while weighing that with the surrogate wishes on reserving the patient's dignity. Apparently, the wife cared about the best interest and the dignity of her husband, which she knows better. A family meeting was being arraigned the next day to talk to the wife.

Analysis:

If we were to follow the standard substitute decision making; the medical team would follow the surrogate's wishes which are assumed to be the patient's wishes and values. By evaluation such a decision, it seems that the values used by the surrogate might be compatible with respect for persons but not with equality. Even though care for dignity is a principle that is embedded very much in Christianity, yet it is not the only principle to be followed.<sup>292</sup>

Secondly, the decision should not deprive the incompetent patient of an opportunity that interferes with the patient's development as a person in the society. The colostomy operation would enable the patient to live normally and would not suffer of more fatal infections. The decision should treat the incompetent patient like any other person with equality and fairness. It is imperative to remember that while society does allow a competent person to take decision for themselves that might not follow the principles of equality and justice, these decisions should not be taken on behalf of an incompetent patient that had never expressed those wishes. Through the family meeting we would be able to know if the patient has ever expressed such a decision to his wife and children. Using these two steps would help the wife weigh her current decision for

substitute judgment avoid any form of bias.<sup>293</sup>

However, more effort can be done while using the new suggested approach. The steps that are included in the new approach can help the surrogate understand the bigger picture and be educated about the available treatments and the quality of life that would result from each one.

This can begin by having the intensive unit specialist meet with the patient's surrogate and agreeing on figuring a shared decision for the patient. The hospital would have a ready profile of a competent patient with the same clinical presentation. With the help of someone specialized in using the Patient Preference Predictor or the quality of life indicator; the surrogate and the physician would be left with the available suggested treatments that a competent patient with the same profile picture would consider and the resulting quality of life for each treatment. This ensures applying the principles of equality and justice. All subjective expression of satisfaction with life, psychosocial impact and other evaluative parameters that are relevant will be considered.<sup>294</sup>

It is expected that several treatments would be considered; the colostomy surgery would be one of them. The wife will have the chance to be fully understanding the resulting quality of life of each treatment. Besides she will understand that it is disproportionate to risk further infection by refusing the colostomy specially that the patient won't be able to survive another sever infection in the future. The wife will get the chance to use substituted judgment properly. Having the physician or clinical ethicist ask a few questions about the patient and help the wife think like the patient. it would be important to get the wife to explain more of her thought process, her values, and the values of the patient. A shared decision between the physician and the wife by taking into account that one of the treatments – assuming that it is the colostomy

surgery- would result in the best quality of life for the patient. This decision must also be taking the patient's wishes and values into account.<sup>295</sup>

This decision must be weighted again to see if it does satisfy the principle of equality and justice as well as dignity and respect for persons. equality and justice were applied through the use of the quality of life tools and comparing the treatment to a competent patient's treatment and quality of life. It had the principle of beneficence applied through considering the role of the physician whom shared his input regarding the appropriateness of the treatment. It applied the principle of person respect through respecting the surrogate's role whom applied the patient's values, wishes and prevented medical and personal biases.<sup>296</sup> Finally it would have reduced the anxiety levels that the wife would normally have besides promoting a timely decision which is extremely critical in this patient's situation.<sup>297</sup>

## **2.6 Conclusion**

Decision making for incapacitated patient can be extremely problematic. The existing standard used approach and several suggested approaches are not helpful. They leave healthcare givers and surrogates worried, troubled and sometimes unsatisfied with the decision.<sup>298</sup> Even with the availability of an advance directive and the help of a proxy or a surrogate, dilemmas still do exist. Each single factor has its own issues and limitations. Advance directives and substitute judgments could both conflict with the patient's best interest.<sup>299</sup> However, advance directives remain important but should not be relied on completely.<sup>300</sup> A shared decision that combines the medical expertise of the physician and the care, love, values and wishes the surrogate holds for the patient is viewed as a better approach. This approach meets the six ethical goals besides the ethics principles of equality, justice, dignity and respect for persons.<sup>301</sup> It also respects the HIPAA Privacy Rule at 45 CFR 164.510(b), hence there is no violation of privacy.<sup>302</sup> And although life of humans cannot be measured by numbers; using technology and numbers to

measure the quality of life can have a great influence when deciding on an end of life treatment for an incapacitated patient.<sup>303</sup> Finally, obtaining the help of an ethics consultant in these situations can help both the healthcare givers and surrogates be assured that their decision is not an idiosyncratic reflection of their own personal views.<sup>304</sup>

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## **Chapter 3 Clinical Ethics**

### **A. Privacy & Abortion:**

This chapter studies privacy in two special clinical settings. The first section gears privacy issues on abortion, while the other studies privacy related to mandatory vaccination under the umbrella of Public Health. The outcome of the arguments covers up most of the privacy issues in the clinical field while examining them through HIPAA's privacy rule.

#### **1. Introduction**

The cultural pluralism in this world we live in appears in several religions, ethnicities and cultures. Pluralism also appears in different nations and countries that hold to these religions and cultures. Some countries have an official state religion while others do not recognize an official state religion. Some have a constitutionally protected separation between the state law and the religion. The pluralism also shows clearly in the relation between the religion and ethics. This can be witnessed in the Islamic and Jewish codes of ethics. Abortion is a good exemplar to demonstrate such religious pluralism.<sup>1</sup> Since religion is an essential source of ethical values and principles for everyone in the society even for governments that do not follow religion in its State laws. In a progressively growing multicultural environment that is furthermore advancing in the biomedical field, people face many religious principles, some of which may be unfamiliar to them.<sup>2</sup> Understanding the three most prominent religious ethical systems is important to everyone especially professionals in solving daily ethical dilemmas.<sup>3</sup> All three Abrahamic religions bind together on the immorality and prohibition of abortion.

In tradition, all Abrahamic faiths prohibit abortion due to the value of the unborn life. Yet, abortion is ethically allowed in each of the religions when the mother's life is in danger due to the fetus presence in her body. Catholicism, Sunni Islam and Orthodox Judaism have their

own medical ethics that show their position on how they permit some types of abortion. All three religions have extensive literature that discusses indirect abortion in case of saving the mother's life. They all use the clinical perspective that is considerably extensive enough to change the normative prohibition against abortion. Catholic Christianity uses the four conditions of the Principle of Double Effect to distinguish between direct and indirect types of abortion and justify some indirect types of abortion. Orthodox Judaism uses the concept of rodef, or pursuer, to permit abortion in this case, and Sunni Islam schools stands on the higher objectives of the Sharia law and uses the rule of necessity, to permit abortion when it comes to saving the life of the mother. Both Islam and Judaism codes of ethics have a link to the Catholic Principle of Double Effect. In relation to this and in such a contemporary world where medicine advances everyday new cases emerge in the field and require clear answers so that people can apply it from the perspective of each faith. Local, State laws and Federal laws such as the HIPAA privacy law would take part in the decision on the abortion case.

## **2. Religious Teachings on Abortion**

The Abrahamic religions have cared and valued the fetus and its personhood. Even though each religion has its own different views and rules, they all agree that human fetuses and embryos have always been the focus when discussing the abortion matter. They have the potentiality to develop and have both cognitive properties and moral agency. Due to this potentiality, fetuses and embryos have the right to life. Furthermore, it is wrong, immoral, unethical and prohibited to harm or kill them just like any other human being who already has advanced capacities.<sup>4</sup> Nevertheless, the mother's life has value and in some cases, her life takes precedence over her fetus's life.

### **2.1. Christianity – the Catholic Church teaching**

Roman Catholicism is the only major religion that has a unified position towards the

issue of induced abortion.<sup>5</sup> The Catholic Church adopts the Canon Law that is sometimes referred to as the ecclesiastical law. The sources of these laws are the natural divine law and the positive divine law that are both contained in the scriptures and the tradition. The Pope is the only authority that has the power to abrogate laws made by his predecessors.<sup>6</sup>

The Catholic Church follows the principle of supremacy of the right to life when dealing with the abortion matter.<sup>7</sup> God, and who is the only Lord of life, has assigned mankind with the noble mission of safeguarding life. Without life, there cannot be any other goods. Life must be protected with the ultimate care from the moment of conception. That makes abortion and infanticide both are offensive crimes.<sup>8</sup> Ethicist Daniel Callahan states that God is the only lord of life so human beings do not have the right to take the lives of other innocent humans. To him, life starts at the moment of conception and taking the life of an innocent human at any stage of the pregnancy makes abortion wrong. The Catholic Church teaching differs from both Islam and Judaism teachings in that it sees the lives of the mother and fetus as equal from the very beginning. This explains the strict position that the church follows towards abortion.<sup>9</sup> However, there are situations where Catholics allow indirect abortion in order to save the mother's life through the use of the Principle of Double effect.

### **2.1.1 Defending life from its beginning: the personhood debate**

In Catholic teaching, the fetus is considered an unborn child and is entitled to human rights as an adult. Its rights cannot be of less value than the mother's rights. Similarly, more liberal thinkers agree that through most of the pregnancy, the fetus is a person and has rights as other humans. Richard McCormick sees arguments that justify abortion as justifying infanticide.

**Charles Curran** who argues for more flexibility in some cases of abortion through the combination of both tradition and reason. Still he agrees with the magisterial teaching and views

the intrauterine life as worthy as the extrauterine life. Nevertheless, there are some Catholic writers who think that a fetus, especially in early stages, is not thought of as a person. While others relate the personhood of the fetus to the gestational stage.<sup>10</sup>

It is well recognized that the human life is made out of the existence of both the body and soul. There are many arguments about when does the soul enter the body. In other words what is the moment a fetus is considered a person with rights. Some argue that this starts since the moment of conception.<sup>11</sup> According to the Church teaching and the Declaration on Procured Abortion, human life begins at conception and must be fully respected. An embryo is a full human with a soul not simply a potential human being as viewed by others.<sup>12</sup> Yet, the Church never revealed when the exact moment of ensoulment occurs.<sup>13</sup>

### **2.1.2 Prohibition of direct abortion according to Catholicism**

Direct abortion is referred to the act by which the fetus is directly removed from the uterus or directly killed in the uterus. According to Principle of double Effect, all direct intervention are forbidden. An act is direct or indirect depending on the first two conditions of the PDE.<sup>14</sup>

The Catholic Church disputes and condemns direct abortions. It sees abortion as the termination of an innocent life, and therefore, it's always sinful and immoral. To the catholic Magisterium, all direct abortions that are intended to end a pregnancy before viability or the ones that intend to kill a viable fetus are prohibited and evil. The prohibition of abortion in the Roman Catholic tradition comes from the sanctity and sacredness of life. Pope Pius XI states that an abortion isn't justified even though sympathy is felt for the woman's life or health. He comprehends abortion as murdering the fetus, so the prohibition is absolute. Ashley and O'Rourke share the same view. However, they add that with contemporary medicine can save

both the mother and child or at least save the mother without ending the child's life directly. They refer to some indirect abortions accepted by the Magisterial and justified by PDE.<sup>15</sup>

The reason for these debates and conflicts comes from the differences between the pro-life and pro-choice groups. MacIntyre and Taylor refer this issue to the weakness of moral philosophy that is pictured in autonomy or what they call atomised individualism.<sup>16</sup> This brings a challenge between the mother's rights and the fetus's right. That's when people use logic without going back to the religious traditional teaching.<sup>17</sup>

Christian Catholicism has great value on life; therefore it does not allow abortion unless there is a need to save the mother's life. That is also guarded by the Church's rules and principles. They govern abortion that it only can be indirect.

## **2.2 Islam – the Four Sunni schools**

The Quran 23.12-14 describes the development of the embryo in seven stages.<sup>18</sup> The human in the maternal womb is created from the essence of clay. Then he is placed as a drop of sperm in a restful place that is firmly fixed. Then the sperm is turned into a clot of coagulated thick blood. From that clot God made him a lump that is known scientifically as the fetus. That lump creates the bones and flesh that cover the bones. Then God creates out of it another new creature, which is the soul. Sunna has its own rich sources that help Muslims identify the rules related to abortion. This seems complicated due to the several stages of pregnancy, animation and the matter of the soul infusion.<sup>19</sup>

### **2.2.1 Personhood debate: before and after ensoulment**

There are two phrases where Quran talks about the fetus's development. In one phrase, it mentions the fetus with ensoulment and the other phrase mentions the fetus without ensoulment.



The last phrase in 23.14 clearly states that God ensouls the fetus. <sup>20</sup>This is very important to Muslims in many aspects of life, specifically in abortion. The Quran does not particularly state when the ensoulment takes place but the prophet Muhammad's saying makes it clearer for Muslims. The germ of a person is concentrated in the mother's womb as a drop for forty days, then it becomes a clot of blood after another forty days. After an additional forty days it then becomes a little piece of flesh then God sends an angel to ensoul him. This means that ensoulment happens in the one hundredth and twentieth day from ejaculation into the uterus.<sup>21</sup> Two other saying of the prophet show that between the fortieth and the forty-fifth day, God sends an angel to differentiate the organs of the fetus, determine the sex and give the fetus its features and shape. Muslim jurists and scholars consider a fetus as a human being when the soul exists in his body in the hundred and twenty days as agreed on.<sup>22</sup>

### **2.2.2 Abortion in the four Sunni schools:**

Islam uses Sharia as the source of teaching as it presents the correct path of action as determined by God. Islam gets its ethical principles from either one of four sources: the Quran, the Hadith, the Ijma and the Qiyas. The Quran is the literal word of God. Hadith is the collection of reported sayings from the prophet Mohamed [peace be upon him]. Ijma is the scholar's agreement about a legal or a moral assessment of an act or practice. Qiyas is the juristic reasoning by analogy, which is similar to the halachic reasoning in Judaism. It gets a certain ruling from an established ruling of a known case that is found either in the Quran or the Hadith.<sup>23</sup> Ijma and Qiyas are the sources that jurists and scholars can use to solve a moral or legal mater after the death of the prophet.

Islam identifies five goals from Sharia regarding abortion. They are the protection of religion, life, intellect, ancestry, and property. Only a dreadful necessity is enough to overturn

any normative prohibition based on the principle of necessity. In Islam and in a strictly manner, some necessities allow what is prohibited in general, “al-ḍarūrāt tubīḥ al-maḥzūrāt.”<sup>24</sup> As in abortion when the mother’s life is at stake. Such a necessity to save the mother’s life, allowed a major prohibited act that is abortion. This necessity is to be defined by a competent Muslim physician who is religious and a medical expert. Several interpretation to both Quran and Sunna; agree that abortion and infanticide are prohibited by Islam before and after ensoulment. Islam sees it as interfering with God’s role who is the only ultimate owner and decider of life and death. The value of Human life comes from the sacredness that it is made by God.<sup>25</sup>

The only allowed type of abortion is the therapeutic abortion such as in case of saving the life of the mother. Yet this differs according to the different Sunni four schools: Hanafite, Shafi’ite, Hanbalies and Malikite. The legal reasoning in Islam leads to varying opinions on the abortion issue according to each school.

Hanafite School is open to tolerate abortion, though abortion is allowed only if there is a valid reason. A common case is a breast-feeding woman who gets pregnant and cannot afford having a wet nurse; if she goes with the pregnancy she won’t have much breast milk to feed her first infant. That makes abortion allowed unless the fetus began to form. This means before the one hundred and twentieth days of the pregnancy life. Most of the Hanafite school scholars accept abortion before ensoulment with and without justifications but some insist that there should be a valid reason. They do not require the spouse’s agreement. The Shafi’ite School uses the seven stages of the fetus’s development that are mentioned in the Quran. The more advance the pregnancy goes the more serious the prohibition becomes. That makes the major murder when the infant is developed and equal to infanticide after birth. Shafi’ite see that life begins as early as fecundation occurs and it is an offence to kill even in this early life. If becomes worse

after ensoulment. Most Shafi'ite scholars allow abortion before the 40 – 42 days with the permission of the male spouse. Never the less, abortion is considered a legal despicable act to Shafi'ite. Most of the Hanbalies abides abortion in the first forty or one hundred and twenty days. Some say that when the embryo is already solidifies its prohibited to abort him, because now he is not like the drop of sperm that is not solid and cannot produce a fetus. This school allows using a lawful medicine to induce the abortion but only in the first four months of the pregnancy as the embryo is not yet alive and is not a person. Abortion is prohibited from the moment of conception but seriousness of the crime is proportional to the term of the pregnancy. The Malikite School is strict when it comes to abortion. They prohibit the abortion in the first four months and even some prohibit it in the first forty days. They all agree about the prohibition after the four months. Malikite scholars allow and understand the therapeutic abortion. They believe that the embryo is a creature that's waiting for the soul to come from god. They say they prohibit abortion in the phase where the embryo is fully formed but still without a soul. The prohibition becomes stronger when the animation starts. Malikite School imposes the blood price on anyone who causes the abortion even if the pregnancy was still a clot. This means that abortion is a major sin. Traditionally, after ensoulment the abortion is prohibited by all means. This doesn't apply to the therapeutic abortion. Therapeutic abortion is considered when either the continuation of the pregnancy would kill the mother, or the pregnancy would have serious consequences on her physical or mental health or if the new pregnancy will dry up her milk and threaten the life of the suckling infant whereas she and her husband can't afford a wet nurse. This acceptance to therapeutic abortion comes from the greater value the mother has over the fetus as she can produce more new lives. The mother is the pillar of the family; she has more duties towards her family, husband other children unlike the new fetus. Muslims use the principle of

lesser ill in this case. The mother and her fetus are like a tree and branch. The branch can be sacrificed in order to save the source, the tree. There is a minor group of jurists who don't allow abortion after ensoulment. According to them, it is not known for sure if the mother would die if the fetus weren't aborted. It is not allowed to kill the fetus on the base of assumption. The second reason for prohibiting abortion after ensoulment is that fetus is a human being and must always be protected.<sup>26</sup>

Generally, abortion is a prohibited act in Islam. Before ensoulment, Muslim scholars and jurists differ over abortion. Some permit it others prohibit it. Some simply morally discourage it others sees it as a reprehensible act. After ensoulment and through Ijma, they all agree about therapeutic abortion after ensoulment but not for any other reason, as abortion becomes a major sin that requires blood price.<sup>27</sup>

### **2.3 Judaism – the Orthodox teaching**

Just like Sharia of Islam, Jewish Halakah encompasses all aspects of life to Jewish people but more into a general way than Sharia does. The three main sources of Jewish principles are the Hebrew Scriptures, the Talmud, and the Responsa literature. The Hebrew Scriptures is the holy book of Judaism and holds the prominence of the highest source of law. Halakah also takes its principles and ethics from the Mishna and Gemara. It uses reasoning that is equal to Qiyas in Islam to find a solution for a case that is not found in the traditional sources. The reasoning process requires a trained rabbi to response to an inquiry. Then a principle is stated and can be applied to new circumstances that were not covered clearly by the earlier rulings of Halakah.<sup>28</sup>

#### **2.3.1 Abortion in Halakah**

As Orthodox Jews follow the traditional law, the Halakah views the human's life as of having infinite value. They consider the killing of an unborn child as a serious moral offense. Abortion shouldn't be performed unless it is crucial to the mother's life and the decision must be done with a consultation of a competent rabbi. The Maimonides says that the fetus is a being that can sometimes be considered as an aggressor if it threatens the mother's life. Only then its life can be forfeit. So, if it doesn't endanger the life of the mother then it can't be aborted. This shows that feticide is considered a non-capital homicide. That code of Maimonides became the primary source that many Jewish authorities use when they state that the Jewish law forbids the therapeutic abortion in non-life-threatening situations. This is the source that the Chief Rabbinate of Israel used to announce that performing any other type of abortion is an act of murder. Even if the fetus is malformed or has mental abnormalities, it is entitled to the right to life no matter how deformed it is. It is forbidden to destroy it by an overt act or in a passive way such as starvation. Rabbi Judah the Pious in the thirteenth century gave his ruling about the prohibition of terminating a life of a monster like child born with features of animals such as teeth and tail. Later in time, another authority ruled that killing such kind of a born child is considered murder. This has an equal weigh to destroying a malformed fetus. If a malformed fetus has the right of life, a normal one shouldn't be aborted unless there is a threat to the mother's life. The Mishnah clearly acknowledges that the mother's life takes precedence over her fetus's life if the pregnancy endangers her life. Yet the Mishnah shows that the fetus has the right to life. Early rabbinic authorities declared that Shabbat observance, the Day of Atonement and the fasting of Yom Kipper, which are important Halakah rituals are suspended in case of preserving the life of the fetus. It also makes it clear that the Judaism value the fetus's life and doesn't permit abortion unless the mother's life is in danger.<sup>29</sup>

The Locus Classicus of the prohibition through the Mishnah, Oholot 7:6 announces that in hard labor that is endangering the mother's life, the fetus can be extracted limb by limb. That is justified in the Mishnah: "for her life has precedence over its life".<sup>30</sup> This makes it obvious that when the mother's life is not threatened, it is not justified to destroy the fetus. Such a permission to kill an infant in halakah comes from interpretation of the term *rodef*, which means a pursuer. The concept allows killing a thief that is breaking into someone's house. Assuming that the *rodef* is armed and has the intention to kill. The fetus is also considered as a pursuer that is threatening the mother's life. Such a threat can only be stopped if it is killed.<sup>31</sup>

Sanhedrin 57b renders Genesis 9:6 as "*he who sheds the blood of a man within a man, his blood shall be shed*". In this versus; "*a man within a man*" is understood as the fetus, and feticide is paralleled to murder. A fetus is considered a '*nefesh*' for the children of Noah. The Talmud expresses feticide as capital crime under the Noachidic law. Judaism sees that legalizing abortion in the modern world is as equivalent to legalizing infanticide.<sup>32</sup>

### **2.3.2 Personhood according to Orthodox Jews**

Even though the Halakah values the human life. It still sees the unborn child as a pre-human with no rights. That means a fetus is not a person yet till it is born. Besides that, the Jewish tradition does not consider a baby as a human in its first thirty days of life, as it is not counted as a viable living '*a bar kayyama*'. There is also no mourning to a baby that does not survive a full term. Bleick who is an orthodox Rabbi, states that Halachah assumes that morality during the first thirty days of life due to premature birth and that serves as an indication that the infant was not viable. He clarifies that this shouldn't be a justification to destroy neither an unborn fetus nor a newly born infant. Brickner and Bleick agree that in Halakah, the fetus in the womb is not a person '*lav nefesh hu*'. Furthermore, Judaism doesn't have a capital punishment regarding

feticide, as it doesn't see the fetus as a '*nefesh*'. The continuous misrepresentation of the Halakah teaching made it seem that Jews do not face a moral dilemma towards abortion. Orthodox Jews see that this is a huge ethical issue; to distort the traditional Judaism teaching for other purposes such as justifying any abortion.<sup>33</sup> The fetus is not simply an attached addition to the mother, but is a being in its own right". The Sages also taught: "*there are three partners in the [generation of] man: the father, the mother, and God*"<sup>34</sup>

Judaism does not allow abortion unless the fetus is harming its mother. Thereby it allows therapeutic abortion. Still Orthodox Judaism is considered to have the least strict rules governing abortion being compared to Islam and Catholic Christianity.

### **3. The Principle of Double Effect**

The Principle of Double Effect identifies morally acceptable actions that would cause two effects; one of which is direct causing well and the other one is indirect causing some kind of harm. It includes four conditions that must be fulfilled to consider the action valid. First, is that the action by itself—regardless of its other effects—shouldn't be evil in the moral sense. Secondly, the bad effect shouldn't be the means of producing the good and still it is unavoidable. Third, the bad action is not intentional. Finally, there's a proportionate reason for having such an action regardless of its undesired effect that must be tolerated.<sup>35</sup>

#### **3.1 History of PDE**

The Principle of Double Effect was the primary operative principle used long time ago to solve issues of the professional practices of the medical field. The pre-Vatican II Catholic medical ethics dealt with specific topics concerned with physical interventions. With the help of the PDE, it gave precise absolute answers to those matters. Since then the PDE became commonly in use even by secular bioethics.<sup>36</sup>

#### **3.2 The four conditions of PDE**

The PDE forces the question: is this action morally right or wrong? From a deontological view, if it is wrong, it is wrong. Nothing can justify it even it had good consequences coming out of it, it remains evil itself. The act itself should not be morally wrong. This condition is the first condition. The second condition is: the bad effect must not cause the good effect. There are three probabilities of an act, it can cause the good effect then to produce the bad one, it can cause both of the good and bad effects without affecting each other or it can produce the bad effect that leads to the cause of the good effect. The first two are acceptable, as they do not justify a wrong act through the consequences or the intention. The last one is not allowed because the act is wrong by itself. The way the action is named has an effect on its acceptance or not in the PDE.<sup>37</sup>

### **3.2.1 The first condition:**

The act in itself – considered apart from its circumstances and consequences – should not be morally wrong. This condition is deontological and usually seen as a physicalist method. This means that if an act is wrong, then it is wrong regardless of its plural effects or its circumstances. So, the action will be considered wrong even if had good consequences.<sup>38</sup>

### **3.2.2 The second condition:**

The bad effect must not be the cause for the good effect. This condition requires that the chain that starts with the act and continues with either a single or multiple effects, must not have a link where it is found that the bad effect is causing the good effect. In this case, there are three possibilities: the first is that the act might cause a good effect that effect would cause a bad effect. The second possibility is that the act might cause a good effect and the bad one in the same time without having any of the effects causing one another. The third possibility is that the act might cause the bad effect, which will cause the good effect. The first two possibilities will pass the second condition of the principle of double effect but if the act consisted the third



possibility, then it will fail to pass the second condition of the double effect. The way of naming the act can give it a different interpretation when applying the principle of double effect. The first and second conditions are corresponding each other pretty much like the moral principles of beneficence and non-maleficence. The combination of the two conditions helps making sure that intention is good and the chain of actions do not include a bad effect to get to the good one. Catholics do not allow actions that are morally wrong to justify a good action.<sup>39</sup>

### **3.2.3 The third condition:**

The agent must not intend the bad effect. This condition can be rephrased to: ‘intend as an end to be sought’. It shouldn’t be interpreted as ‘intended either as a mean or as an end’ nor as ‘the agent may not intend the bad effect either as an end or as a means to that end’ as this makes the principle of double effect useless and not as beneficial as Catholics proposed it to be. This condition should be interpreted, as ‘the agent may not intend the bad effect as an end to be sought’. All accepts this condition: deontologists, Catholic moralist and proportionalists. Intentional actions are very controversial. This is a gray area that troubles many people while judging if an act was intended or not through the principle of double effect. It is viewed as having a blue print or a representation of both the means and the ends planned for the implementation of an action. So, to say that an action is intentional it must match with the plan the person had in mind. In some cases, there are some actions that a person intends its effects because it is needed to but the person does not desire that effect. That undesired effect is not what he aims for but it is part of the process. Bad effects are then accepted because the good effect cannot come alone.<sup>40</sup>

### **3.2.4 The fourth condition:**

The bad effect must not outweigh the good effect. This is simple and helps in reaching a decision whether an act is correct or incorrect. It shows that weighing good and bad had been there for a long time as a part of the Catholic tradition. Proportionalists agree that this is an important condition to reach to a conclusion regarding the act in view of the principle of double effect.<sup>41</sup>

The Roman Catholic teaching, explored the difference between ordinary and extraordinary means related to abortion by the use of the doctrine of Double Effect. However, differences between physicalists, proportionalists, utilitarians and other competitors raise many arguments and conflicts.<sup>42</sup> The Principle of Double Effect can result in different decisions on abortion in a specific case depending on how each group interprets it. An indirect abortion can be seen as a direct abortion to the opposing group.

#### **4. Islam and Judaism sharing the PDE**

Catholic reasoning comes from a general principle to specific situations while Islam takes a normative example found in Quran and Sunna and applies it to new situation such contemporary issues with abortion that are not stated in either Quran nor Sunna. Judaism does almost the same by interpreting the Talmud and getting answers through the commentaries and response to the new situations. Still we can find that both Islam and Judaism have similar principles that agree with the principle of double effect to some extend around the indirect abortion.

##### **4.1 Islamic principles and their relation to PDE**

The main idea of using the principle of double effect is to find out if an act or procedure is morally and ethically sound. The act has to be beneficial and not harmful besides having the right intentions around it. Islamic ethics principles have pretty much the same values and concepts with the Christian Principle of Double Effect regardless some little different specifications. The Islamic bioethical principles are anchored to the divine laws that exist in both Quran and

Sunna.<sup>43</sup>

#### **4.1.1 The rule of prohibition:**

In Islam, what is prohibited and is an absolute major sin and is clearly stated in the words of God in the Holy Quran. Some life issues were not revealed in Quran because God intended to give mankind the space of think them over, judge and make decisions that suits the mean future time with its advancements. This rule of prohibition resembles the first condition of the principle of double effect that is the act itself should not be morally wrong.<sup>44</sup>

#### **4.1.2 The rule of “do no harm, no harassment”:**

This rule is one of the most fundamental ones that deal with deducing rulings of Islam social ethics. It is considered one of the most important rules because it serves as a justificatory principle among all jurists to deduce fresh rulings. It is authentic as its ascription goes to the Prophet himself. It can be addressed in three different ways: as meaning that God does not wish any kind of harm to his creatures, neither from him nor from human beings to each other. It can also signify proscription or the proscription of harm without compensation. Muslim jurists link this rule to the rule of “rejection of probable harm”. This rule pertains to welfare of the person. In addition, it orders Muslims in an indirect way, to promote good. That makes the rule of “do no harm, no harassment” a central one as it resembles the identity of Islam. In case of conflict between doing no harm and promoting benefit, preventing or removing the harm takes precedence over probable benefit to reach a final ethical decision. The rule has two parts that relate to each other. First, harm can mean detriment loss that is the total opposite of benefit. This rule clearly connotes any type of lose suffered by a person to himself, dignity, personal interest and property. Secondly, harassment means harming, injuring or hurting in return. The rule can be rephrased to: “there shall be no harming, injuring or hurting of one man by another, in the first

instance, nor in return or requital”. When applying this to the abortion matter, the rule would be as: “there shall be no [adopting a course of action that leads to] injuring or hurting of one man by another”. The harm is clearly not limited to the person of the agent but it is general and includes all kinds of harm such as violating someone’s rights or causing harm to a person’s psychological state.<sup>45</sup> This rule can be seen comparable to the second condition of the principle of double effect: the bad effect must not be the cause for the good effect.

#### **4.1.3 The rule of necessity:**

This rule is related to the previous rule of no harm, no harassment. It can be rephrased as “necessities make the forbidden permissible, as long as it does not lead to any detriment”.<sup>46</sup> This is one feature of Islam, it does not make life hard on its followers. Nothing can show this feature better than “necessities make the forbidden permissible”. In Islam when it becomes a necessity to choose between two 4.2 Jewish principles and their relation to PDE matters where evil exists in both such as in the case of abortion due to the mother’s illness or life threatening situation, Islam directs Muslims to choosing the lesser of two plausible evils. This rule is like the fourth condition of the principle of double effect, the proportionality between the good effect and the bad effect. It simply asks Muslims to weight the risks and benefits of the two matters.

#### **4.1.4 Actions depends upon intentions:**

This is also a rule that is deduced from the Prophets tradition. Intentions are very crucial in Islam and only God knows what a person’s heart and mind intends. Although some actions can reveal a person’s intentions, Muslims always tend to believe that others have the good faith in their actions. Yet care must be taken in consideration when it comes to the lives of a mother and a fetus.<sup>47</sup> This rule has a complete resemblance to the third condition of the principle of the double effect: The agent must not intend the bad effect. Even though in Islam it is not clearly

stated as specific as it is in Catholicism. Even though intentions are very obscure and uneasy to be interpreted by others, both religions take it into consideration as a very important factor with regards to moral actions. Islam seems to correspond a lot with Christianity on the abortion matter. They share many similar characteristics in their principles that govern abortion specially the therapeutic abortion when the mother's life is at high risk.

#### **4.2 Jewish principles and their relation to PDE**

Although Judaism differs from both Islam and Catholicism in that it does not have the set of formulated rules regarding abortion. Still it uses normative examples found in the Jewish tradition to develop answers for questions around issues such as abortion. Unlike Catholicism where reasoning comes from a general principle then applies to specific situations. Judaism does not have the same amount of restrictions that governs abortion as Catholicism and Islam as it does not see a fetus as a human being until it is thirty days after it is born. Yet Judaism values the pre-human life of the fetus and embryo. It agrees with the principle of double effect on many levels in regard to the indirect abortion and when the mother's life is in threatened by the pregnancy.

##### **4.2.1 The Halakah prohibition of abortion:**

*“Whosoever sheddeth the blood of man in man, his blood shall be shed” (Genesis 9:6).* The phrase “man in man” is understood to be a fetus. Feticide is equal to murder in Halakah.<sup>48</sup> This can be like the first condition of the principle of double effect in which the act should not be morally wrong. However, feticide is considered as a non-capital homicide if the mother's life was in threat.<sup>49</sup>

##### **4.2.2 The fetus as a *rodef*:**

There is an exemption to the previous prohibition in the Jewish law. It permits an abortion when the mother's life is in jeopardy. What differs Judaism here from Catholicism, is that the

danger to the mother's life does not necessarily have to be definitive. It can be a possible threat to the mother's life, health or psychological state. In this concept, the fetus is seen as an innocent pursuer that is harming the mother. In Halakah law this threat must be stopped, even if it means killing the fetus. This concept allows someone to kill a thief who is breaking into someone house, because it can be assumed that the thief is armed and may kill that person. Nevertheless, when a pregnant woman's life is endangered but the fetus is not the one causing the threat, he can't be aborted, as he is not a pursuer.<sup>50</sup>

#### **4.2.3 Levels of necessity:**

There are four categories of illnesses to distinguish between different levels of necessity to abortion in Judaism. First, the discomfort level which, simply includes minor coughs and rashes. The second category is the minor illness, it includes severe sickness but that does not require bed rest such as irritating coughs and headaches. The third category includes patients who are severely sick but not fatally ill or whose limbs and organs are in danger but not their lives. This category includes illness that requires preventative treatments and requires bed rest. The fourth category includes any potentially fatal condition.<sup>51</sup> All these categories have their own different restrictions depending on what type of normative prohibitions can be violated. These rulings range from no permission to violations for the first category, to all prohibitions being invalidated for the fourth category. Abortion can be justified for the third and fourth category and some cases in the second category in the Jewish context. When applying this model to abortion leads to the conclusion: that abortion in Judaism is allowed if the mother's life is in peril. If a woman's pregnancy is causing her a serious fatal illness, then the case falls into the fourth category and everything must be done to save her life. This means violating the command from the Torah. If this is not done, then whoever is responsible for the woman's health is guilty of murder.<sup>52</sup> The

woman's death is considered much graver offense than abortion by Jewish law. This can be viewed to include both the third and fourth conditions of the principle of double effect to some extent. Having a necessity to abort a fetus due to the mother's condition mean that the intention is not harming the fetus but saving a life that is the mother.<sup>53</sup> Having levels of necessity applies to the fourth condition where the bad effect must not out-weight the good effect. Even though in Halakah the act or procedure in which the abortion would be performed does not matter. Mishnah states: "not to take pity on the life of a pursuer. Therefore, the Sages ruled that when a woman has difficulty in giving birth, one may dismember the child in her womb –either with drugs or by surgery- because he is like a pursuer seeking to kill her"<sup>54</sup> That means abortion is allowed when the mother's life is in danger regardless if it was direct or indirect.

#### **4.2.4 Sacredness of the existing life:**

A general principle in the Jewish law is that the existing life always takes precedence over a potential life. The mother's life that is endangered by her fetus, takes priority in Halakah.<sup>55</sup> It is stated in the Mishnah: *"if a woman has a life threatening difficulty in childbirth, one dismembers the embryo within her limb by limb because her life takes precedence over its life. Once its head or its greater part has emerged, it may not be touched, for we do not set aside one life for another"*.<sup>56</sup>

One condition of the principle of the double effect does not seem to appear in the Jewish law context that is when the bad effect causing the good effect. This can be due to the generality of the rules that feature the Jewish tradition teaching. Still there seems a high level of resemblance to the matters around the therapeutic abortion in Judaism and Catholicism. From the understanding of the principle of double effect, it becomes clear that some acts or procedures that are traditionally deemed prohibited and immoral.<sup>57</sup> Sometimes in specific cases that pass the

conditions of the principle of double effect or other similar rules in the other religions, these acts become justified and not an absolute prohibition.<sup>58</sup>

## **5. Cases of Abortion & PDE**

### **5.1 Cancerous womb**

A classic case of restoring the mother's life and health is when a pregnant woman finds out that she has a cancerous womb. The only way to save her life and prevent metastasis is by performing a hysterectomy. This operation will lead to the death of the baby but without touching him, as he is not directly attacked. The intention is to save the mother not to kill the baby. The baby's death would neither be an end nor a mean.<sup>59</sup> According to PDE first, the act itself is good which is the removal of the diseased organ. Secondly the intentions are only to remove the diseased organ. And the unborn child will die as a result of the removal of the diseased organ. According to the third condition the good action that is the healing of the woman only happens with the removal of the diseased uterus and not from the death of the baby which is foreseen and unintended. This is justified by proportionality. The fourth condition also applies, as the indirect death of the child is not disproportionate to the good act of saving the life of the mother. In this case, terminating the fetus's life is a mean to save the mother's life.<sup>60</sup>

### **5.2 Pulmonary hypertension**

A nun in a Catholic hospital authorized a dilatation and curettage procedure for a pregnant lady with pulmonary hypertension in November 2009 in Phoenix, Arizona. She took that decision to save the live of the mother who was dying. In such a case the fetus would have died even if the procedure weren't done. Later on, the Bishop of Phoenix automatically excommunicated the nun for allowing a direct abortion. Many Catholic philosophers and theologians gave their input about this case. They all agree the nun took the right decision and that this wasn't a direct abortion. On the other hand, automatic excommunication has specific



requirements –according to some scholars- that weren't encountered at this case. As many have taken the side of the hospital and defended the nun's decision, still some sided with the Bishop's pronouncement. Their argument is based on the Principle of Double Effect. They say that the act was directly killing the fetus in order to save the woman's life. That is totally immoral and against the PDE.

This case introduced many discussions and debates. Kevin L. Flannery used the Principle of Double Effect to argue that there was a possibility to separate the placenta from the maternal side to eliminate the pulmonary hypertension. Subsequently, the fetus would die and later the womb can be evacuated. Dr. Gerard Magill proposed that the procedure was intended to remove the placenta that caused the maternal pulmonary hypertension, not to remove the fetus. The removal of the placenta required the removal of the amniotic sac that contains the fetus. Therefore, that was not a direct abortion. In the contrary comes the argument of Nicanor Austriaco, who sees the placenta as a vital organ of the fetus. To him, placentectomy is a direct abortion.

The conflict seems to go around the second and third condition of the Principle of Double Effect. Both groups used the PDE but with totally opposite conclusions. Using the traditional teaching of PDE, the Bishop and others who sided with him saw that second condition was not fulfilled. It was a direct assault towards the fetus and that was immoral. On the contrary, Dr. Magill and others saw that the procedure was ethical and the intentions were to save the mother's life. The removal of the placenta was the only way and that caused the unintentional fetus's death.<sup>61</sup>

### **5.3 Ectopic pregnancy**

Earlier in the 1930s surgery was allowed only when the fallopian tube ruptures. As the Catholic medical ethicist thought the fetus was cause. They considered the removal of the fetus

before the rupture occurs as a direct abortion. It was suggested to remove the tube along with fetus but that was also refused. In many cases, women would die from rupture of such a vascular organ but that was the only permitted Catholic traditional teaching then. Bouscaren was the first to argue a procedure that would cause both the good and the bad effect in the same time. He thought of salpingectomy as a solution that isn't direct abortion as it passes the first and second conditions of the Principle of Double Effect. When fallopian tube that contains the pregnancy is removed, it's clear that the fetus is not attacked directly; therefore, this is considered an indirect abortion.<sup>62</sup> He argued that in this case the bad effect didn't cause the good one. What are important are the casual chain of interventions and not the rupturing of the fallopian tube. He stressed that salpingostomy is a direct abortion. In 1971, the US Catholic Bishops adopted his views. Later arguments go around if the fetus can be medically removed from the tube.

With time and advancement of medicine, new methods were discovered such as laparoscopy salpingectomies and methotrexate abortion. They were safer healthier choices that could save the mother's fallopian tube for future procreation. It is better to have what produces the most good and least hard as the fetus is going to be lost in anyway. Physicalist tradition but not the proportionalists prohibited this. Since 1991 and until 2009, the Ethical and Religion Directives were revised several times. The last revision mentioned that in such cases any interventions that constitute direct abortion are not allowed. In 1995 and similarly to Bouscaren, John Tuohey suggested that the fetus is made of two sets to tissues; the trophoblast that becomes the placenta and the cytotblast that develops to become the fetus. His suggestion was to attack the trophoblast in case of an ectopic pregnancy through salpingostomy. This was a solution to be pondered by the physicalist. Bouscaren suggested salpingectomy and Tuohey suggested salpingostomy on the trophoblast side, that was main difference between them. They both agree

that cytotblast which is the fetus cannot be touched as that will lead to direct abortion. Tuohey's way can help in solving many cases where abortion was considered direct and prohibited.

Nevertheless, it can justify any kind of abortion.<sup>63</sup>

Germain Grisez suggested having a revised understanding to the PDE. Different consequences to an action can be considered equally immediate. He argues that this will help justifying other medical problems but in a more strictly manner.<sup>64</sup>

We can say that the abortion in relation to the principle of double effect can be viewed in three ways: first there are the cases where nothing can be done to save the life of the infant and the mother. Knowing the certainty of the outcomes for both and that there is no conflict of interests, as the baby will die in either case. It is always better to save someone in such a circumstance than doing nothing. It should be justified to use any method of treatment to save a life, such as in the cancerous womb case through hystectomy. Even though some would object to it by arguing that it is a direct intention to kill the baby. The death of the baby is a foreseen consequence. Secondly there are the cases where there's a chance to save either one. The act will save the mother and kill the baby or save the baby and kill the mother. There is no conflict of interest and it is better to save one than letting them both die. When a decision must be made on whom to save, usually the mother is picked as she life weight more than the unborn baby. She can provide other lives if she's alive to other children.

Third group of cases are the tough ones, where to save the mother we must kill the child. In those cases, the baby can be delivered after the mother's death. The principle of double effect shows that if the death of the baby occurred, then it was directly intended to save the mother. In the unacceptable cases by the principle of double effect, the fetus's death is viewed as a mean to save the mother's life. While in the acceptable cases, the fetus's lose is only a side effect to the

procedure that saves the mother.<sup>65</sup>

## **6. Conclusion**

Religion is a very important source of ethical values and principles for everyone in the society even for governments that does not follow religion in its State laws. In a progressively growing multicultural environment that is also advancing in the biomedical field, people face many religious principles, some of which may be unfamiliar to them.<sup>66</sup> Understanding the three most prominent religious ethical systems is important to everyone specially professionals in solving daily ethical dilemmas.<sup>67</sup> Abortion is a suitable example that illustrates the ethical question with a significant religious impact of taking one life to save another.<sup>68</sup> All three Abrahamic religions bind together on the immorality and prohibition of abortion. Again, they all agree on the indirect abortion especially when it is required to save the life of the mother. They all harmonize on the Principle of Double Effect as a helping tool in such a case. Each religion has its own methods and principles that help when being applied to a case to reach a decision about the permissibility of abortion. The Principle of Double Effect that is utilized by the Catholic Church is one of the best-developed principles to distinguish between direct and indirect cases of abortion. Catholic moral theology values the sanctity of life above everything else. Accordingly, it only allows abortion through the concept of double effect when abortion is an indirect consequence of a necessary procedure when the mother's life is endangered by her pregnancy. Sharia of Islam, views the protecting life as one of the five higher objectives of the Sharia law. Therefore, Islam only permits abortion when the situation mandates the saving of the mother's life. This is tolerated through the means of the principle of necessity allowing what is generally prohibited. Furthermore, it can be done even after the one hundredth and twentieth days of pregnancy where all Muslims agree about that ensoulment had occurred and the prohibition of abortion researches its maximum level. Jewish Halakah uses the concept of *rodef*

to allow abortion when the fetus threatens its mother's life under the examination of an experienced physician and a knowledgeable Rabbi. These principles in Islam and Judaism have some similarities with the Principle of Double Effect, but they are not typically the same. However, they all reach the same conclusion on saving the mother's life, but they do not match on the indirect method. Considering the classical clinical cases, it seems that there are some conflicts in the Catholic Church when using the principle of double effect. Two opposing conclusion can be reached using PDE. Eventually, what really matters is having the intentions of doing the good and weighing it while trying not to do any harm as much as possible. Throughout the examination of each religion's views and rules on abortion, one common conclusion is reached; life can be taken to save another. That life is the fetus's life when it is threatening the source; that is its mother's life.

This religious based debate interferes with other public debates on the right to autonomy and the privacy of abortion, where privacy is a personal right. It's been argued that abortion is a medical procedure, hence it is covered by the HIPAA Federal law within the United States. This means that religion is not the only controlling factor when deciding on abortion. Moreover, Federal laws suppress any state law or local law. Some healthcare facilities eliminate the abortion procedure or place some restrictions on the practice. This is a form of interference between the patient and their physician. Moreover, it is a violation of the woman's right to autonomy, which interrupts the HIPAA privacy law. Therefore, whatever the decision was agreed on that was weighed by the double effect rule, ethically it shouldn't interfere with the right to privacy and autonomy.<sup>69</sup> In countries that follow religious law and forbid abortion, abortion might affect a woman's employment, health insurance and leads to discriminaton. Hence, it must be covered properly by HIPAA.

## **B. Privacy & Mandatory Vaccination**

### **1. Introduction**

Policies that use mandatory vaccinations have existed long time ago since the 1800s yet, many anti-vaccination movements opposed them throughout the world and until this mean time today. Not all governments and public health policy makers believe that this is the best method used when it comes to vaccination. However, some countries use the compulsory vaccination legislation, as they trust that it is the best public health intervention created to protect communities from infectious diseases.<sup>70</sup> Many use the moral principles to debate the need for such policies. Communitarians and Utilitarians are the most proponents to mandating vaccinations while on the other hand many argue that this approach is too paternalistic and doesn't respect the individual's autonomy and human rights. Current practices of mandatory vaccinations provide a better picture on why governments mandate vaccination and create many mass immunization programs. In addition, this need differs according to the disease and the targeted population. It is known that some diseases were eradicated due to these policies.<sup>71</sup> However, it is recommended that public health policies use the least invasive methods to reach the benefit goals of public health. Therefore, some Interventions are introduced and suggested to reduce the objection to mandatory vaccination.<sup>72</sup> Privacy becomes a big matter when tackling mandatory vaccination.

### **2. Vaccine Mandates and Objections**

#### **2.1 History of mandating and objecting to vaccination**

Opposition to vaccination has existed as long as vaccination itself. Criticizers of vaccination have taken a variety of positions, starting with the opposition to the smallpox vaccine early in the mid to late 1800s in England and the United States where that has resulted in anti-vaccination leagues. Moreover, there were more recent vaccination controversies that

appeared every now and then such as those surrounding the safety and efficacy of the diphtheria, tetanus, and pertussis (DTP) immunization, the measles, mumps, and rubella (MMR) vaccine. In England, it all started with Edward Jenner's cowpox experiment. He proved that he could protect children from the disease by infecting them with lymph that comes from the cowpox blister. However, the public criticized and refused his idea. They had many reasons for objection that varied such as sanitary, religious, scientific, and political objections.<sup>73</sup> In 1853 the British vaccination Act made smallpox vaccination compulsory for all newborns in their first three months of life. In addition, the Act of 1867 extended this age requirement to 14 years, adding that refusing parents were liable for imprisonment or fine. This is considered the first time that law breaches the civil liberties of its individuals.<sup>74</sup> These acts and laws produced the Anti-Compulsory Vaccination League and an anti-vaccination League demonstration in Leicester that were attended by more than 100,000 activists.<sup>75</sup>

Having such demonstration and opposition to the vaccine, led to the establishment of a commission aimed to study vaccination. Subsequently, in 1896 the commission ruled that the vaccination did really protect against smallpox. However, it suggested removing the penalties for parents who fail to vaccinate their children. The Vaccination Act of 1898 removed the penalties and integrated a clause that was "conscientious objector", so that parents who did not believe in vaccination's safety or efficacy could obtain an exemption certificate.<sup>76</sup>

In the end of the 19th century, many smallpox outbreaks started in the different States of the United States. This has led to vaccines campaigns, which also was opposed with anti-vaccines movements. In 1879, William Tebb who was one of the British anti-vaccinationist visited the United States. After that the Anti Vaccination Society of America was founded in America.<sup>77</sup> Later in 1882, the New England Anti Compulsory Vaccination League appeared and

in 1885, the Anti-Vaccination League of New York City followed. The American anti-vaccinationists took the complains to the American courts in different states such as California, Illinois, and Wisconsin.<sup>78</sup>

## **2.2 Mandatory vaccination in the U.S.**

In 1809, the state of Massachusetts started its compulsory smallpox immunization program. Conversely in 1922, the court sustained the laws that required vaccination as a requirement for school entry. The United States of America still required mandatory immunization as a condition for entering daycare and school. Laws were created to enforce immunization on the community though the enforcement level varied among different states. At the 1970s unimmunized children were excluded from school when a measles outbreak occurred in Los Angeles County. Moreover, after immunizing hundreds of thousands of schools age children, it was found out that 50,000 out of 1.4 million students were still unimmunized; therefore, they were excluded from attending school. That led to a huge drop in the number of measles cases in 1977.<sup>79</sup>

Now a day, the United States puts greater emphasis on compelling immunization for entering school and daycare. While there is no national immunization law that mandates vaccination, regulations are being bases on a state level. There is the exact requirement for immunizing children against diphtheria, measles, polio and rubella but slight variation.<sup>80</sup> Some states threaten to take childcare proceedings if parents persistently fail to immunize their children. Forty-eight out of fifty states allow exemption from immunization if parents had religious believes against immunization. In the same time only fifteen states allow parents to exempt their children from compulsory immunization due to their own philosophical reasons. It is found out that 2.5% of the students in the United States are exempted from vaccination for philosophic reasons.<sup>81</sup>



### **2.3 Other approaches in European countries**

Many countries do not have compulsory routine immunization when it comes to children's immunization and these are some European and Asian countries. Instead they use other strategies that seem to work very well for them such as education. These countries see that educating the community and healthcare givers about the importance and the benefits of immunization does achieve the levels of vaccine uptake that are needed to prevent the passage of infectious diseases that are aimed to be depressed by vaccination. Therefore, these countries see that there is no necessary need to change their legislation to have compulsory immunization for either children or adults.<sup>82</sup>

Another method would be through using inducements. Inducements are being offered to parents or to health care providers such as general practitioners. In the case of parents, inducements usually take the form of linking childcare benefit payments and/or maternity benefits to immunization status. This is viewed as a form of coercion especially to the low-income families who depend on these payments. A communitarian might argue that if society provides child and family payments, it is reasonable for society to expect and even demand that children be immunized to help protect the whole community. If a family chooses not to immunize its children, the benefit payments that are saved will help the country or the healthcare system pay for the costs of the result of infectious disease.<sup>83</sup>

School exclusion during outbreaks and epidemics is practiced in New Zealand and some states of Australia. This happens in case there was no immunization status present, but that is considered better to those countries than making immunization compulsory.<sup>84</sup> However, when an outbreak occurs it is possible that these countries would endorse an emergency legislation to mandate immunization such as during influenza pandemics or a bioterrorist smallpox attack. Both legislations that mandate and that keeps immunization voluntary, must consider the "no

fault vaccine injury compensation systems”. It seems more ethical to have the states that have mandatory immunization consider having a form of compensation to the children and even adult individuals who got injured due to receiving the vaccine. The compensation should be for the medical costs, the suffering, pain, disability, loss of earning and even death. On the other hand, even voluntary immunization programs need to have the same kind of compensation as the parents had their children immunized in good faith. In the meantime thirteen-vaccine injury compensation program exist throughout the world. Amazingly, only four of these programs are for countries with compulsory immunization laws.<sup>85</sup>

### **3. Vaccination and the moral principles**

#### **3.1 Autonomy and consent**

Competent individuals have the right to determine their destiny according to their own view and perspective of things such as immunization. They have the right to receive accurate information too as it will affect their decision. However, the principle of respect of autonomy is not as basic as it seems. The principle of respect of autonomy has been broadly criticized because it seems like over simplified. The other reason is that it degrades the other bioethical principles and values. This principle allows the individual to have his autonomous choice in selecting whatever medical resources he likes and in the same time he can refuses whatever treatment or tests even if that would affect the entire community in a negative way. This is an inadequate conception places the autonomy of any person over the community, his family, other patients, healthcare givers and even over the other virtues and principles.<sup>86</sup>The main debate remains in public policy is to what extend is it right to restrict a person’s liberty to protect him and others from harm. It is so important to respect people’s autonomy but without neglecting other principles and virtues as the situation is not only controlled by the autonomy principle. In the case of respecting autonomy of individuals receiving vaccinations, if a group of individuals

rejected being vaccination based on the respect of autonomy principle, they will be violating many other principles such as non-maleficence which is not to cause the entire community and justice and being even with others who took the vaccine and not use them and take advantage of the herd immunity. Herd immunity is achieved when there are enough people who immunized in the community the infection can no longer be spread from a person to another therefore the disease dies out altogether.<sup>87</sup> These all take presidency over the principle of autonomy. However, respecting individuals' autonomy is very important in immunization in public health. It can be achieved though giving them complete accurate information about the vaccines to provide them with informed consent. It also can be done through negotiation to discuss the actual and the perceived thoughts that the patient has about the vaccines. Providing informed consent is a must and can be either accepted or not by the patient only if doing so doesn't harm anyone else beside the patient himself Here in the case of mandated immunization, the winning argument is that not having individual get the vaccine would endanger another individual and probably the whole community.<sup>88</sup>

Mass immunization is one of the best interventions achieved by public health. It has been supported by many international health agencies. Its only problem that most of the time it lacks informed consent. Informed consent can be achieved by either informing each person on a one to one level or through media and educational campaigns that talks about the importance, the need, the risks and adverse events of the vaccine used in such mass immunization program. Some say that the world is facing uninformed consent due to the paternalistic approach that the governments are using with mass immunization programs.<sup>89</sup>

### **3.2 Beneficence**

Vaccines contain many unknown toxins, pathogens and carcinogenic agents that threaten the health of its recipient. However, these risks maybe accompanied by any medical treatment a person may receive through his life. The problem with some vaccines is that they are introduced very early in life and usually the bodies are immature at that time. Some argue that the long-term effect of the immunization is more harmful to some people than the effects that are caused by the diseases themselves. The harms that are caused by the vaccines are not doubtful, however, those risks are justified by the overwhelming benefits.<sup>90</sup> It is known that humans take risks in everyday of their lives. These risks are accepted due to the favored benefits that are pursued. It is very known by now that the risk of vaccine-induced injury is hundreds to thousands of times lower than the risk of similar complications of the natural infection.<sup>91</sup>

Vaccines are responsible in diminishing many diseases or at least the incidence of their occurrence and subsequently declining the morbidity and mortality rates of those diseases. It would be foolish to denounce any medical treatment according to its lack of adherence to one of the ethical principles such as non-maleficence when such a treatment promises to fulfill other important ethical principle. Even though immunizing agents violates the principle of non-maleficence, it is justified by the benefits that it brings which outweigh those risks. Although beneficence and non-maleficence principles are closely related they sometimes overlap and create some confusion. Beneficence demands more than the principle of non-maleficence in the case of public health and immunization. In addition, beneficence requires positive interventions to help others and provide actual benefit and not purely omitting the harmful activities. This makes the harm that is being caused by the immunizing agent accepted to receive the benefits which is the positive intervention. Vaccines have proudly eradicated smallpox earlier and are expected to eradicate poliomyelitis and measles soon.<sup>92</sup>

Parents who are afraid of the risks of immunization tend to over emphasize the risks of vaccine injury and to minimize the risk of wild-type disease. This leads to having parents harm their children by not doing something because they are worried about causing damage through using the vaccinations. This is the fear of commission rather than omission.<sup>93</sup>

### **3.3 Non-maleficence**

The undue harm is when the risks associated with the treatment are seen proportionally higher than the risks of the disease or the condition itself.<sup>94</sup> Whatever the condition was, the patient's health should never be endangered unnecessarily under the principle of non-maleficence. However, as much as medical professionals try to adhere to this principle, it cannot be observed all the time. Logically, any medical intervention would be associated with some level of risk. So, if governments and health care professional banned any medical intervention that has some form of risk along with it, very limited interventions would be left to use to treat patients. The same thing with mandatory vaccinations. Opponents to vaccines state that the toxins and pathogens of the vaccine can cause unnecessary harm to the recipient and even cause death. Their argument is associated with the non-maleficence ethical principle. Vaccinations are being imposed on the individuals by their governments, international health organizations and their health care officials.<sup>95</sup>

While immunization programs are being mandated by governments, that doesn't mean that they are safe for everyone in the community. The dilemma around vaccinations is a bit different than what the healthcare system is used to. Usually it is whether to harm or benefit but in the case of vaccination it is how to harm and benefit in the same time. The quintessential ethical problem of public policy in this case of mandatory immunization is how to define, identify, justify and balance the harms and benefits. It is not simply striving to ensure providing

the benefits and preventing harm. This dilemma is the conflict between the private gain of individuals and the collective gain of the whole community.<sup>96</sup>

### **3.4 Justice**

Everyone should get equal access to healthcare including to preventive medicine. However, equal access does not have to mean equal distribution of benefits and burdens. Sometimes burdens are placed more on individuals than the burdens shared by the community, as in mandatory immunization programs.<sup>97</sup> In the case of serious adverse events related to vaccinations, the damages are usually irreversible. Financial compensation is suggested as an attempt to re-establish equity between the community members. It should cover the medical, educational, wage loss and the pain and suffering the individual has. Though, the balance of benefits to burdens can never be re-established when a person suffers a lifetime disability or the death of a beloved one. Financial compensation to those vaccine-injury families may only allow them to have a chance of a more equitable decent life rather than leaving them bear with the burdens by themselves.<sup>98</sup>

In 1975 DPT lot 1182 was manufactured in the state of Michigan. It passed the toxicity test but subsequently was found to be a “hot lot” in the FDA tests. It was three times more virulent and stronger than what the FDA allows, therefore the FDA didn't allow Michigan State to use the vaccine. However, Michigan State's health officials decided to go on and use the vaccine to see how reactive it was. 400,000 doses were not destroyed and rather were used on the children of Ingham County. This resulted in at least three children with seizures, paralysis and brain damage. Ideally, immunization especially the ones that are being mandated on the community are expected to protect the individuals from diseases, present long term immunity to protect contacts from those diseases without imposing any serious risk on the individuals' health.

However, this ideal situation is not the reality that exists. Adverse events can occur causing death or lifetime injuries. It seems ethically reasonable to provide compensation for those people who suffer the undue burdens because of the immunization that is an act of utilitarian good. That would be the proper way to serve justice in a community.<sup>99</sup>

Another issue under justice is when people tend not to get vaccinated and are being beneficiaries or free riders of herd immunity. They are subjected to social disapproval in a community that has mandatory immunization programs. Parents who choose not to vaccinate their children, put their kids and other kids at potential risk. This has led to many cases that ended in the courtroom. Questions of autonomy, parental choice and control and justice were addressed.<sup>100</sup> Such parents need to know that the concept of herd immunity only applies to disease that are confined to humans and transmissible person-to-person only such as diphtheria, measles and pertussis. The children and other community members who do not get vaccinated do not benefit from the herd immunity when it comes to disease that can be transmitted through animals such as for tetanus or rabies. Additionally, the critical level of population immunization to achieve herd immunity varies from disease to another. For example, Measles requires approximately 95% immunization rates in the community to stop any outbreaks. However, Pertussis continues to circulate, though it has reduced very much, even when high levels of immunization are retained. Therefore, parents need to know that the immunization of a child against a transmissible infection protects the community as well as protecting that child.<sup>101</sup>

#### **4. Arguments favoring compulsory immunization**

##### **4.1 Communitarianism**

Communitarianism is a philosophical theory that recognizes the value not only of individual freedom but also of the common good of the entire community. Although Communitarianism is a modern term, many philosophers such as Aristotle and David Hume

recognized and embraced its concept earlier in times.<sup>102</sup>

Based on the Communitarian theory, many vaccination advocates argue that that immunization benefits the whole community and protects the common good of society and that since its significance in protecting the common good outweighs its significance in limiting individual freedom. Therefore, immunization is ethically justifiable to be compulsory. Some very extreme communitarians believe that everyone in the community should be immunized. They also demand that anyone who refuses to be vaccinated should be forced into leaving the community unless they have a medical contraindication not be vaccinated. However, moderate communitarians tend to find less stringent sanction for individuals with vaccination non-compliance.<sup>103</sup>

#### **4.2 Utilitarianism**

The utilitarian theory argues that that actions or policies are good or bad according to the balance of their good and bad consequences.<sup>104</sup> According to this theory, it prefers compulsory immunization policies to the voluntary immunization ones as it gives the best overall result from a perspective that gives equal weight to the interests of each affected party. In the utilitarian balance, the mandatory childhood immunizations outweigh vaccine adverse events.<sup>105</sup>

Certainly, childhood vaccinations are responsible in having less diseases and less suffering in the world. However, the only bad consequence to consider is the coercing parents to immunize their children and hence limiting their personal freedom and autonomy. Some consequentialist suggests that if voluntary immunization could achieve almost equally high rates as compulsory immunization, then voluntary immunization programs should be used by governments. However, it appears in many countries that compulsory immunization is the best way to protect children in those countries.<sup>106</sup>



### **4.3 Rights-based**

Children's rights advocates argue that children need to be protected all the times including from diseases and dangerous infections. This right can be provided and maintained through immunization. This is a duty that parents must fulfill, however if they neglect it, it becomes a duty on the state to make sure that the children are immunized.<sup>107</sup> Eventually there are parents who neglect or object to respect this duty; therefore the government must ensure that the children are immunized. This can be best ensured through mandating childhood immunization by the government or healthcare officials. All in all, advocate of the child's right may well claim that the child's right to protection has priority over the parents' right to decide.<sup>108</sup>

Going back to the communitarian view, a communitarian might argue that community's interests should take preference over individual rights. However, the right-based proponents would ask which right should be paramount; the child or individual, the parents or the community. The best ethical answer would be by determining the level of risk. If the risk to the child or the community was higher than the risk to the parents then it is compulsory to over-ride the parent's wishes.<sup>109</sup> Therefore, if there was an outbreak of a devastatingly severe disease and children could not be protected simply by exclusion from school. If the disease can be prevented and children could be protected by receiving the vaccine then compulsory vaccination is ethically justified.<sup>110</sup>

## **5. Arguments against compulsory immunization**

### **5.1 Paternalism**

Governments tend to mandate some public health interventions as they have proven to prevent injury such as: seat-belt legislation, motor- cycle helmets and bicycle helmets. The reason behind these compulsory legislations is that the public cannot be trusted to comply unless there is a degree of coercion. Fines and probability of losing the license are possible for sanctions

for disobeying regulations.<sup>111</sup> Opponents see that these regulations are paternalistic and argue that the interventions may be harmful by themselves. Seat belts can lead to crush injuries to the chest or spine, while being thrown from a car is likely to result in injury or death, being thrown out occasionally avoids injury just as being stuck in fire. They see that these interventions are similar to immunization as immunizations can have a harmful side to them too.<sup>112</sup> They add that it is an assault to compel someone against their will to have foreign material injected in their bodies.<sup>113</sup>

## **5.2 Respect for autonomy**

Respect for the autonomous choices of other persons is one of the most deep-rooted concepts in moral thinking. Whether it was an adult or it was parents who decide for their child, autonomy and parental decision-making shouldn't be interfered with.<sup>114</sup> Societies and governments do not disagree on the individual's autonomy or on accepting parents' choices in rearing their children. However, the only exception to this is when the parents' actions or choices result in serious harm or neglect to the child. Even if protection of the community is a compelling communitarian argument, yet parents are aware that the risk-benefit equation varies from disease to another and varies over time for a single disease, depending on incidence. To make all routine childhood immunizations compulsory there is a risk that these important intrinsic differences are being ignored.<sup>115</sup> HIPAA aims to protect the individuals' privacy yet allowing health authorities to maintain optimal health levels. HIPAA enabled that under the 45 CFR § 164.512(b), where permits disclosure of patients' information without authorization, to a public health authority that is sanctioned by law to control or prevent a health hazard.

## **5.3 Rights-based**

The right-based approach is used here to argue against compulsory immunization. Every member of the community has the right to freedom and choice and every parent has a significant emotional and financial investment in their child's current and future well-being.<sup>116</sup> This creates

an obligation on governments, society and others to respect every individual and all parents in rising up their children as they see appropriate, unless this could cause serious harm to the child. To have children vaccinated against their parent's will is to ignore the fact that a child is part of a family. Parents can have religious or philosophical reason. This could cause problems in the family and psychological problems to the child as they feel different and unaccepted or related to the family.<sup>117</sup>

## **6. Current Mandatory vaccinations practices**

### **6.1 Annual vaccination**

The Center for Disease Control and Prevention, the Advisory Committee on Immunization Practices and the Healthcare Infection Control Practices Advisory Committee recommend that all community member especially health care workers get vaccinated annually against influenza.<sup>118</sup> The annual vaccination is important, as influenza is unpredictable. Viruses tend to change their strains constantly and the immunity from last year vaccination declines. Influenza can be serious and lead to hospitalization and even death. Everyone above 6 months of age should be immunized including health people and other high-risk groups.<sup>119</sup>

### **6.2 Basic vaccination**

They are also called routine vaccination strategies and they have different kinds. The Population wide vaccinations are usually given during childhood. They are meant to protect those individuals for their lifetime from known infectious diseases. These vaccinations include diphtheria, tetanus, whooping cough, polio, some types of meningitis (Haemophilus influenzae type b (HiB) and meningitis C), measles, mumps and rubella.<sup>120</sup> Through time some of the communicable diseases have been eradicated throughout the mass immunization. Some of these vaccinations contribute to what might be called population immunity or herd immunity. Herd immunity is achieved when a sufficient number of the population develop immunity towards a

specific disease through immunization. So, if one person was infected with one of those diseases all the people who get in contact with the infectious person are already immune, and therefore there would be no further transmission of the disease. Subsequently, the small groups who are unvaccinated are at a lesser risk of having the disease as the chances of the disease outbreak is reduced. Such a success with vaccination mass programs has established good grounds to continue with those public health efforts. Yet, these efforts are seen as ethically problematic.<sup>121</sup> It has been noted that 80% to 90% of the population have to be immune to reach the sufficient level to have the herd immunity. This varies according to the infectiousness of the disease, the effectiveness of the vaccine and many other factors. Herd immunity is ensured through very high levels of vaccination through the world along with outbreak control. Eventually this might lead to complete eradication of diseases.<sup>122</sup>

### **6.3 Pandemic vaccination**

When a pandemic outbreak occurs, public health uses vaccinations in two main roles. The first is through the local restraint of the epidemic at its early stage. This is referred to as the rapid containment strategy. Secondly, if the pandemic becomes more established the vaccine would be used more widely through the use of pre-pandemic stocks of vaccine and later with the pandemic-specific vaccine. Margaret Chan, Director-General of WHO said in 2007 that vaccinations are the single most important medical intervention for reducing morbidity and mortality when influenza pandemic occurs. These categories of vaccination are being mandated in some countries while they are voluntary in others.<sup>123</sup>

## **7. Mandatory vaccination on different groups**

### **7.1 Healthcare givers**

The mandatory vaccination of healthcare workers results in indirect protection of the patients especially the ones with low immunity, the elderly and children. It is commonly reported

that the voluntary uptake of the influenza vaccine for instance, is commonly low between health care givers. Therefore, it is the responsibility of health institutes and hospital to start mandatory vaccinations programs when the vaccination rate between workers seems low. There are many reasons that justify the mandatory vaccination on health care givers. The main reason stems from the duty of health care givers not to harm patients when they know that there is a significant risk of harm and the intervention to reduce this chance has a favorable balance of benefit over burdens and risks.<sup>124</sup> Another reason is that healthcare givers have a Special obligation towards their patients and the community. If the prima facie duty not to infect others were a duty for all individuals, then this duty would be more important on the health care givers part.<sup>125</sup> Farther, the public's trust might diminish in the health care workers if they continue to fail to prevent serious consequences for their patients due to refusing to be vaccinated.<sup>126</sup>

## **7.2 Children**

Childhood immunization is considered one of the most successful interventions in public health worldwide. It is one of the most important and cost- effective public health measures though it has and still being fought against by many anti-vaccination movements through the continents. Nevertheless, childhood immunization has been reducing the incidence and severity of infectious diseases and saving many children's lives regardless of the rare adverse events that can happen occasionally and cause injury.<sup>127</sup>

It is important to vaccinate children form some specific disease early in their childhood ages before reaching the age group where those diseases tend to rise more often. Successively this would make them the disease-free adults of tomorrow. By giving those mandatory vaccinations, artificial immunization is being established. Although some of these vaccines' effects tend to diminish overtime therefor a booster dose is required. Another reason to mandate vaccines on children and infants is that small doses have the tendency to provide cost benefit as

the dose can be cut by  $\frac{1}{4}$  and  $\frac{1}{2}$  respectively leading to cost-benefit over vaccinating adult. In the case of mandatory immunization, beneficence is partially utilitarian and partially communitarian in nature. The benefits out of it are experienced by the whole society even though parents have the right to worry and check what kinds of vaccines their children are taking.<sup>128</sup>

### **7.3 Communities during pandemics and emergencies**

Vaccinations are considered the best line of defense when a pandemic or even an epidemic hits a community. They do not protect the vaccinated individuals from being ill only, but they also reduce further transmission which prevents infection and protects the enter community.<sup>129</sup> A community is a group of people living in the same place or having a particular characteristic in common. Subsequently, the global community is the people or the nations of the world, considered as being closely connected by modern telecommunications and being economically, socially, and politically interdependent. That makes the world as a one close small community. Whenever an epidemic hits a country, all other countries must be alerted and work together to control it and prevent a pandemic from happening. Mandatory immunization programs are ethically justified during pandemics and emergencies. The communitarian policy is ethically comfortable with these measures as they protect the public health.<sup>130</sup>

Once the virus has spread through countries and globally, governments should start using the antiviral stockpiles primarily to treat patients who got infected and avoid using it as a prophylactic measure at the national level. Governments must also support low-income countries that may not be able to afford the antiviral drugs.<sup>131</sup> After a pandemic has occurred it is recommended that governments or at least national institutions play the role of ensuring a fair allocation of resources. This would help in sustaining the trust and in the professional ethics of healthcare providers. It would give the medical staff the time to focus on treating their patients

and patient selection on site and personal preference in triaging the patients. No policy would function better in such chaos better than the Communitarian policy.<sup>132</sup>

At this phase, governments are expected to be prepared with advance decision making procedures which would permit the government and the other international governments and institutions to make rapid assessments regarding the level of risk, priorities and needs when the pandemic is at its peak.<sup>133</sup> This should provide governments with a good foundation to make suitable decisions about the national and international actions that have to be taken in order to mitigate the effects of the pandemic and figure out the amounts of available and needed vaccines. If this cooperation is not maintained, it will be very hard to make soundly –based decisions. Fairness and effectiveness of the policies would be lost leading to other consequences. There will also be losses on the human cost beside possible great economic cost over the long term.<sup>134</sup>

## **8. Interventions towards objection to mandatory vaccination**

### **8.1 Reviewing and evaluating the current vaccination mandates**

Immunization programs should review vaccination mandates operational in their jurisdictions but with the consideration of having them based on ethical frameworks. In addition, they need to reduce the existing ethical conflicts as much as possible. It is recommended to have vaccines mandated policies in the countries where there are diseases outbreaks and epidemics that can be prevented through vaccination. All the fifty states in America have vaccination as a requirement for entering school for both children and adults. However, these requirements can be exempted if there was a medical excuse. Forty-eight states out of fifty allow the person or the parents' philosophical believe and even religious exemption. In a legal challenge to the lack of a religious exemption in one state (Boone v. Boozman), it was ruled that: “the constitutional protection to freely exercise religion does not excuse an individual from compulsory

immunization; in this instance, the right to free exercise of religion and parental rights are subordinated to society's interest in protecting against the spread of disease."<sup>135</sup>

## **8.2 Increasing the use of non-compulsory vaccination strategies**

To minimize the existing ethical conflicts that appears around the mandatory vaccination governments need to maximize strategies that are less than compulsory achieve and maintain high vaccination coverage levels just like other European countries. There are some specific circumstances where compulsory vaccination and exclusion practices are considered ethical and justifiable. An example is when unvaccinated children are excluded from attending school during diseases outbreaks. On the other hand, there are situations where less than compulsory vaccination strategies are better to use such as allowing for philosophical/personal belief or religious exemptions when it comes to school vaccination requirements that has been practiced in the United States in forty-eight states so far. This strategy has proven to work just fine as the United States have maintained a relatively high childhood vaccination coverage levels. Also, Australia has implemented a unique approach that seems to work very well. Financial incentives are given to families of children with complete vaccine records. This has resulted in the families' good compliance with school vaccination requirements without having the need to use compulsory policies. In addition, there are other strategies that have shown to be effective and to improve the vaccination coverage in the absence of using mandatory vaccination rules. These include patient recall and reminder system, provider reminder systems that ensure all medical encounters are being employed to assess patients for needed vaccinations, and school-located vaccination programs.<sup>136</sup>

## **8.3 Addressing parents' vaccine safety concerns**

The best people to inform the parents or the guardians about the vaccination related information and its safety are the physicians and nurses. They usually get the parents' trust when



they demonstrate their care, concern, honesty and openness with their knowledge and expertise when they deliver the routine health care to the patients. When parents change their minds, and allow giving their children the vaccination, this is usually after a convincing conversation with a good healthcare giver.<sup>137</sup> It is normal that all parents get concerned at a point when their children are supposed to receive such mandatory vaccinations. They are worried about all the harms that are considered even rare. Any vaccine that has a significant adverse event profile would not likely be considered a good candidate for a mandatory universal vaccination requirement that parents would allow their children to have. Earlier in the 1986 the National Childhood Vaccine Injury Act placed a major focus on the vaccine safety. This Act has started the Vaccine Adverse Event Reporting System (VAERS). It mandated that all clinically significant events that occur after vaccination should be reported even if it is not believed to be caused by the vaccine. Besides that, the Act established the Vaccine Injury Compensation Program, which is also known as the no-fault system to resolve the monetary vaccine injury claims. It gives the government the responsibility to compensate the individuals who were injured from the vaccine's side effect.

In 2001, the United States established a huge network of Clinical Immunization Safety Assessment Centers. These centers dealt with individuals who suffered from serious adverse events related to vaccinations. The centers performed standardized clinical assessments on them to get a better understanding of the pathophysiology and relevant risk factors for these events. It is critical to ensure that these vaccines are safe however; it is found that the public's perception about vaccine safety is not consistent with the scientific evidence. Addressing this perception discordance is made more difficult because the benefits of vaccinations are reflected through the prevention of diseases they are made for. The fact that the public knows a little about these

diseases and is not familiar to its dangerousness makes it a problem and does not serve to counterbalance the rare adverse events to vaccination that might occur.<sup>138</sup>

Studies have found that a substantial number of parents believe that governments are not trustworthy when it comes to the vaccinations that they mandate. They are suspicious that government regulators and policy makers work in conspiracy with vaccine manufacturers. It is recommended that governments to strengthen and publicize the policies and procedures that eradicate the parents perceived potential conflicts of interests between the organizations that regulate and recommend vaccines, and the manufacturers that produce them. All in all, this could enhance the parents and the entire public's trust in the mandatory vaccination programs and in their governments. It would also address the transparency of these programs and enables the building of the ethical framework that the governments need to consider.<sup>139</sup>

#### **8.4 Enhancing public awareness of vaccine-preventable disease risks**

One of the most important affecting factors in getting the most amount of attention to the immunization programs is through enhancing the public's awareness to the vaccine-preventable diseases (VPDs). This should include not only the acquired benefits of the vaccines but even the risks and the serious complication that vaccines might cause. Beside educating people about these VPDs, these awareness campaigns give the individuals the freedom to balance their own autonomy against the harms of the risks that might occur and the benefits they are acquiring from the vaccines. The most important thing is that the information reported has to be right and accurate. Currently, the United States there are not so many VPD outbreaks as there were once but they still tend to occur. Whenever that happens, it is not reported in the mass circulation media. However, even if it was reported on media, there is no focus on the key link between the relapse of the disease and the vaccination.<sup>140</sup> It is known that mass media can coast a lot but it is a huge opportunity that can affect the public's health through heightening the public's awareness

of these disease terrorizations that have particular relevance for the unvaccinated persons. Moreover, it is the public's right to be kept informed whenever these outbreaks occur in a part of the world.<sup>141</sup> They need to be reminded repeatedly that air traveling can expose unvaccinated individuals to the threats of those diseases especially when they come from countries with low disease prevalence. It is important to educate people that going to crowded places and even emergency rooms can expose them to a communicable VPD.<sup>142</sup>

The MMR vaccine controversy that happened in the UK between January and September of 2002 was found out to be behind a story that was presented through media about the risks of the vaccine. It was not about the risks of acquiring the vaccine preventable diseases that the MMR vaccination can prevent. That move was made by the anti-vaccination groups to claim the harms of the vaccine. Therefore, immunization programs need to be prepared to take advantage of media opportunities and oppose those untruthful anti-vaccination campaigns with true beneficial information that protects the public health, maybe in emotional touching stories too.<sup>143</sup>

## **9. Conclusion**

The mandatory vaccination approach is justified in public health on the basis of minimizing the risks of harm to other people, protecting vulnerable individuals such as children and emphasizing good and fairness to the community. Such directive policy is accepted when it is linked to serious factors such as the seriousness of the danger of the disease to the population and the risks associated with the vaccination and with the disease.<sup>144</sup> This is proven from both the utilitarian and communitarian theories points of view. In addition, it protects the right to well-being of many high-risk groups such as children. Current practices of mandatory vaccinations have proven its success through the many type of those vaccinations such as the annual, basic and pandemic vaccinations. Even some diseases are eradicated and others have lesser rates such as smallpox and strains of deadly influenza.<sup>145</sup> Nevertheless, each infectious

disease and its vaccine must be studied individually as if it should be mandated or not on the communities to get the public's acceptance to the mandatory practice. Yet there are some circumstances where vaccination becomes mandatory such as when the disease is highly contagious and severe or when the eradication is possible through vaccination for such a serious disease.<sup>146</sup> It is recommended that public health policies use the least invasive methods to reach the benefit goals of public health. It is also important not to ignore parents' concerns and worries. Awareness campaigns can help in educating parents and the entire community.<sup>147</sup> Mandatory immunization programs are justified as long as there is an ethical rationale to have them. In addition, the level of coercion can be lessened with paying attention to the public's concerns and correcting them by the means of media educational campaigns and allowing them to participate in changing and reviewing the public health policies.<sup>148</sup> Mandatory immunization is a need and one of the best interventions in the history of public health that protected and still protects communities of the world.

Several public arguments around vaccination and privacy arose again with the execution of HIPAA. However, the Privacy Rule was able to maintain a balance between the protection of the patient information and allowing traditional public health activities to continue. Under the 45 CFR § 164.512(b), HIPAA permits disclosure of patients' information without authorization, to a public health authority that is sanctioned by law to control or prevent a health hazard. This must be achieved with the minimum required amount of information. Moreover, once the protected health information has been disclosed, it can be stored conveniently to conduct the public health activity. The storage must be complying with the State and Federal laws.<sup>149</sup>

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## **Chapter 4 Research Ethics**

### **A. Privacy & Research on Children:**

#### **1. Introduction**

In the 20<sup>th</sup> century, many biomedical and social researches have resulted in the lowering the mortality and morbidity rates in infants and children. Many vaccinations, treatments and cures were found for diseases that caused children's sicknesses and deaths.<sup>1</sup> Yet and through history, some of these researches were developed and conducted unethically mostly because they lacked the consent process. Due to that, guidelines and regulations were developed to protect children and prevent further exploitation due to their vulnerability and incapacity to give informed consent. These guidelines understand the need for research on children.<sup>2</sup> They stress on protecting children's autonomy through the provision of assent when having children as prospective participants in research that has no direct benefit to them. Through the years, children were either under protected or over protected in clinical research, but by limiting the amount of risk in research with no prospect benefit, children can be protected. Some suggest excluding them from research and that research on adults would be better and enough. The most important reasons to include children in research are that some disorders only belong to them that never affect adults. The efficacy and dose of medications can be influenced by the child's age and level of development.<sup>3</sup> This is considered to be unfair to children, to avoid having research on them, as they are a vulnerable group when research is needed so much for their welfare.<sup>4</sup> Children cannot consent like adults on putting themselves under the risk of research with undefined benefit.<sup>5</sup> Institutional review boards gives more attention when reviewing researches that include children specially when there is no direct benefit. They usually preform risk assessments and stress on the assent's language according to the potential participant's ages.



Some theories such as deontology and utilitarianism support pediatric research with no direct benefit and stress on the need for providing assent. Assent along with parental approval can justify those researches with no direct benefit. <sup>6</sup>

## **2. The importance of research on children**

The Belmont report presents three basic principles for that identifies the ethical human research. They are the respect for persons, beneficence and justice. <sup>7</sup> All that is important in pediatric research that has no direct benefit to them.

### **2.1 Autonomy of children as research participants**

There are two important conditions for autonomy: liberty, which means that a person is independent from controlling influences, and agency that refers to having the capacity to intentional action. <sup>8</sup> Both conditions vary in children according to their age, level of capacity, understanding and development. To respect the autonomy of a subject is to recognize his right to make a choice, hold his own views in order to take an action according to his own values and beliefs. Therefore, assent is considered an important part of the consenting process when having children participate in research studies. Children's choices must be respected when they are selected to be potential subjects in research that has no direct benefit to them. Assent is not the same as consent and is not seen equal to it. The purpose of using an assent is to treat children as autonomous agents as they supposed to be when they are helping in serving the community with their participation in uncomfortable risky procedures. <sup>9</sup> Most children would rather be playing instead of being part of a study. Assents are not meant to be used to treat children as if they can make the decisions after being fully informed and autonomous just like adults. Rather than that, assent requirement reflects the belief that even though some children might not completely understand or consider all the implications of research participation, their level of understanding

and decision-making ability are sufficient to decide whether they would like to participate in an activity that offers no possibility of direct benefit to them.<sup>10</sup>

The principle of respect of autonomy can be expressed as a positive obligation and a negative obligation. The positive obligation involves having respectful treatment and the releasing of information that enhances the decision of an autonomous person. This has to be applied when disclosing the information about a research to the parents in order to ensure their voluntariness and full understanding to give permission and have their child as a participant in a study. That alone will not ensure the child's participation; the child needs to make a decision around participation the study too. That can be done through the appropriate assent process. While the negative obligation states that the actions of an autonomous person are not subjected to control, it is a must that there are no influences, neither on the parents nor the child. Even with those obligations, the respect of autonomy is not clear enough to show what is considered as a valid justification for restraining autonomy. This principle can be overridden by other principles in specific situations where harm can be caused to others if the respect of autonomy is applied.<sup>11</sup>

Assent requires researchers to treat children with dignity and respect regardless their age. Respecting children as moral agents requires a respect for their developing capacity and their ability of making choices, in order for them to exercise autonomy. Most school-age children have the capacity to understand what they are being asked to do in the setting of non-beneficial research and to understand that their participation is not something they must do.<sup>12</sup> While altruism might be something ideal and adults must understand it when participating in a research with no direct benefit to them, it is not necessary for children to decide whether they want to participate in research procedures.<sup>13</sup> It would be disrespectful to attempt to involve children without first discussing the procedure and securing their permission. A person does not have to

be a fully autonomous individual to be owed this level of respect in negotiating the boundaries of interactions with others. When children can have a role in decision-making, they start developing being autonomous individuals. It is a hard process that children and adolescents go through till they reach the legal age and be free to make their own choices. This helps in promoting the child's emerging capacities for becoming a better, more involved decision-maker. It enhances their self-esteem and well being when they feel that their wishes are being respected. They get to practice making decisions and have control on their lives, which will increase the sense of responsibility in their lives. This will also reduce their anxiety and will likely increase the child's commitment to the research project.<sup>14</sup>

The relation between children and the investigators is viewed as a partnership. When children participate in research with no direct benefit they become the real partners and they should be accorded an appropriate degree of respect. Assent reminds parents and researchers that children are persons with interests not mere vessels to serve in a research. Children are supposed to be recognized as partners in the research. This will result in a more respectful relation between the child and the investigator and avoids the danger of using the child as a mere end. All in all, respecting children's choices regarding participation in research with no direct benefit to them teaches them that respect for persons includes honoring their choices.<sup>15</sup>

## **2.2 Children's beneficence**

Beneficence in medical ethics refers to a statement of moral obligations to act for the benefit of the patients or subjects whether they are young or adults. Morally it includes conferring benefits, preventing harm, doing good and weighing possible goods against possible harms. Non-maleficence is the principle that mandates not harming patients and subjects. Beneficence requires a positive action towards the person and does not have a legal issue if it wasn't followed but non-maleficence is a negative prohibition of actions that has legal action taken if it wasn't performed.

It is mandatory to do no harm than to do good. Some people argue that beneficence cannot be obligatory because it is a virtuous ideal of doing good deeds such as charity. Meaning a person does not violate the principle if he fails to act beneficently. This can be right if we are considering the optional kind of beneficence or the ideal beneficence where sacrifices are made and extreme altruism. The positive beneficence includes: Protecting and defending a person's rights, preventing harm from happening to a person, remove the causes and conditions that will harm a person and helping the ones in danger and the ones with disabilities.<sup>16</sup>In medical research, the benefit sometimes can be not directed towards the participant himself, but rather to achieve a result that would benefit the whole community. This must be considered so carefully when including children in a research. Finding effective treatments or cures for childhood diseases and contributing to the healthy development of children can justify the research on children that has no direct benefit.<sup>17</sup>

Paternalism is the intentional overriding of the person's decisions and preferences, the justification is usually stated as; to benefit that person or to prevent harm from happening to him. Paternalism can come in many forms: simply by not applying a person's own wishes. It can be done through manipulation, deception, coercion, and non-disclosure of information. A kind behavior can only be paternalistic in case the person was autonomous only. Non-maleficence must be applied when investigators have children in their researchers that have no direct benefit to the children. No maleficence applies to all ages regardless if they are autonomous or not. When asking children whether they want to participate or not in a study that had no prospective benefit to them, the investigator protect them from harm. It is a must that children can first understand and comprehend the research purpose before asking them to be a part of it.<sup>18</sup> Having in mind that children can change their mind or experience distress just after starting the study, they should be respected for their dissent wishes. The principle of non-maleficence supports the

dissent requirement. If children express any kind of distress this can be a sign of dissent that must be respected by the researchers. Sometimes, researchers can modify a procedure or give a pause and some reassurance to the child to figure out if the distress is related to the study or not before accepting a dissent. Parents are the best in figuring out if their children are in distress or not than anyone else.<sup>19</sup>

### **2.3 Consent and assent**

Since children cannot consent, as they did not reach the legal age. The international norms and regulations provided many forms of protection through history for children included in research. In 1949 the Nuremburg code stated that only individuals who can give a free informed consent could participate in research studies. That time, this meant that children could not be research subjects. Then in 1964 the Declaration of Helsinki stated that if the research participant is legally incompetent, his legal representative should give an informed consent for the minor's inclusion in the study.<sup>20</sup> CIOMS also asked that the legal representative or the parents permission must be taken when a child is included in a study. It is obvious that only the involved person in the study can consent, but when it is a child that becomes impossible. Thus the parents are authorized by law to act on the child's behalf and best interest.<sup>21</sup> The UNESCO underlines the importance of making decisions that are in the best interest of the child. Now even the parental authorization must meet a number of requirements set up by the international norm such as voluntariness and the informed character.<sup>22</sup> However this is not considered a full permission to have research on children. Beside the parental permission, there must be the obtaining of assent from the child. Assent is the will of the child to participate in the proposed research. According to the Belmont report, it is demanded that legally incompetent individuals be given the chance to choose whether they want to be a part of research or not and that their refusal must be respected and not overridden.<sup>23</sup> In addition, the Declaration of Helsinki clearly states that researchers must obtain

consent from the child whenever the child is capable of doing so. This has to be additional and after the parental permission is provided. The Declaration of Helsinki also requires the respect of the dissent of the child. Moreover, the CIOMS requires the researcher to seek assent from a child in accordance to the child's maturity and intelligence permit. Both the Convention on Human Rights and Biomedicine and the Additional Protocol to the Convention on Human Rights and Biomedicine, both agree on that the minor's opinion must be taken into consideration as the determining factor to his/her inclusion in the research. This should be proportional to the child's age and level of maturity. <sup>24</sup>The European Commission divided children into three categories; children from birth to the age of three years old, children from three years old and onwards and adolescent. It is impossible to obtain assent from the first group. The second and third may be able to understand the purpose of the study and the level of the risk and benefits according to level of understanding and age. They also can understand the notion of ultraism that might be the motivation for them to participate in the research. <sup>25 26</sup>

All the previous international norms and regulations clearly states the importance of involving children in the decision making process when they are included in a research. This becomes more significant when the research does not offer a prospect benefit to the child. It makes also clear that it is impossible to obtain consent from a child, thus the parents permission has to be provided before moving to the assent process.

Some regulations allow classes of adolescents such as the mature adolescents and the emancipated to the right to consent to treatments or procedures involved in a clinical investigation for some disorders or conditions. They are allowed to participation in FDA-regulated research and consent for themselves without the need for parental or guardian permission. This regulation differs according to the different states in the US. <sup>27</sup>

According to the higher capacity that adolescents acquire, they need a different model of assent that includes more informational elements of the research study similar to what an adult would require to consent. Some studies have found out that adolescents older than thirteen years old can have the ability to understand medical decisions like adults. Consequently, Adolescents younger than twelve years old have less understanding than the older Adolescents. They also tend to avoid releasing their personal information. Nevertheless, adolescents' executive function is not as fully developed as adults. This makes their judgment more prone to distortion. This implies that the parental permission remains important even though adolescents may be able to undertake responsibility for deciding whether to participate in research that has no direct benefit to them. Studies found out that Adolescents are more willing to participate in researches that have more the minimal risk than their parents would permit.<sup>28</sup>

### **3. Theories used to justify research with no direct benefit to children**

#### **3.1 Deontology**

Deontology is a non-consequentialist theory derived from the work of the philosopher Immanuel Kant. Deontology has a duty-based ethical viewpoint, where one's actions are based on what is morally acceptable, regardless of the consequences. Kant sees that a universal law should provide the basis for each act, and that the intentions are more important than the outcomes. Deontology demands that people be treated as ends and never as means to an end.<sup>29</sup> According to this theory, the only acceptable kinds of research are the ones that have potential benefit to children or when children are capable of giving assent. Deontology followers are very careful when evaluating research that has no direct benefit to pediatric subjects. They see that such kind of research uses children as means to serve the need of other children. Attempts are made to address the need to respect a child's autonomy by obtaining assent from those children capable of providing it. Yet, not all children have the same level of cognitive development. Some

children will not develop it until they are eighteen by then they are not considered children. This will struggle any pediatric research. This is why parental permission must be provided before children can assent. This requirement differs in cases of adolescents who are emancipated minors or when the research is related to pregnancy, substance abuse, human immunodeficiency virus or acquired immune deficiency syndrome, sexually transmitted diseases, or mental health issues. Hence, IRBs have to determine about every adolescent if he or she are able to consent or assent. Beside that, every IRB needs to take into account the ages, maturity, and psychological state of the children involved. It is important to note that a child's ability to understand a study would depend also on the complexity of the study.<sup>30</sup>

From a deontological ethical point of view, assent regulations must be firm enough to provide protection and respect for children however they should be flexible enough to allow considering different cognitive and emotional levels. Children must not be exposed to harm in order to serve the benefit of others. This perspective mandates assent from a child in order to participate in research that does not have the potential to directly benefit that particular child.

### **3.2 Utilitarianism**

Utilitarianism is one of the major teleological and consequentialist theories. Consequentialism is related to the concepts that hold actions are right or wrong concurring to that it balances their good and bad consequences. The right act is the one that would produce the best overall result as determined by the theory's values. The value of a theory is determined by the rightness and wrongness of its actions.<sup>31</sup> It is derived from the work of both John Stuart Mill and Jeremy Bentham. Utilitarianism deems that the determination of whether or not actions are correct depends on the overall balance between the risks and benefits resulting from that action. The Collins English Dictionary and Thesaurus defines Utilitarianism as the doctrine where the morally correct course of action consists in the greatest good for the greatest number of people,



this is in the maximizing of the total benefits and burdens.<sup>32</sup> Utilitarianism concentrates on the welfare, well-being, preference satisfaction and like. It only accepts utility as its basic principle of ethics. It justifies the research that is more beneficial to many children than harmful to the pediatric participants, therefore it does not mandate assent.<sup>33</sup> Utilitarianism sees that there is too many restrictions on children's research and that have denied children from the benefits of research advancements. That is why many children's medications were chosen anecdotally or by estimations according to their therapeutic optimal when they were researched on adults. However, children are not little people, they differ from adults in their body physiology and biology. Even the pharmacokinetics and pharmacodynamics differ depending on the age and developmental stage of a child. Consequently, absorption, metabolization, and excretion of medications all are different than adults. According to the principle of distributive justice, it is unethical to exclude pediatrics from research even the ones that would not provide direct benefit to them. Worrying about the children's vulnerability and ability to assent that leads to excluding them from research studies is considered unfair and unjust to them. It is clearly noted that the unethical risky researches in the past, lead to the scientific advances that children are benefiting from now. The best example would be the immunizations against common childhood illnesses that lead to significant mortality in previous generations. Therefore, in order to distribute the maximum benefit for children, some researches associated with risks, some of which are greater than minimal and that will not directly benefit the pediatric participants, needs to be approved. They must be well designed with an adequate sample size and carefully monitored by IRBs. In addition, every effort must be made to prevent children's exposure to unnecessary risks. Finally, pediatric participants must be monitored for any signs of distress and they should be allowed to dissent and be dis-enrolled from the study without any consequences.<sup>34</sup>

If regulations did not allow the participation of children in research that has a limited amount of risk and had no prospect benefit to them, then the pediatric population is exposed to higher risks. This will lead to the off-label use of medications.

#### **4. Issues with using children as participants for research with no direct benefit**

##### **4.1 Vulnerability**

Children are being considered one of the vulnerable groups when it comes to including them in research whether it is a medical or non-medical research study. Their vulnerability comes from their capacity limits to have mature decisions as adults. Usually they are subject to other's authority. Their rights, desires and interests can be socially under valued. Children and their parents can be deferential in many ways that mask underlying dissent. It is also understood that children and their parents may not understand the importance of socially distributed goods.<sup>35</sup> Regarding their medical situation; it must be taken into consideration that they might be having serious medical conditions that cannot be treated. They also may be having an acute medical condition that requires immediate medical attention that is not consistent with the informed consent.<sup>36 37</sup>

##### **4.2 Ability to consent**

When children or minors whom are younger than eighteen year old are included in research as subject, the regulations require the assent of the child or minor and the permission of the parents. This places the consent required from an adult subject. It is agreed on that children are legally incapable of giving informed consent, but nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons they should be asked whether or not they wish to participate in the research, specifically if the research does not involve interventions that are likely to be beneficial to the subjects.<sup>38</sup>

William Bartholome discussed assent in the pediatric population. He defined four essential

elements that have to be included in order for the assent to be ethical. Those four elements of assent imitate the basic requirements of the informed consent that are identified in the Belmont Report, but modified to reflect the child's developing capacity. First there must be a developmentally appropriate understanding of the nature of the condition. Secondly there must be a disclosure of the nature of the proposed intervention and what it will involve. Third, there must be an assessment of the child's understanding of the information provided and the influences that impact the child's evaluation of the situation. Finally, there must be a solicitation of the child's expression of willingness to accept the intervention. If the child agrees to participate and be a part of the study, he must know why is he being picked to participate and what might be his experience like. This is the right time for the researcher or investigator to assess the child's capacity to understand and evaluate these facts.<sup>39</sup> It is important to keep in mind that the child's assent should differ from the parental permission in the means of the amount of information and details. The parents' permission form should include the foreseeable risks and benefits in details, and appropriate alternate procedures or courses of treatment. This supports the importance of parental permission for understanding the role of child assent.

##### **5. Amount of risk in research with no direct benefit to children**

Research can be either providing direct benefit to children or with no direct benefit to children. Research with no direct benefit to children has to have a limited amount of risk. All international regulations harmonize on limiting the child's exposure to non-therapeutic risks in research. There is a general agreement worldwide that states that a child's exposure to risk in pediatric research must be minimal or low in the case of no direct therapeutic benefit to that child.<sup>40</sup> Regardless the differences in the used terminology such as minor increase over minimal, low risk, minimal burden and minimal risk. The European directives and the U.S. Code of Federal Regulations explain the two categories of minimal risk and minor increase over minimal

risk in the context of no direct benefit for the individual pediatric participant.<sup>41</sup>

There are two ethical principles that safeguard children when they are enrolled in research that has no direct benefit to them. First, the risk that the children would be exposed to must be low to enroll them in a research with no direct benefit to them. Second, children should not be disadvantaged by any means because they are participating in a study, neither through exposure to excessive risks or by failing to get necessary health care. This means that the study protocol must show either an acceptably low amount of risk of the experimental intervention or a sufficient prospect of direct benefit to justify the risks of the intervention. Such principles make it hard for researchers to bridge this risk gap between the research involving procedures and interventions that present only a low risk given the absence of sufficient data to establish the direct benefit when generating a new medication or intervention.<sup>42</sup>

### **5.1 Minimal risk**

When the research does not offer direct benefit to the non-consenting subjects, the International Conference on Harmonization Guidelines demand that the foreseeable risks to the subjects must be low and that the negative impact on the subjects' well being is minimized and low.<sup>43</sup> FDA regulations define minimal risk, as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This definition seems to provide two comparators for assessing minimal risk: the ordinary daily life, and the routine physical or psychological examinations or tests.<sup>44</sup> It appears that there is well-documented variability in the interpretation and application of the term minimal risk. Therefore, the Institute of Medicine (IOM), The Secretary's Advisory Committee on Human Research Protections (SACHRP), and The National Human Research Protections Advisory Committee, all three panels recommend the international use of a uniform standard for

defining what is minimal risk.<sup>45 46</sup>

On the grounds of justice applied as an ethical principle, research interventions or procedures should not encompass potential harm or discomfort beyond that which an average, healthy, normal child might encounter in his daily life or in a routine physical or psychological examinations or tests. Such a recommendation would help in protecting children who are at increase risk from being subjects in researches that are not related to their condition or might exploit them due to the greater level of risk.<sup>47</sup>

The moral ethical principle beneficence enforces two huge requirements on researchers and investigators. They must ensure both of maximizing the benefits and minimalizing the harms according to the Belmont report. Doing no harm that is known, as the principle of non-maleficence is derived from Hippocratic oath. These two principles require researchers to act in the best interest of the children and preventing them from harm when the study has no prospect benefit to the children.<sup>48</sup>

The National Commission listed some procedures that are minimal risks such as routine immunization, physical examination, obtaining blood and urine specimens, modest changes in diet or schedule, developmental assessments, most questionnaires, observational techniques, noninvasive physiological monitoring, psychological tests and puzzles obtaining stool samples, administering electroencephalograms, tests of devices involving temperature readings orally or in the ear. SACHRP lists a number of physical routine procedures or examinations that are being no more than minimal risk such as measurement of height, weight, and head circumference; assessment of obesity with skin fold calipers; hearing and vision tests; testing of fine and gross motor development; non-invasive physiological monitoring. Psychological ones would include child and adolescent intelligence tests; infant mental and motor scales; educational tests; reading

and math ability tests; social development assessment; family and peer relationship assessments; emotional regulation scales; scales to detect feelings of sadness or hopelessness. Surprisingly, some classified the exposure to radiation from diagnostic procedures as minimal risk. Nevertheless, it should be kept in mind that some of the mentioned procedures may be pondered as greater than minimal risk. This would depend on the context of the research and the age and condition of the child who will be enrolled in the study. <sup>49</sup>

When assessing minimal risk, the age of the child should be taken into consideration. The harm and discomfort, duration, cumulative risks, and reversibility of harm also have an impression on the level of risk. Even though the standard of risk of daily life or routine examinations or tests is debatable, it is the conscientious parents responsibility to assess and weight the risks.<sup>50</sup>

## **5.2 Minor increase over minimal risks**

FDA regulations classify some accepted procedures as having minor increase over minimal risk. An intervention or procedure that is approved under this category must involve experiences to subject child as that that are reasonably proportionate with those inherent in the child's actual life or expected from the child's disorder or condition. It is accepted because it helps understand and improve the subject's disorder or condition. This class of risk has been justified due to the medical necessity. The minor increase of risk is necessary and acceptable, in order to understand some childhood conditions.<sup>51</sup>

Disorder or condition is defined as the set of specific physical, psychological, neurodevelopmental, or social characteristics according to the IOM. The Institute of Medicine states that there is a scientific proof that these conditions do compromise the child's health. They also might increase the risk of developing another health problem for the child in the future. A child can only participate in a study if has the condition or might develop it meaning that he is

healthy but in risk according to clinical evidence. A condition would have a vital importance connected to its scientific necessity only if it is related to the child's disorder or condition. Only very conscientious parents can be entrusted with the authority to evaluate such non-beneficial risk exposures. According to the National Commission, the activity or procedure can reasonably be similar but not identical to other procedure that the child might experience. The IOM explained 'although a child might not have experienced a particular research procedure...the procedure could still be described to the child as potentially presenting levels of pain, immobility, anxiety, time away from home, or other effects that would be similar to those produced by procedures that they have experienced'.<sup>52</sup>

Researcher and investigators must make sure the intervention or procedure does not present more than a minor increase over minimal risk. They must collect sufficient data that any research-related pain, discomfort or stress will not be severe and that any potential harms will be temporary and reversible. Parents and children must be reassured about that in order to accept participating in research with no direct benefit. The risk cannot be considered as a minor increase over minimal if the investigators cannot estimate it yet or if it reflects a large degree of variability.<sup>53</sup>

According to the Institute of Medicine, the Procedures that might present a minor increase over minimal risk are such as lumbar puncture, bone marrow aspirate with the appropriate procedural sedation, placement of a blood-drawing peripheral intravenous line for a limited time period, some selected methods to procedural sedation and the limited radiation exposure. The risk will depend on many factors like the skill of the investigator, research context, the population of children with a specific condition.<sup>54</sup>

Finally, it is very crucial to restrict the pediatric exposure to research risk from an ethical

point of view when the research lacks the direct benefit to the child. Some regulations are not clear about the amount of risk and other related definition.<sup>55</sup> Other regulations were challenged to provide explanations that would help the investigators in assessing the amount of risk. This has generated many debates and a range of interpretations. There are many persuasive ethical arguments for implementing a uniform standard for minimal risk. The FDA assesses the minimal risk on the children's routine experiences of average, healthy children. This has to be modified according to the child's age and the research risk duration, cumulative risks, and reversibility of harm. The risk assessment can be determined by another method that is the daily life risk factors. Equally important, the FDA regulation defined the category of minor increase over minimal risk. This provided another dimension for researchers for more challenging evaluations of risk acceptability when there is no direct benefit to pediatric participant. With the permission of responsible parents, the risk can be evaluated for every individual child. The goal of these regulations is to protect children from research possible harms and make the research procedures tangible for the child and parents, thus improve the child assent and parental permission.<sup>56</sup>

## **6. Ethical requirements for research with no direct benefit to children**

As children develop, they gradually become the responsible guardians of their own personal health and the primary partners in medical decision-making, assuming this responsibility from their parents. Obtaining assent from pediatric participants is an interactive process in which information and values are shared and joint decisions are made just like the consent process. Parental permission is the other requirement that investigators must have in order to start the assent process. The Parental Permission Form must contain the same elements as the Consent Form but it should be addressed to the parents not to the participant. It should be called a parental permission form not a consent form. The assent form should be addressed to the prospective pediatric participant. It should explain the research procedures in a language that is



suitable to the child's age, experience, maturity, and condition. The assent has to discuss any pain, discomforts and inconveniences the child may experience if he or she agrees to take part in the research. All of this cannot be done unless the Institutional Review Board or the Research Ethics Committee approves the research. The IRB will ensure the scientific validity of the study, the amount of risk and the prospect benefit to the community. The IRB will review the amount of information and the proper language used in assent forms according to the child's range of age and condition.<sup>57</sup>

### **6.1 Parental permission**

Any person who is unable to decide for himself is entrusted by law to the custody of adults. Children are under the custody of adults whether they are their parents or other guardians. Parent's authority is roughly limited to that which is required to discharge their responsibilities for familial well being.<sup>58</sup> Therefore the boundaries of parental authority and responsibility are marked by the ideas of abuse and neglect. It is a normative matter that the parents are obligated to provide the basic needs to their children and prohibited from harming them and subjecting them to significant risks that does not hold any expected compensating benefits to their children. As children grow to reach the legal age this responsibility gets off the parents shoulders as adolescents become responsible for them and have the right to make full decisions and consent.<sup>59</sup>

The parental permission implies to the agreement made by the child's parents or guardians in order for the child to be involved in a research, after that the child's assent can be taken. Parental permission for the participation of children in clinical research would only be considered valid if it was informed and voluntary just the same as informed consent.<sup>60</sup> Parental permission must have the same standards, as does the informed consent when adults participate in a research study. There must be a full disclosure of information in order for the parental permission to be voluntary and informed. The process should include a discussion of the purpose

of the study, the potential risks and benefits, and alternatives to research participation.<sup>61</sup>

The permission of one parent is not considered sufficient for research involving minimal risk and greater than minimal risk if the research does not have direct benefit to the child participant. It is a must that both parents' permission be present unless one is incompetent or alive. Another exception would be in one has full custody in case of a divorce.<sup>62</sup>

There were studies made to evaluate the parents' ability to provide valid informed permission for their children participation in studies that had no direct benefit. The studies made on the parents generally assessed their memory of the study from months to years after the time the child participated.<sup>63</sup> The studies have reported a therapeutic misconception, a therapeutic misestimation, or both. Such a result made it unclear if these problems suggest that an informed decision was not done when the permission was given or simply indicate the parents' limited ability to recall past events. Another model of parental permission study states that there are four criteria that must be met in order for the parents to give an informed decision. Those criteria were: parents were able to think clearly meaning they had mental clarity and were not overwhelmed with emotion or occupied by other thoughts, parents understood the information presented to them by the researchers, the investigators gave sufficient information to make an informed choice, and parents were told and understood that they had the right to withdraw from the study. Researchers ensured that the parents understand the elements of the permission form and it showed that the parents overall understanding of the elements of consent were high, but the evaluators' measurements showed that the understanding were significantly lower. This result might be explained by the possibility that a parent's perception of understanding at the time of taking the decision may be high, although the parent may be unable to remember the actualities on which that decision was based. It was also found in other studies that the parents

who allowed their children to participate had a better understanding than those who refused to have their children participate and did not consent.<sup>64</sup>

Many factors contributed to the parents understanding and comprehending of the study and consent elements. Those factors included both parent education levels, the age of the parent, having the child in previous study or their other children, the clarity of the disclosed information, the degree to which the parent read the consent document and whether the parent listened to the disclosure. The factor of having adequate time to decide about research was associated with willingness to enroll the child in research.<sup>65</sup> Other studies suggested that the poor recall might have been somewhat responsible for the results of previous studies. The rest of the studies had different factors that influenced parental decision-making about the children's research participation. Those factors were demographic characteristics, previous experience with a similar decision and concern about upsetting medical personnel, time pressure, and the amount of information provided.<sup>66</sup>

Most studies of parental permission have focused on the parents understanding to the informational elements of informed consent. Not many were concentrating on the parent's voluntariness on their children participation although such studies are important from both ethical and a legal view. Decision-Making Control Instrument defined voluntariness as control over the decision about whether to agree to a research or treatment protocol.<sup>67</sup> Some qualitative studies found out that parents of very sick children were having high levels of distress and that made discussions about research participation more difficult and many parents perceived an inadequate discussion of the research aspects of treatment they also perceived few alternatives to the treatment regimen or clinical trial procedures. In a setting where the child is very ill, the parents' voluntariness to have their child participate can be compromised.<sup>68</sup>

The Data collected with the DMCI instrument suggested that that lower perceived voluntariness was associated with less formal education, male gender, minority status, and not having previous experience with a similar decision. Parents who reported lower voluntariness were the ones who had more external influence and time pressure. They were worried that the child's care will be negatively affected if they refused to have their child participate in the research. They also perceived that they had either too much or not enough information about the decision. That is why the parental form must be made with care and reviewed by the IRB so it would achieve its purpose clearly. <sup>69</sup> Some studies suggested that there are parents who preferred to assume in treatment decision-making, but most parents preferred sharing the decision-making with medical personnel instead of being solely responsible or not responsible for the decision around their children's participation. Yet the relationship between decision-making autonomy and measures of understanding or voluntariness is not understood very well. Even the predictors of voluntariness in vulnerable groups needs to understood better and whether the medical staff or the other family members can influence that. <sup>70</sup>

It is recommended that parental permission be taken in advance when it can be more feasible. But the good timings are hard to predict in a research, medical setting, so there are concerns about the validity of permission during times of stress. It was suggested that a technique such as continuous permission. In this technique information are given to parents and pediatric participants at different stages in a trial. This might improve the quality of permission but initial information provided to a parent must satisfy all of the required elements for informed consent. <sup>71</sup>

For all the previous findings that makes parental permission a very hard process and not equaled to giving consent, researchers cannot have a full permission to include children in studies

unless they ask for their assent. Just as Consent is a continuing process, assent and parental permission are too. This means that if there were any changes in the research, the investigators must inform the parents and have new permissions and assent from the child.<sup>72</sup>

## **6.2 Child's assent**

After the controversy that was initiated by Ramsey about the morality of the participation of children in nontherapeutic research, the National Commission was developed. The National Commission acknowledges the need for research on children but it realized that children are a vulnerable group that needs to be protected. Hence the National Commission established very strict criteria for research on children.<sup>73</sup> First, the research must be scientifically sound and has significance. The study has to be conducted on animals, adult humans then on older children before including younger ones or infants. In addition, the risks must be minimized through the use of safe procedures that are consistent with the sound research design. Plus, adequate provisions must be made in collecting the assent and the parental permission and ensure the privacy of the parents and children. There are additional that the National Commission required that depends on the amount of risk included in the research and the risk and benefit ratio of the study compared to risk and benefit other alternatives.<sup>74</sup> The National Commission mandates the review of a local Institutional review board to make sure that all of these precautions are fulfilled.<sup>75</sup>

Assent is simply defined as the child's affirmative agreement to participate in a clinical investigation. There are several factors, which are specified by many regulations and should be taken into account when asking for an assent from a child. These factors are: assessing capacity, child's age, level of maturity, and the child's psychological state.<sup>76</sup> The old regulations that protects human subjects, did not postulate the informational elements that are required for assent. Therefore, the National Commission recommended four essential elements for obtaining

informed and voluntary assent in individuals with limited capacity including children. The assenting child in this context must have knowledge of procedures that are going to be performed on him. The child must be free in his choice whether to take part of the research and undergo the procedures or not through communicating his choice unambiguously. Finally the child must be aware of his right to withdraw from the research.<sup>77</sup>

There are disagreements about many essential components of assent, such as at which age investigators should seek assent from children; the quantity and quality of information to disclose to children and their families; how much and what information children understand and need; how to resolve the disagreements between children and their parents around their participation decision; who should and who shouldn't be involved in the assent process; the relationship between assent and consent; the necessity and methods for assessing both children's understanding of disclosed information and of the assent process itself; and what constitutes an applicable, practical, and realistically decision-making model. There are many studies that were conducted to examine the understanding of the children and adolescents when being part of a study and going through the assent process and its elements. Most of the studies demonstrated that children who are younger than seven years old generally could understand the concrete concepts such as the freedom to withdraw, the freedom to ask questions, and the potential benefits of the research. On the contrary, another study had the opposite result; it found out that there is low grade of understanding of most aspects of the studies in children who are less than nine years old. They couldn't comprehend the study goals, risks or the alternatives. One study showed that older children could understand more about the explained researches more than younger children. Another study reported that chronologic age was not related to the knowledge of the elements of informed consent. Every study has its own methodological limitations that

make the results difficult to interpret.<sup>78</sup> Recently, researchers tried to find more standard measurements determine children's understanding of research such as the MacArthur Competence Assessment Tool for Clinical Research for use in children. Some studies found it practicable and that the time required was acceptable when dealing with children. However in the MacCATCR there is no threshold for a competence score. For the complex judgment about a person's decision-making capacity, the threshold could be set based on its relevance to the research project and its risks. Children performed less well than their parents on this test. Other researchers performed a global assessment on children. It showed that all children are competent regardless their scores that were obtained by the MacCATCR. This suggested that children are capable of giving assent because they generally understand what the investigators tell them when going through the assent process. Even though the parents' views differ about the stage at which, and degree to which, children should be involved in decision making about their lives. Regardless, in medical research, it is mandatory to ask for the children's desire to be a part of a research specially when it does not offer them any direct benefit. It is has been proved that a joint decision-making which will open communication between parents and children can decrease the perceived risks of the research on the child.<sup>79</sup>

Assent can be seen in many ways according to the child's age and level of maturity. It can be understood to develop from a choice by young children who are dependent on the parent's decision, to a joint decision-making as children grow and mature, to a largely independent decision made by an older adolescent with their parental confirmation. Children's voluntariness to participate can be compromised because they might belief that failure to complete the study would displese the medical or research staff or even their parents.<sup>80</sup>

Assent can be waived if the child is judged incompetent and unqualified of providing it.

This waiver of assent requires appropriate parental authority and consent. On the contrary, if the research has no direct benefit to the child, the assent becomes a legal and ethical must.<sup>81</sup>

## **7. Conclusion**

There is a need to have research on children in order to protect them from potential harm that can be caused by medications and procedures that have been researched on adults and estimated to suit children. Research on children can advance the understanding of their own diseases and on how they develop and grow in different stages.<sup>82</sup> The outcomes can impact directly and indirectly on the lives of those researched and other children in similar situations and on even the whole society. In order to achieve such a honorable goal, children require extra attention with the protection from the risks of researches that does not provide direct benefits.<sup>83</sup> Researchers, IRBs and parents should always act in the best interest of the children in the research context. That can be done through the careful planning and carrying out of each stages of the research. Considering also ethical and legal issues, consenting process, power relation, dissemination process and methodology.<sup>84</sup> More importantly, respecting the children's autonomy through the assent process and their beneficence through the parental permission. Parents must be provided with detailed information concerning the nature and purpose of the research, the risks and benefits and any alternatives. Parents are the best to assume the preferences of their children when the risks of participation are low.<sup>85</sup> Children who are capable of assent must affirmatively agree to participate. The amount of information that a child must comprehend should vary with the age, development and maturity of the child in order to give an appropriate child assent or dissent.<sup>86</sup> In addition, adolescents have the capacity to understand important informational elements in a research study in a manner similar to adults. However, the age of considered as a proxy for the developmental point at which a child is deemed capable of assent may be lower (i.e., 5 to 7 years old) if assent is understood as the ability to express a simple



preference regarding research participation.<sup>87</sup> HIPAA has already dealt with issues related to research on children. Subpart D of the 45 CFR part 46 was dedicated to deal with children as human research subjects. These are considered additional requirements that research investigators must meet along with the other HIPAA and research regulations. Institutional review boards make sure that subparts A and D are met when research includes children.<sup>88</sup> Parental permission along with the assent or dissent process will qualify the notion of consent in adult research. Assent must be an interactive, instructional process that includes the investigator, the parents, and the child with the goal of assuring that the child has at least a simple understanding of the study purpose, the procedures that will directly involve the child, and the possible harms and benefits of his participation.<sup>89</sup>

## **B. Benefit Sharing:**

### **1. Introduction:**

Benefit sharing has been a known concept even before science and research existed. The principle of benefits sharing forms a major part of the Holy writings in many religions. However, this principle has not been followed properly through mankind's history. Whether it was on agriculture, seas, commons or even biotechnology. Many inequalities existed in the world and still do live today.<sup>90</sup> In the 1990s drug research became a global business. Clinical trials became international and outsourced. That means that it was held in both developed and developing countries. Clinical trials became suddenly expanded but without regulations and with a just few ethics experts to accommodate this huge expansion. This created many ethical problematic cases and new debates.<sup>91</sup> The globalization made research problems turn from being domestic to largely intercontinental requiring new global policies and approaches. That required internationally fitting solutions and the development of regulating principles that would work

global context for all.<sup>92</sup> Benefit sharing is one of the most important principles related to international research. In order to unify an understanding globally, the meaning of Benefit sharing has to be agreed on globally and discussed in relation to humankind heritage then reflected on research. From the biomedical research arena, many ethical issues appeared that had a relation with improper application of research benefit sharing. These issues included different inequalities and injustices in the application of research and the use of its results. The difference in power between the North and the South countries was another huge matter, where the difference was obvious in the using of the resulting biotechnology and scientific data. Conflicts of interests also appeared and were related to pharmaceutical companies in the context of benefit sharing. Therefore, the principle of benefit sharing is crucial in global research and can result in other benefits when applied properly. Such results would include international cooperation in terms of research solidarity and having equal access between all countries. It would also add to the human protection as it ensures the rights of the research participants and the future generations. That all would result in ethically conducted researches around the globe that is fair and benefits humanity.

## **2. Benefit sharing**

Benefit sharing has been a recurrent theme in several international debates, however the concept has never been defined adequately. By linking linguistic, legal and ethical considerations, this may provide a good understanding for the concept of benefit sharing to specifically understand research benefit sharing.

### **2.1 Definitions and sources**

In English ‘benefit’ is described as an advantage or a profit gained from something and ‘‘to share’’ means to give a portion of something to another. That makes the straightforward linguistic definition for benefit sharing as the action of giving a portion of advantages or profits

to others. The terms advantages and profits show that benefit sharing may indicate monetary and non-monetary benefits. In the legal arena, it is used in the setting of access to and utilization of biological resources. Benefit sharing is a technical term that implies to the access to and use of human and non-human genetic resources. The term describes an exchange between individuals who allow access to a particular resource and others who provide compensation or rewards for using it. The international legal definition states that benefit sharing is the action of giving a portion of the advantages or profits that are derived from the use of genetic resources or traditional knowledge to resource providers. This definition seems wide enough to comprehend human and non-human genetic resources. There were several national definitions for benefit sharing that were stated in the Convention on Biological Diversity. Czech Republic defined it as “Taking part on [sic] benefit(s) of any kind arising from utilization of genetic resources”, while Madagascar defined benefit sharing as: “the Monetary advantages sharing deriving or not from exploitation of these genetic resources between possessors country and users, but also at the level of possessor country in taking into account local communities and traditional knowledge”. The United Kingdom saw that the sharing of benefits arose from the use, whether it was commercial or not, of genetic resources, which can encompass both monetary and non-monetary returns. However, Costa Rica mentioned that benefit sharing was an obligation that must be accomplished in all actions related to access to genetic resources or to traditional knowledge. Such an obligation is derived from the Convention on Biological Diversity. Costa Rica continues: “The participation must be fair and equitable. To fulfill these essential requirements, before an authorization is granted, there must be access to information, sufficient time for the resource supplier to independently analyze the information received and definition of control mechanisms regarding the use that will be given to the elements being accessed”.<sup>93</sup>

## **2.2 The concept of benefit sharing in relation to humankind heritage**

When God formed the Earth, the soil, light, oceans, plants, stars, animals, and human beings; there was no clear message regarding the distribution of the earth among humankind. Religions came later on and directed humans around sharing and distributing the earthly benefits with each other. Invasion and war were there too and against all legal orders with international reach.<sup>94</sup> Humankind heritage is the notion of protecting the cultural heritage on a global scale.<sup>95</sup> After the Second World War the idea that the goods that are coming from artistic or cultural creation belong to all humankind took a juridical form. This was due to the robbing and destruction of cultural goods during the wars. Conventions and resolutions took place to ensure special protection of cultural goods in case other wars happened. They stated that the common heritage of humankind involved all cultures and countries. UNESCO assured the conservation and protection of the world's inheritance of books, art, history and science.<sup>96</sup>

One of the important conventions in history was the Convention on Biological Diversity. It was held in 1992 in Rio de Janeiro and was known as the Earth Summit. It provided a platform for discussing the continuing destruction that is happening to the global biodiversity. The CBD had an important realization, which was that the conservation of biodiversity was a common concern for all humankind. The Convention had three important objectives, which were: the conservation of biological diversity, the sustainable use of its components and the equitable fair sharing of benefits from the use of generic resources. The third objective was a summary of the demands that were made by the developing countries since 1970s. They required users of their resources to share the resulting benefits with the resources providers to prevent exploitation. This included traditional knowledge, plant, microorganisms and animals. Before adopting the results of the Convention on Biological Diversity; both traditional knowledge and non-human biological resources were used and regarded as common heritage of humankind. Bio-prospectors used to

use resources from their natural habitat or use traditional knowledge and develop commercial products but without sharing any of the resulting benefits with the local communities that provided these resources and knowledge. That was justified under the idea that the planet's biodiversity should to be shared by all humankind and not be restricted by a specific state. However, in 1970s and 1980s, the common heritage of humankind was defined internationally by the Agreement Governing the Activities of State on the Moon and Other Celestial Bodies and by the Convention on the Law of the Sea. Two conflicting interpretations resulted from the previous convention in 1982 and the agreement in 1979. The first interpretation stated that common human heritage must be used and enjoyed on the terms that it benefits all humans. The other interpretation stated that common heritage is accessible to use and exploitation at the basis of first come, first served. This became a serious worldwide justice issue.<sup>97</sup> There are mainly two types of benefit sharing that can be recognized. The first type is mentioned clearly in the UNESCO 's Universal Declaration on Bioethics and Human Rights. This type emphasizes that all human beings have an equal right to access and share the benefits of science. This is a human right however it is not being applied in real life because of the actions of the affluent states. The Declaration states "Benefit resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular within developing countries". The other type of benefit sharing aims to reward who contribute to the scientific knowledge whether it was by providing plants, traditional knowledge or by simply being a part of a medical study. This type is clearly mentioned in the Declaration of Helsinki and the Convention on Biological Diversity. It tends to avoid the obvious exploitation that takes place in many developing countries and on vulnerable groups. Both types of benefit sharing are hard to apply in the real world and the two seem to come in conflict with each other. Between the

compensation right and the human rights having an open access and an open source movement may violate the compensation right and some other rights. Moreover, the application of patents can provide a good chance for compliance however it hinders the human right protection. In addition, patents can deliver financial means to comply with compensation but again this would hinder the protection of human rights. Finally, there must be an international organization that would facilitate benefit sharing and ensure it as a human right.<sup>98</sup>

### **2.3 Forms of Application in research**

Benefit sharing can be understood as an end result of research that was properly conducted. Whether this was a non-human research or a research involving humans, in a wealthy or a poor country, on an international or on a domestic level; scientific research and its application should be shared with the entire society and the international community as a whole. Sharing benefits from scientific research can be applied in many different forms such as giving special assistance to the individuals and the groups who have been a part in the research. Providing new diagnostics and facilities for new treatments also can accomplish that. Making drugs that stem from research available is another way to share benefits from scientific research. Furthermore, benefit sharing is achieved through the sharing of the scientific and technological knowledge that were the result of research.<sup>99</sup>

The Universal Declaration on Bioethics and Human Rights stated in 2005 the following: *“Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.”* According to that benefit sharing can take any of these forms such as giving special and sustainable assistance to the participating individuals and groups that have taken part in the research. This would include having access to quality healthcare and having the advantages of

the new diagnostic and therapeutic products or procedures that are stemming from the research. This could also be achieved through providing support to the health services in the participating countries and by giving them access to related technological and scientific knowledge. These are few modes of research benefit sharing that can be accomplished. However, it is important to make sure that the benefits do not constitute improper inducements to the research participants.

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However, moral issues keep arising in regards to equity, fairness and benefit sharing. Benefit sharing is not only consistent to the notions of property; it improves resource distribution in the entire world and therefore contributes and enhances global justice.<sup>101</sup>

### **3. The ethical problems related to global research**

The world faces many bioethical issues that include the traditional known issues such as abortion and transplantation; these are seen as related to developed countries. However the developing countries face concerns such as research and exploitation. The new bioethical problems are such as pandemics, international clinical trials, bioterrorism and climate change. Global bioethics is known with its own new issues that clearly affect everyone in the world. Research and benefit sharing are part of the global bioethics.<sup>102</sup>

There are general and specific issues involved. Two general ones, and a specific one will be discussed in regards to ethical issues that are related to global research.

#### **3.1 Inequalities and injustices**

It is well recognized that research has become more globalized. In most cases, researchers lead clinical trials from high-income countries but the research itself is conducted in many low and middle-income countries. This raises issues concerning global justice, which includes fair benefits to the participants and the communities that contribute to the research. Global research justice includes proper consenting, ensuring a local ethical review, having proper

education, reasonable inducements and protecting the vulnerable groups.<sup>103</sup> The unethical conduct of research whether it was for using improper inducements, lack of appropriate consent or enough education around the dimensions of the study can be a factor that prevents benefit sharing.<sup>104</sup>

### **3.1.1 At the beginning of the research**

In order to be fair to the low and middle-income communities; research protocols must be locally reviewed by their ethics committees. Approvals must be secured before the beginning of the research. This means a substantial amount of pre-departure preparation. The researcher is responsible to know all the regulations and laws in those countries. This raises the importance of having a strongly built ethics review boards in these countries where researches are frequently performed. It is also ethically important to respect these communities and their cultures by engaging them in the research. This means to create a dialogue between the communities and the researchers in order to understand their beliefs, traditions, customs and cultural sensitivity. This is crucial in order to insure beneficence and avoid harm. Therefore, Tindana et al. have identified several goals for community engagement such as to avoid exploitation through ensuing fair distribution of the research benefits.<sup>105</sup>

All types of research require obtaining a free informed consent before engaging in any interventions related to it. The consent should have adequate information and is based on adequate information. The consent maybe withdrawn by the participant at any point without any prejudice or disadvantages. Consent is a manifestation of respect to the individual's autonomy and self-determination. Through informed consent bioethics can ensure proper education and proper inducements provided to research participants on a local or an international level.<sup>106</sup>

Consent must be adapted properly to the targeted community in each country. This means to have a precise translation of the consent besides understanding the culture and the norms of



the country from the researcher's side. Out of fairness, investigators must understand and keep in mind that there are high rates of illiteracy among those groups; therefore, comprehension must be properly ensured. Many indigenous communities were used for research without their explicit consent to take and analyze their blood or tissue samples. They also did not benefit anything from the research. This has extended to the level where researchers did not care about the indigenous people's culture, beliefs about creation or even connection to the land. This has led to several fights where communities tried to return their samples. Some refer to this as stealing cultural property and artifacts. Furthermore, this has led to the development of some indigenous organizations, groups of academics and funding agencies that have published ethical guidelines to guide research on indigenous communities.<sup>107</sup>

Another major ethical problem that can face researchers in developing countries is the family hierarchy. This must be understood and respected as part of the country's culture. However, each participant can be asked in private regarding his or her willingness to participate or not in the research. This issue leads to community consent. Some communities provide assents where only their leaders would consent on behalf of the entire community.<sup>108</sup> Finally, researchers must be careful when providing incentives in these low and middle-income countries. They need to avoid direct cash payments unless it was justified for lost working hours or travel expenses.<sup>109</sup> All for this must be ensured in order to maintain justice and fairness to the research participants while preventing exploitation to these vulnerable groups.

### **3.1.2 After the conduction of the research**

A very important element of the community engagement is the provision of the results of the conducted research in the participating countries. This result from the idea of social justice, therefore the knowledge should be utilized for the benefit of the participants and the country. Ethically, the research contribution is not seen to be over until the results are being shared with

all relevant stakeholders.<sup>110</sup> Usually researchers share results with their peers and professional colleagues through conferences and peer-reviewed publications, however communities that shared in the research are less thought about especially if they are far from the researcher's place. Therefore it has been argued that the researcher has an ethical obligation to share the results with the individuals who participated in the study. Such an action is seen as a collaborative partnership. Studied communities are entitled to benefit sharing and sharing the results of the study is the least amount of benefit sharing that the researcher can provide them with.<sup>111</sup>

Research especially international ones should always be transparent and fair specially when dealing with poor and developing countries. This would unify the international standards in research. Eventually this will ensure fair benefit sharing with other countries and globally. This can take place through an international adoption to the UNESCO declaration principles that are related to research. Those principles are concerned with obtaining consent, reducing harm and maximizing benefits to protect participants and ensure equity.<sup>112 113</sup>

### **3.2 Differences in power balance**

Very important parts of the scientific research are both the information related to it and the possible biotechnological application. Exchanging of information is very important and can be facilitated by the use of technology and communication. The wealthy countries are mainly the only ones benefited from these two results. It is important for all countries to have access to both the scientific knowledge and the biotechnology.

#### **3.2.1 Biotechnological gap between developing and developed countries**

There is an obvious biotechnological gap between developing countries and wealthy countries in the human and biotechnological research fields. This is mainly reasoned for not sharing benefits of research between countries. Having access to the resulting technology can

help reduce this gap. In addition, this can be done through building equipped research centers in the developing countries and having the locals trained there to start researches of their own.<sup>114</sup>

Solidarity and cooperation is important on the global level. It forms one part of the conceptual framework of principles that the UNESCO Declaration suggested to help countries form their policies and regulations in bioethics. This would enable proper research conduct that will lead to sufficient benefit sharing internationally and among the globe. Ultimately, solidarity and cooperation can become a reality on the individual level. Achieving solidarity and cooperation depends on international cooperation and the authority of the international community. This is useful but insufficient to share benefits out of research to have a common humankind heritage. Other principles have to be taken into consideration.<sup>115116</sup>

### **3.2.2 Data sharing issue among countries**

Many international organizations like WHO, UNDP, UNFPA and the World bank have provided data that show that there are many inequalities among the world countries. Taking that from the research point of view; inequalities appear clear between wealthy countries and poor countries where the researches are being conducted. There are some known prerequisites for having successful research as having optimal education and training, modern instrumental facilities, sufficient financial means and opportunities for international communication. Apparently, these prerequisites are going to be available to many wealthy countries but not for the poor developing ones. Benefit sharing can only be conducted if there was a national and regional form of sharing which enables other countries to act as partners in research creating an international collaboration. Such collaboration has been done several times on the international level. This can be seen in the international collaboration on the gene map to identify the genetic and environmental factors that are responsible for many known disorders such as cardiovascular diseases, cancer and diabetes. Pharmaceutical companies await these discoveries to create

medications using the genetic information. Therefore, it would be fruitful to investigate the DNA sequences in isolated populations however this has been conducted unethically several times. It is obvious that these countries do not have any organization of bioethics committees or any regulations to ensure that human rights and the principles of the UNESCO Declaration are being followed. Benefit sharing can be addressed by collaborating with experts from other countries that already have the appropriate substructure and set-up for bioethical trial.<sup>117</sup>

Indigenous communities in Canada are a good example for implementing the right to data that resulted from research on that community. It is known as “ownership, control, access and possession of data”. The word ownership refers to the collective proprietary relationship that exists between the indigenous people and their traditional knowledge, information and data. The word control is important because it asserts that indigenous people maintain control and authority over the research that includes the hypothesis, the concept of the study, the development and the approval on the study design, data collection, data analysis, the management of the data and the writing of the final report and its distribution. The word access refers to the right of the indigenous people to manage and decide who can study them, their data and their knowledge. Finally, the word possession indicates that the indigenous communities have ongoing data retention. This ethical imperative is valid in order to support the right of the researched communities to determine their own knowledge processes.<sup>118</sup>

Conventions state many shared principles such as benefit sharing however they do not any form of protection. This depends on the legislation that enable an international coherent access to benefit sharing as a regimen.<sup>119</sup>

### **3.3 Conflicting interests**

It is important to understand what is mean of conflict of interest that is related to research benefit sharing. It is a set of circumstances that creates a risk that professional judgment or

actions regarding a primary interest that will be unduly influenced by a secondary interest.<sup>120</sup>

### **3.3.1 Pharmaceutical companies and human welfare**

Long time ago Pharmaceutical started what is known as biodiversity prospecting or bio-prospecting. Bio-prospecting indicates to the process of looking for potentially valuable genetic resources and biochemical compounds in nature for the make of medications. Usually these genetic resources were collected from indigenous community lands without sharing any benefits with them. Therefore, that issue raised a serious concern such as how the benefits should be shared from these commercialization activities. Other concerns included the prospective impact that is held by the growing use of these natural products in the drug industry on sustainable use and conservation of genetic resources that are as commons. Finally, there were concerns about the consequences of this industrial activity on capacity building in developing countries.<sup>121</sup>

Mainly the benefits of collaboration with industry are obvious in biomedical research. New medications and medical devices that resulted from research have significantly improved the health outcomes for many people around the globe. This success resulted through long complex processes of research. It translated basic science discoveries into many products and services that are preventive, diagnostic, or therapeutic. These discoveries come from laboratories from the developed countries and only some come from developing ones. However, studies were and still being largely conducted in the developing poor countries. The issue that faces those countries is that their communities cannot benefit from these products, as they are expensive to afford.<sup>122</sup> Shockingly it is estimated that it takes more than fifteen years and it costs more than eight hundred million to discover and develop a new drug. However, the FDA for marketing approves only about ten percent of the drugs that are clinical tested. This makes it almost impossible for the poor researched communities to benefit from the research results.<sup>123</sup>

In order to apply the principle of benefit sharing properly in research; resource users must

return benefits to resource providers so justice is applied too. The duty of post-study obligation was found to be one of the most effective tools tool within health research is the duty to provide a health care intervention which has been proven to be beneficial (or alternative benefits) to research participants after a study has been concluded. This duty can be found to be mentioned in the Declaration of Helsinki in 2000 and re-emphasized in 2008 however there are only few good practices that follows it.<sup>124</sup> This is extremely important in order to consider the benefits that can be shared by the pharmaceutical companies that are involved in these researches. It is also important to guarantee the welfare of the participating individuals and communities with no conflict of interest resulting from the pharmaceutical companies that are researching them.

### **3.3.2 Pharmaceutical companies' profit**

The public benefit comes from the constructive collaboration between academic medicine and pharmaceutical, medical device, and biotechnology companies. However, many medical leaders, public officials, public interest groups, and others have expressed their concerns about the risks that result from the extensive financial which are bonding industry with the individuals and institutions that carry out medical research, medical education, patient care, and practice guideline development. It is clear that financial interests may influence the professional judgments of the parties involved. The biggest concern is that these financial interests might threaten the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine, which will then lead to the conflict of interest.<sup>125</sup>

Having this increasingly continuous growth in the pharmaceutical companies and their investment in biomedical research too has affected the distributive principles of the business-world within genetic research. From a justice point of view there is a conflict between health care and business in terms of their distributive principles. The spheres of health care and business

overlap in this context; therefore, principles of need and reward create conflicts with both sides utilizing the arguments of justice for their own cause.<sup>126</sup>

#### **4. Expected benefits resulting from the application of the concept of benefit sharing in research**

Sharing the research benefits seems to have many other good benefits beside itself. This includes international cooperation, which can be achieved in many ways. It would also include a high level of protection to the research participants and the next coming generations who will inherit these shared benefits in an equal justified way. Having that will lead to fairness, justice and beneficence among all people in this generation and coming generations.

#### **4.1 International collaboration**

##### **4.1.1 Equal access to scientific knowledge**

After discovering the Gene map, humans were able to read life, then they learned how to write life by isolating and creating genes, and now they can correct life by repairing the gene errors. All of this has been discovered through excessive scientific research work. This has been monitored closely and governed by ethics and principles in order to achieve the wanted benefits.<sup>127</sup> Every human society has always been concerned with ethical principles and morals that can help guide its individuals and assist in regulating their lives. The world is transforming in a fast pace to an uncertain future therefore each society is adapting its own morals and principles to stabilize itself in that future. Those societies believe that ethics is important for humanity. The future is going to be faced with more research that leads to more astonishing scientific knowledge and facts. The international community needs to adopt the same ethical and professional codes of conduct in order to govern the relations between scientists and others in a global context.<sup>128</sup> Every country can share these benefits that come from research and its results and enjoy at least a minimal level of prosperity. However, there are various barriers that prevent that sharing. By adopting the Universal Declaration on Bioethics and Human Rights, there is a

great chance to have its principles unifying the principles everywhere in the world. Such a thing would lead to international cooperation on many levels in life including research benefit sharing. All countries must foster the dissemination of the available scientific information that comes from medical and scientific research. This would help in sharing such valuable information with other countries especially the developing ones. This is one dimension of the international cooperation framework where developing countries can build their capacity to participate and be a part in the new generated scientific knowledge. It would promote solidarity between countries with special respect to vulnerable groups, environment and countries with limited resources.<sup>129</sup>

Research benefits are seen mainly as having access to the resulting scientific knowledge. The target is to help developing countries have that access along with the developed countries. This would give the developing countries the chance to achieve, discover and share later on with other countries its research so they won't be dependent on patents. This would also prevent exploitation to the individuals to those countries because collaboration would develop partnership between the countries. The Declaration can provide a universal framework that serves this purpose and that foster the important ethical principles that are related to research collectively. International cooperation in research ethics should be regarded as an investment in human beings and not only as harvest of benefits that comes from research discoveries.<sup>130</sup>

Sharing research results can be ensured through several steps such as including the data-share plan in the protocol and have it approved by the sponsors before starting the research. The data-share plane should clarify who, when and how the results are going to be shared. In addition, the consent should state that the results are going to be shared with whom, whether it was the individuals themselves, the leaders or the health officials. By accepting the last two; participants waive their rights to know the results. This demands the researcher to collect contact



information from the leaders of the community, the local health authorities that are related to the field of the study and the participants too. This also demands a level of confidentiality of this information. Sharing the results should be done in the most appropriate way that suits the culture of the participating county. Moreover, having local co-investigators is preferred as they can easily share results with the community in a better way than the principle investigator. <sup>131</sup>

According to the very nature of the scientific knowledge, which is seen as an accomplishment for the entire human race, therefore it is a common property for all mankind. In other words, all nations must share their scientific knowledge that is a universal public good in order to achieve international collaboration. <sup>132</sup>

#### **4.1.2 Solidarity**

Solidarity has always been related to co-operation. It is considered the center of all benefits related to research benefit sharing. It is also related to the fundamental freedom of individuals. In the research context it is related to international cooperation, which is subordinate to solidarity. International cooperation is known as the province of liberty in history. However solidarity among human beings is mainly the domain of human being as social beings in the world and in living nature. This means that there are two levels of solidarity; the first is the freedom of actions within countries and the other is understood as cooperation between countries. Freedom is explained by the UNESCO Declaration as the freedom personified in an existing individual who is displayed in its singularity but also complimentary with other's freedom. This happens in cooperation and under the supreme law of the nation and its social framework. Moreover, the freedom that is controlled, mindful and conscious becomes cooperation in between nations. This generates sacred relationships between individuals and unites other free stakeholders who are the concrete human beings. In regards to research, the

UNESCO Declaration states that “Any decision or practice shall pay due regard to the solidarity of human beings and encourage international co-operation to that end”. This implies to international and transnational research aims to satisfy the needs of the research hosting countries especially developing countries. This would encourage international and transnational research to contribute towards solving the global health problems.<sup>133</sup>

Solidarity in research, which is seen as participation in research for the common good, will lead to trust of the participants and the participating countries in researchers as they have confidence that their rights and benefits are cared for. This will only be achieved when the ethical conducting the research. The final result would be fruitful to everyone especially when results and other benefits are shared.<sup>134</sup>

## **4.2 Human protection**

### **4.2.1 The protection of research participants rights**

The UNESCO Declaration states that: “*in applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be protected and the personal integrity of such individuals respected*”<sup>135</sup> The most common used meaning for vulnerability is used in bioethics, it stems from the Belmont report: *ethical principles and guidelines for protection of human subjects of research*. It can also be found in Declaration of Helsinki: *The ethical principles for medical research involving human subjects*. The notion of vulnerability has always been used in the field of research and human experimentation. This notion is linked directly to the principle of autonomy that is presented in the form of informed consent.<sup>136</sup> Benefits that come from research that are supposed to be shared are not possibly or properly shared unless the human’s vulnerability is protected. This would ensure the ethical conduct of research whether it was human experimentation or biomedical research. Protection

should include exercising autonomy through consent, preventing exploitation and avoiding undue compensation.<sup>137</sup>

Vulnerability becomes a complex issue in the era of globalization as clinical trials expand internationally to include developing and emerging countries. Vulnerable individuals and groups must properly protect and bioethics needs to ensure that they and their countries do benefit too for those clinical trials.<sup>138</sup> The protection of research participant's rights can be achieved through providing new treatments stemming from research to the participating communities. However, there is a need to ensure that these treatments are affordable to these communities' individuals.<sup>139</sup> Protection could be sought by providing assistance to the countries' communities. Assistance can come in the form of building healthcare facilities or training the local professionals properly. It can also mean providing social amenities. All of this would result in the community mobilization towards positive social and health changes. These are important factors that would ensure the research benefits are shared with all research participants and the future generations having that these benefits are a heritage of humankind.<sup>140</sup>

#### **4.2.2 Protection of next generations**

The Universal Declaration on Bioethics and Human Rights states: “ the impact of life sciences on future generations, including on their genetic constitution, should be given due regard” it also included “ the aims of this Declaration are: to safeguard and promote the interests of the present future generations” Protecting future generation includes the protection of research participants' rights by Promoting ethical research, providing new treatments stemming from research and assistance to the research participants. It also includes the free distribution of the scientific knowledge that resulted from the research. This will ensure that these benefits will be all inherited fairly to the next generations. The Declaration believes that all bioethical issues should be considered for all generations and not only the present one. It also shows that there is

responsibility on the present generation towards the future generations. This underlines the relationship between all humankind, life on earth and environment. Protecting the future generations is a form of international justice that protects the entire humanity. Humanity is not the only the current living international community; it includes also the chain of coming generations. Sharing the benefits of research and the resulting scientific knowledge between the international communities gives a bigger chance that this data would be inherited fairly to the future generations. It can also contribute to the improvement of their lives, as it would improve this generation's lives. Nevertheless, science has two sides; it can also result in undesired outcomes that can affect the future generations later. This can happen while manipulating genes that would only result in undesirable outcomes in the future descendants. Therefore, the bioethical decision should not only take into account the effect on the present generation. This becomes crucial in the field of genomic science and stem cell research. This calls for having people other than scientists and doctors to be involved in the decision-making regarding these studies. That is why research ethics committees always include laypersons and social scientist too. However, such decisions on these types of research should be taken on international levels to ensure the protection of the future generations and maintain international cooperation. The UNESCO Declaration will help as it can form a universal framework.<sup>141</sup>

### **4.3 Ethical conduction of research**

Conducting ethically sound research is the best way to ensure benefit sharing of that research. This can be achieved under the principles of justice and beneficence. In views of research, the principle justice holds that particular individuals, groups or communities should neither tolerate any unfair share of the direct burdens when participating in a research. Moreover, they should not be unfairly excluded from the potential benefits of research participation. This

indicates that excluding and over protecting some vulnerable groups is unethical as it is unfair. And would result in groups with no tested medications on their condition or age group.<sup>142</sup>

Researchers should consider fair inclusiveness method beside fair distribution of both benefits and burdens on research participants. This is also the duty of the research ethics committees, the sponsors and the research institutions. It is true that some research ethics committee's positions and some researchers and the research institutions practices can lead to over-protectionist attitudes. These attitudes are seen as unethical whether it was intentional or inadvertent because it can exclude some members of society from participating in research. Eventually this would constitute a failure to treat some individuals, groups or communities in a fair just way due to the exclusion. Therefore, the application of the principle of benefit sharing results in fair ethical research conduction where all appropriate age groups or communities are included in the research in order to ensures that treatments frequently given to these populations are effective and safe. For example, sufficient research has to be done on groups that fall outside of narrow age criteria, this means inclusion of the young and the elderly in research.<sup>143</sup>

Whenever research institution and researchers fail this obligation, it becomes the research ethics committees mission to ensuring a fair distribution of the benefits and burdens of research and maintains the ethical standards on the research conduction. They must circumnavigate between the dangers of imposing unfair burdens on particular participants, groups and communities while preventing overprotecting them. However, it should be noted that research ethics committees should not intervene in the choice of research topics.<sup>144</sup>

#### **4.3.1 Fairness and justice**

Fairness and various justice-related concepts in research benefit sharing are extremely difficult to agree on. This can be due to the complex nature of genetic information that could

hinder the successful application of this concept in benefit sharing.<sup>145</sup>

Giving fair opportunities to research participants is important especially when dealing with vulnerable groups who are at the risk of exploitation. Focusing on recruiting the economically disadvantaged communities seems like a recurrent theme in many pharmaceutical trials. Economically disadvantaged individuals are persons who lack the significant access to healthcare, or who are malnourished, or improvised, maybe homeless but however do possess the mental capacity to decide and volunteer in research studies. This means they are competent and have the ability to reason, consider, decide and consent. It is reported that between fifty percent to a hundred percent of research participants are healthy subjects who participate for the financial reward that are provided in the research.<sup>146</sup> All researchers must keep in mind how to maintain equitable distribution of any benefits and what forms of benefit sharing is appropriate for the research participants. Research benefits can be direct such as improving the health condition of the participant or as learning new information about social issues as a result of participation in a research focus group. The direct benefit to the community can be achieved through training the local personnel, sharing the information that resulted from the research with the appropriate departments in the country, or by establishing centers that can provide the same services.<sup>147</sup> On the other hand, benefits can come in an indirect form such as contributing to the advancement of knowledge that eventually would lead to the improvement to the conditions of the community that that individual belongs to. These benefits must be shared out of fairness and justice to the participating communities and their individuals.<sup>148</sup>

Furthermore, researchers should give attention to the expectations, need and opinions of the participants regarding the potential research benefits before starting the research. These benefits must be discussed and outlined. It is the research ethics committee's attentive job to

ensure that the proposed distribution of benefits is fair, without imposing undue burdens on the researcher that would make it too difficult or costly to complete research. It is the researchers' duty to ensure that the participating individuals, groups and communities are informed of how to access the results of the research. The results must be available in a meaningful format. This can include plain language reports and technical ones. It can be provided through copies of publications, or other research reports or products, arising from the research to the institution. This might be the best method in some communities such as developing countries while it can be available electronically in other developed countries.<sup>149</sup>

In the past, incentives and research rewards were banned and outlawed. This was done in order to ensure that no coercion or pressure was put on the volunteers. Presently, compensation for fairness as a moral argument seems to be the strongest basis for benefit sharing and thus according to different international documents.<sup>150</sup> Compensation results out of fairness and includes several international and social justice concerns. The justification for benefit sharing comes out of morality that is based on justice and solidarity. This means that those who have the power and are able to act in alleviating suffering of others, have the moral obligation of doing so. Therefore, all communities in a global sense do accept ethical research to help humanity.<sup>151</sup> Moral duties appear in numerous international documents through history such as the Duty not to exploit the vulnerable that appears in the Nuffield Council. This duty refers to responsibility to refrain from taking advantage of the unequal circumstances of power, resources and opportunities in this world. This is negative duty to abstain from a specific action. There is also the duty to alleviate other's suffering which is also included in the Nuffield Council. This duty designates the requirement of providing benefits to others who are in need by those who have the power to act. Therefore, it is a positive requirement.<sup>152</sup> HUGO ethics committee mentioned in its

statement about benefit sharing that health is considered a fundamental value for humans, it is a base upon which much else in life can be built. This is what is referred to as the moral obligation of medical enterprises.<sup>153</sup> This means that companies which are involved in healthcare have a special moral obligations towards human being in compare to companies which have no medical relation. This suggests that benefits are allocated and based according to the needs.<sup>154</sup>

#### **4.3.2 Beneficence**

There are four concepts that were identified through the concept of beneficence; first the researcher must not do evil or harm. Secondly, he must prevent evil or harm. Thirdly, he must remove evil or harm and finally the researcher must practice good. All of this can be achieved through ethically conducted research.<sup>155</sup> The Belmont report states that research participants are treated ethically not only by respecting their decisions and protecting them from harm but also through making the effort to secure their wellbeing. Ensuring the research participants' wellbeing falls under the principle of beneficence. This can be accomplished by forcing the researchers to design research protocols that maximize the probability and magnitude of benefits to individual research subjects as well as to society while minimizing the probability of harm to the research participants.<sup>156</sup> Benefits can be discussed during the process of informed consent. Benefits can be collective or individual depending on the type of research. Some see this as part of the Fundamental ethical principles, beneficence that is to do good, and non-maleficence that is to do no harm. However, others argue that in a research context beneficence must be viewed as a single principle, because it is necessary to consider harms and benefits in relation to each other. The fair benefit framework was held in Malawi in 2001. It is the best-detailed framework that can work as an alternative to the reasonable availability requirement. It includes two fundamental assumptions. The first states that the key to avoiding exploitation is to make sure that the participants who undergo the research with its burdens and risks do receive



benefits throughout the conduction of the research and/or from the results of the research. The second states that all kinds of benefits that flow the conduction of the research must be considered in determining the fair benefits and this does not include the use of the tested drug. This framework is appropriate for ensuring the beneficence for the research participants as it adds to the risk-benefit ratio of the study. In addition, it adds three principles to make sure that the subjects receive a fair share of the research benefits. The first principle is having fair benefits, which can be tangible benefits to the participant or the community or both. It is important to note that as the burdens increase, the benefits must increase to achieve beneficence. The second principle is the collaborative partnership that ensures that the population having a free and un-coerced decision-making. This would result in the population support to the study when they understand the burdens and the benefits of the study on them, they can decide properly. Finally, it results in transparency as equity is determined by the comparison of similar interactions, which makes fairness relative especially in a developing country that is being studied by a researcher from a developed country. Therefore, there should be an independent body that would do a comparative assessment of fairness of the benefits agreements.<sup>157</sup>

## **5. Conclusion:**

Benefit sharing can be applied to do domestic and international research through following the international guidelines and principles. This could also be achieved through the ethical research conduct. The global community has first to agree on a definition for benefit sharing and update the understanding of what is considered as common humankind heritages. Eventually, this would diminish the ethical issues that are faced in the biomedical research arena.<sup>158</sup> All research participants and all participating countries would be treated fairly and equally. Sharing the resulting research benefits between the Northern countries and the Southern countries would result in shrinking the biotechnological gap between them. It would also lead to

scientific data sharing which will benefit the global community.<sup>159</sup> All that will lessen the existing power difference between countries and cause a balance in their strengths. On the other hand, pharmaceutical companies will be forced into caring about the welfare of the participants and into considering a fair research with no financial conflict of interest. That being done would result in the application of other principles that the UNESCO and many other organizations are trying to introduce and apply to be followed globally. International cooperation is one of the ultimate global principles that would produce in solidarity.<sup>160</sup> More specific principle related to research is human protection and would accomplish the protection of the international research participants' rights. Through benefit sharing that principle would lead to the protection of the next generations rights to have the results of fair ethical research inherited and applied. Finally, the application of benefit sharing will force the world into the ethical research conduction. This is the ideal situation when applying the principle of benefit sharing, however it is not happening due to difficulty of application as many claim that there's no consensus about what is considered a fair agreement.<sup>161</sup> Federal regulations that protect research participants' health information has already mentioned data benefit sharing.<sup>162</sup> Healthcare organizations are commanded to de-identify all their patients' records before any data sharing occurs. Hence, many health organizations trust using the Safe Harbor Standard of the HIPAA Rule.<sup>163</sup>

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## **Chapter 5 Genomic Medicine**

### **A. Privacy & PGD for Savior Siblings**

#### **1. Introduction**

Is it ethical to use Pre-implantation Genetic Diagnosis to create babies to save others? The argument is developed through discussing Pre-implantation Genetic Diagnosis and the possible Recipients to the savior child. It is also argued through the normative debate whether a savior child is ethical. It is also discussed through the normative debate over how to use the savior child after its birth. Finally, it is examined through the normative ethical criterion to justify Pre-implantation Genetic Diagnosis for choosing a savior child through the Principles of Double Effect. Pre-implantation tissue typing has been projected as a method for choosing a tissue match child that can help in being a haematopoietic stem cell donor. Mainly this is done to save the donor's sick sibling who is in need for the stem cell transplant. Notwithstanding the promising results of these biotechnologies, many have expressed their opposition to this method by arguing its related problems. In addition, the subject of related recipients other than a sick sibling is discussed as well as the possibility of banking the extra embryos. Subsequently, through the application of the moral principles the harms, the benefits, the conflict of interest and the rights of the savior child are explained. Consequently, the limits that should be placed on what may be done to the savior child in regard to donating its tissue. Finally, the Principle of Double Effect is used to weigh the matter of savior children in the views of the Church teaching. Nevertheless, these concerns do not establish a sufficient ground to forbid parents to use this technique to save not only a sibling, but also other loved one's. PGD and HLA tissue typing is a practice that has the ability of creating a healthy new life besides saving another life. It has proven to be successfully practiced.<sup>1</sup>



## **2. PGD & Recipients**

Pre-implantation genetics diagnosis has been used to detect the presence of genetic disorders. Nowadays PGD is used for many other purposes and needs, which are mostly found to be ethically problematic and calls for a clear ethical discussion. The ongoing debates use different principles to show whether the use of PGD for such purposes is ethical or not. Moreover, the many uses for PGD as a selective reproduction method depends on the parents need to access the services that use such technologies. Each need has several arguments around it, some of which are argued to be ethical and permissible while others remain rejected and perceived as unethical. The needs for PGD can range from selecting a healthy child as an end or as a mean to save a sibling and all the way to choosing a child with a specific genetic combination then enhancing it to be genetically modified.<sup>2</sup>

### **2.1 Uses of PGD & HLA typing**

Physicians have been using Pre-implantation genetic diagnosis as a method to help families have a child who is a tissue match for an existing sick sibling. To achieve that, they use the allogeneic haematopoietic stem cell (HSC) transplantation. The haematopoietic stem cells are found in the bone marrow, umbilical cord blood and in the peripheral blood. It is known that the success of the donation is determined by; how well the human leukocyte antigen (HLA) of the donor and recipient match. Therefore, the transplant from an HLA identical sibling is associated with a greater level of success than the transplantation from other donors.<sup>3</sup>

The main advantage for using Pre-implantation genetic diagnosis for HLA testing is to find the tissue match child that can donate and save its sick sibling or family member. Most importantly, using PGD provides the needed genetic information about the embryos to make sure that these embryos are the required tissue match. These can then be transferred to the mother's womb. Additionally, this prevents other ethical issues that used to exist such as expanding the

family or terminating the pregnancy if the fetus was not the right HLA type. When this process fails, parents tend to go through it again to save their existing sick child. There are many types of burdens in the means of physical, psychological, financial and most importantly the health status of the sick child.

## **2.2 Problems associated with PGD**

For many years, humans thought that some diseases are inherited and cannot be avoided. However, now there is a possibility to prevent those diseases from running in families. This is done using the advanced assisted reproductive technologies that science has provided. Various ethical issues arise on many levels when dealing with these birth technologies. One of the most important issues is tampering with genes and the creation process and playing god. Such interventions can change the human nature. The extreme concern is whether such efforts extend beyond what humans are permitted to do.<sup>4</sup> Therefore, an objection has been raised by some religious institutions towards IVF and PGD. They both involve offensive manipulation of human life, which is created in the image of God and demands full respect and protection from the first moment of conception.<sup>5</sup> This objection is not founded on a modern bioethical assessment but actually is based on religious convictions. Religions and faiths have significance to bioethics; they are served by the principle of respect for persons. Consequently, people should not be compelled nor deceived to act against their beliefs. Correspondingly, people who oppose the use of IVF, PGD or similar practices and find it offensive to their religious beliefs should be permitted the right of conscientious objection. For example, physicians should refer their patients to other non-objecting practitioners as an ethical duty if they have ethical or religious objections to these procedures.<sup>6</sup>

There is another ethical concern regarding the unwanted embryos that are discarded. PGD is designed to choose healthy embryos with a specific genetic combination that makes them the exact wanted HLA type as the sick living sibling. However, the historical moral principle of “do no harm” is not offended since the harm is not inflicted on patients but rather on tissues. Some scholars reject this argument since they believe that an embryo has rights that should be respected from the moment of conception.<sup>7</sup> Nevertheless, the argument remains strong, as the main purpose of the procedure is to prevent harm. Proponents tend to involve the duty to maximum benefit. It is suggested that parents consider the beneficial alternatives to discarding their extra healthy embryos. Therefore, a practitioner should have this as an option for parents and make sure they give appropriate informed consent.<sup>8</sup>

Reproductive tourism presents another concern. When parents are denied access some medical services, they tend to travel to a country that is willing to provide it. For example, when an Italian couple were deprived from having PGD in their country since it was illegal, they traveled to Turkey. This shows clearly how national legal prohibitions may be overcome by travel.<sup>9</sup> Another example was the Whitakers who were not allowed to receive the service in the United Kingdom so they had it done successfully in the United States. This shows that the parents’ ambition to save their child cannot be stopped even with laws and regulation. Parents have self-sacrificing commitment to save their injured children’s lives. This must be differentiated from other unethical acts such as criminalized sex-tourism as it is disrespectful of conscientious parents. Parents act ethically in pursuing their children’s health in legal settings that are willing to accommodate them. Conversely, this calls for having international harmonization in prohibitory laws.<sup>10</sup>

Finally, there is a concern that the use of PGD along with IVF is a slippery slope towards ‘designer babies’. The designer babies allow parents to choose the special features that they want to have in their child but in which they might not benefit the child itself.<sup>11</sup> The only difference is that a designer baby does not care about the therapeutic intent that is found in the therapeutic uses of PGD and IVF when selecting a savior child. Furthermore, it should be distinguished that parents opting for this strategy to develop a savior child are not designing their ideal child. These parents only want a health-normal child with a specific haematopoietic stem cell to save another sick child.<sup>12</sup>

### **2.3 Savior child to save other family members**

Notwithstanding the usually used term “savior sibling”, some use the term “savior child” instead. This aims to indicate the possibility for having the savior child created to save other family members, not only sick siblings. It was published in a newspaper that the first request for a savior child was entered in the United Kingdom where the recipient was not a sibling but the father. The father used to suffer from thalassemia. There is no evidence that a non-sibling might alter the moral evaluation in the request for a savior child, whether it was a parent or a close relative. However, the Australian Infertility Treatment Authority restricts the requests to cases where the tissue recipient is solely a sibling.<sup>13</sup> Additionally, this is done in the same way in many other countries, where it is prohibited to carry out PGD and tissue typing in order to have an embryo that could provide a tissue match for a sick parent or any other family member other than a sibling. The legislations at these countries note that it is less morally acceptable to select an embryo with the intention of saving a parent than it is when the intention is to collect tissue for a sibling, as concern for another is being replaced by concern for oneself. When parents use the

procedure to save a sick sibling, the procedure is justified and seems more courageous and heroic, while in the other case the moral foundation of the technology becomes a lot less stable.<sup>14</sup>

This is argued and not agreed on by everyone to mix and conflate morally acceptable actions with morally commendable actions. Gavaghan argues that to accept a physically, emotionally and perhaps financially demanding process such as IVF and pregnancy to save the life of another may perhaps scale peaks of humanity, sacrifice and selflessness. This is seen greater than to undertake these burdens to save the parent's own life. However, that does not imply that saving one's own life is unacceptable.<sup>15</sup> It can be argued that this gives the children a better life being raised by a healthy parent.

Neither the Act governing assisted reproductive technology in the United Kingdom nor the Common Law require that the parents' intentions to be purely non-selfish when they decide on behalf of their children. Some argue that the policies and guidelines were left open intentionally as there is no explicit prohibition on tissue typing to save a parent or to other relatives. Boyle and Savulescu wonder if there would be anyone harmed by allowing PGD to be performed to select a savior child for the benefit of a relative. They argue that there is no harm to any of the involved parties; the parents, the person who would receive the stem cells to save his/her life, and the savior child who would not otherwise exist. Furthermore, this is considered as an intrusion in the autonomy of the individuals that is based on no valid reason.<sup>16</sup>

The Human Fertilizations and Embryology Authority clearly state that tissue-typing PGD is not to be used when the intended recipient is the parent. However, this is not considered a final prohibition and there is room for further discussion in this regard. Society in the United Kingdom is open to the topic and have acceptance to the idea.<sup>17</sup> The Human Genetics Commission had a good argument that stated that the current situation could not be maintained even though HFEA

did not permit Pre-implantation tissue typing to save a parent or a family member. It's true that it's wrong to have limits on which lives can be saved by embryo selection. All lives are valuable and have the equal right to be saved. It should be noted that the chance of an embryo being an HLA match for a parent is 1/200 and that the amount of stem cells collected from the umbilical cord is not enough to treat an adult. Yet this Problem may be overcome by science and modern technology.<sup>18</sup>

The growing acceptance of this technology makes it hard to ignore the need to save others besides siblings. The argument that distinguishes the kinds of lives to be saved cannot be maintained any longer. Opponents to having the technology serve parents and relatives should realize that a genetic limitation exists on stem cells donation for non-relative. This ensures that no trading or commercialization would develop to use the selected embryos. Therefore, there is no reason not to have the term of savior sibling turned into savior child.

#### **2.4 Banking other embryos to save non-relatives**

Embryos maybe stored for future treatment, used for research after gaining the parental consent or even donated. Another valuable option is to store them in HLA typed frozen embryos banks as a backup. They can be used for unrelated individuals in need of compatible stem cells or tissue, in the form of having the embryo carried to term after being adopted. This would make it an HLA matched child or it could be used in vitro as a source of stem cells.<sup>19</sup> This is a perfect solution for those who accept IVF but oppose therapeutic cloning. Whether this is right or wrong and whether these embryos are seen harmed or not depends on the view of the embryo status. The embryos status is being extensively argued on many levels, including the religious level, whether it is a person or not.<sup>20</sup> Knowing the process of PGD and HLA tissue typing used to choose the savior child and the other possible recipients other than a sibling, there is a need to

know the normative debates on whether it is ethical to have a savior child. This can be discussed through the application of moral principle.

### **3. The normative debate whether a newborn "savior" child is ethical**

The four principles approach is one of the best frameworks to analyze an ethical dilemma. Together they recognize the basic moral principles and moral values. They are weighed against each other by applying them to selecting the savior child matter through the use of PGD. Along with the values, they do not answer how to solve the ethical problem but they can provide an understanding to the conflicts.

#### **3.1 Autonomy of the new born**

It is difficult to characterize the interests of the savior child that has not been born yet. Some see that the given hypothetical existence to it at the time of decision to use PGD and HLA typing does not give the child any interests.<sup>21</sup> Some tend to contrast the welfare principle in the family law context where it shows that the child is in existence. This makes it possible to ascertain its interests. In the case of the savior child, the child's interest does not exist until the procedure is agreed on and the child is born. Furthermore, it is impossible to predict the specific interests of any child before it is born, whether it was a savior child or not. Regardless of whether it is seen as a person or not when it is only an embryo, the child's desires are not known. This is what makes the decision resulting from the use of assistant reproductive technologies as identity affecting. However, there are some generic interests to the child. They are certain and clear universal interests that need to be protected when using assistant reproductive technologies. Bringing a person to existence necessitates a level of respect to its future.<sup>22</sup>

Two points are debated when it comes to the autonomy of the savior child. The first states that the embryo is a human from the beginning of fertilization and is entitled to full moral status. The other argument states that the embryo has some level of moral status from

fertilization. Yet this status is seen as lesser than the moral status of a born human being, and during its development, it gradually acquires the full moral status. This is based on that there is a moral distinction to be made between the embryo that is a small collection of dividing cells; a fetus at the age of twelve weeks, when its body is more shaped and major organ systems have formed; and finally, the viable fetus at the age of five months, which could potentially survive birth.<sup>23</sup> In another argument, it is considered that there are three objectionable moral issues concerning PGD. One group considers embryos as people with human rights at the very first moments of conception. They believe that being an embryo is a part of the life cycle of a human as being an infant, child or adult. This life starts when sperm meets egg at fertilization. This group finds that PGD, where the affected embryos are destroyed, and Prenatal Diagnosis, where affected fetuses are terminated during pregnancy, as unacceptable.<sup>24</sup> They oppose the entire idea of selecting and discarding embryos. Another group objects to the idea of selecting embryos. To them this process is unnatural and produces a manufactured good.<sup>25</sup> Finally, a third group's objection deals with the concerns about the child's future and rights. They state that all children must be treated as ends and never as means. On the other hand, proponents to these technologies say that the failure to implant a pre-embryo is morally acceptable compared to aborting and killing a developed fetus. Meanwhile, assistant reproductive methods and pre-natal diagnosis are generally acceptable. Hence, there is no reason to ban PGD and HLA typing for selecting savior children.<sup>26</sup>

As part of the autonomy of the to-be-born savior child, dignity is important. Some argue that it will be compromised and seen less than the dignity of the existing sick sibling. It might be thought that the savior sibling's dignity is compromised in the fact that he/she is created to make a kind of sacrifice to his/her sick sibling through the use of PGD and HLA tissue typing. This



huge issue might leave parents with a sick child that needs donation with the last solution of cloning in order to prevent compromising the human dignity. However, this argument is weak and is not reasoned. Being born for other reasons or giving an organ does not compromise the human dignity by any means.<sup>27</sup>

Another argument used to oppose savior children is the concern about the lack of consent. However, this is not morally significant. It is known that newborns and small children do not have the ability to give informed consent. The parents have the full authority to make decisions on the behalf of their children. This includes all medical procedures including the use of their umbilical cord blood and bone marrow unless this interferes with the child's welfare.<sup>28</sup>

### **3.2 Conflict of interest**

Generally, medical interventions are not allowed to be carried out on one person for the sake of another. When thinking about medical interventions, they are usually thought of as being invasive and risky, or at the very least inconvenient, even though that is not the case here. Taking blood from the umbilical cord and even bone marrow when the child is older poses no risk on the savior child. However, some people perceive it as morally unacceptable and problematic that such an intervention is done for the sake of another person. Parents of a savior child are seen as having a massive conflict of interest.<sup>29</sup> In vitro fertilization (IVF) permits parents to select the embryo that is free from the serious genetic disease that the other sibling suffers from and, simultaneously, select for a tissue match. The selected child will be able to provide stem cells that are in the umbilical cord blood to treat his/her seriously ill sibling. Both of this procedure and the Pre-implantation genetic diagnosis (PGD) are not proven to cause any risks or harm to the newborn savior child. This has been successfully practiced in the United States, and approved in both the United Kingdom and Australia. Selecting a savior sibling is justified on the bases that

it benefits the newborn against the hereditary disease that the other sibling is suffering from. Therefore, this process is not seen as benefiting a third party, only the sick sibling. There is room for a valid good reason to argue for using this technology, which is to save a sick child. It would be morally remiss if the parents did not.<sup>30</sup>

Consenting by parents is justified when it serves the best interests of the child. Another standard is consent to an intervention that is not against the interests of the child. This is another situation where consent is considered acceptable. This includes parental consent for some non-therapeutic research on children or diagnostic and treatment procedures for legitimate research purposes. These interventions will not involve additional risk or discomfort to the child. In the situation that requires an intervention that includes no sacrifice and no inconvenience by one child to save the life of another child, parental consent is morally acceptable. It may even be morally required. This is exactly the case of the savior child.<sup>31</sup>

### **3.3 Best interest of both siblings**

Many questions should be discussed and considered with parents prior to using the technology. Parents need to know that there is a possibility that the transplant maybe unsuccessful after all. Therefore, they have to be mindful not to blame their savior child even if that was done unconsciously. Additionally, they need to consider the future life of the child conceived to produce stem cells. The best interests of the savior child must be paramount according to the Human Fertilization and Embryology Act. The savior child is as important as the sick child is, and the best interest of both has to be taken into account. Some grim predictions were made about the prospects of the life of Marissa Ayala before her birth. These predictions appeared to be false and wrong. Many predictions appear on how parents might treat their children when a new PGD tissue-typing request is studied. Defining the conditions under which

it is appropriate to allow people to parent is dangerous and likely to be flawed. People need to overcome some fears; otherwise, the good benefits out of these important technologies, where some lives can be saved, would be lost.<sup>32</sup>

Furthermore, the alternative for the child who is going to be a savior and a donor is simply not to exist and have any form of life. It is always better to have a life than not to be conceived, whether the person would save someone or not. The existing cases of savior children are the living evidence that the physiological harms are ruled out. Additionally, the psychological harm is unpredictable and unlikely to occur. Regardless, even if such harm did occur, it is unlikely to be so severe that it would be better for that particular child never to have existed and having to stop bringing up savior children.<sup>33</sup>

Anyway, the Human Fertilization and Embryology Authority – the government’s fertility watchdog – makes a decision on a case-by-case basis. Some people argue that the conditions under which savior siblings are allowed should be documented clearly and governed by law. However, others argue that this would lessen the flexibility that exists in the meantime. There are much potential for unforeseen uses for using PGD and HLA tissue typing that might develop in the future.<sup>34</sup>

### **3.4 Risks and benefits to the new born child**

There are several questions whether there must be a benefit to the donor to justify the donation. However, some assume that savior siblings do not benefit from their donation while others argue that they do. The beneficence is perceived here as a psychological one for being a hero and a savior.<sup>35</sup> However, this has been argued. It is seen that there is a potential psychological harm on the newborn child. Sometimes the child is viewed as not being able to save his/her sick sibling when the sick sibling dies. Other times the initial tissue donation is

unsuccessful and further donations are required. Moreover, the child could also feel stressed not being able to get to his/her parents expectations by the means of donating again or saving his/her sibling if the donation failed. Therefore, the child's welfare might be subordinated to that of the sick sibling.<sup>36</sup> Another major concern is that the amount of stem cells is not enough to treat more than a small child. This puts the parents in a difficult situation where they might have to subject the savior child to bone marrow aspiration when he/she is older or even start thinking about solid organ donation. Some parents would abandon the request for this technology totally to preserve their younger child's autonomy.<sup>37</sup>

An alternative potential harm is perceived where the savior child understands that he/she was a mean to an end. In other words, born to save another sibling or a family member and not for having him as a wanted child for himself. This may be rephrased as; it seems that the savior child can be used instrumentally as an object. This draws several ethical concerns and violates the Kantian principle that states that people should be valued in themselves, and not be treated as mere ends.<sup>38</sup> Therefore, if a child was born to save his/her sibling for a disease and serves as a direct blood or bone marrow donor, the ethical concern becomes stronger than when stem cells are acquired from placental and/or cord blood. Still savior children can be conceived to serve the family as an instrument. To be precise, there are parents who have children for different reasons where they serve as instruments. Some reasons include benefits to strengthen the couple's marriage, the continuity of the family name, economic benefits, psychological benefits, helping parents as they age and even providing a playmate for an existing child.<sup>39</sup> This leads to the conclusion that as long as the tissue donation is ethical if performed on an existing sick child then creating a child into the world to serve as a tissue donor is ethical as long as the child is being valued for him/herself.<sup>40</sup>

However, it is known that savior children do not suffer from any means of abuse or bodily invasion. In fact, using PGD and IVF to choose these children serves them a benefit of being selected and born disease free unlike their sick siblings. Savior siblings are cherished and beloved for themselves.<sup>41</sup> Moreover, the fact that the parents are having such an effort done to save their child indicates that they are caring and loving parents. This ascertains that they will rear and love the savior sibling as much as it is supposed to be loved and cared for. This makes it unlikely that the savior child will be used then not reared as the other siblings.<sup>42</sup> Arguments that favor having savior children state that these children are loved and valued; it is of no consequence that it is also a source of donor tissue. It is better to have them alive than not existing at all.<sup>43</sup>

Opponents to this technology claim that the physiological harm is embedded in the PGD technique, where a biopsy is done to the embryo. This goes beyond the known risks of IVF. However, current studies show that there is no evidence of harm inflicted on the savior child being biopsied when it was selected as an embryo. If any risk is expected, it is going to be minimal. Still more confirmation is needed to check the long-term outcomes on the savior child. The fact that there is a judgment made to select the better embryo to enhance the quality of life for someone else is controversial in itself. This gets us into the other issue of discarding the other embryo.<sup>44</sup> However, discarding and destructing those embryos is acceptable based on the legitimate reasons of the procedure. It is more acceptable to discard embryos than to terminate the pregnancy when the fetus is fully developed.<sup>45</sup>

If people do accept the possible risks that come from using PGD to have a child, they certainly accept the risks for the benefit of having a savior child. However, in both situations, the process should not start unless the risks were minimal. The moral issue is the amount of

suffering can be inflicted on a person to alleviate the suffering of another person. It seems that society has accepted these risks, as there have been more than 1000 savior children born since 1990 using PGD. Current studies assure that there is no risk inflicted on the selected child from the use of biopsy.<sup>46</sup>

Yet, the normative debate over whether a newborn "savior" child is ethical has been discussed. Knowing the moral principle that governs the use of biotechnology to produce a savior child leads to the need to addressing the normative debate over how to use the savior child after its birth. In means of what can be donated and what should not be donated. The frequency of donation is also important to discuss in the case of savior children and compare to other children who were conceived naturally.

#### **4. The normative debate over how to use the "savior" child after its birth**

The organ donation topic is always filled with ethical concerns. It becomes harder when the donor is a child and more alarming if the child was a savior sibling. One of the main concerns is that children cannot give consent for the procedure undertaken to benefit another person. Therefore, they should be called an organ source rather than donors as their parents are the ones to decide on having them created for this purpose.<sup>47</sup>

The selected HLA-match sibling will be the best and most preferable source for any future tissue or organ transplant for the sick sibling. The parents' intentions are very hard to predict even if they were sincere at the beginning. Moreover, it is unrealistic to expect the ethics committee to determine the real parental intentions. Desperate parents who decide to go through this process are unlikely to utilize the umbilical cord blood only in case the donation failed. It is expected that they will desire harvesting further tissue from the savior child. Likewise, even the most well-meaning and sincere plans are subject to failure because of unpredicted circumstances. It might be that the parents genuinely plan to use only the child's cord blood, that plan is unlikely

to bear much weight if the sick child's life is at risk and required further HLA transplant. Once the request for selecting a savior sibling is approved and the process has started, the ethics committee has no further jurisdiction over decisions regarding the savior sibling. The fact that the ethics committee has approved the submission because the parents only planned to use the cord blood of the savior sibling will be of no significance to any of the future decision to use either the bone marrow or any other organs of the child. <sup>48 49</sup>

#### **4.1 Stem cells from the umbilical cord**

The harvest of the umbilical cord blood is generally acceptable. Such a technique does not involve any physical harm or intrusion to neither the newborn nor the mother. Although there have been some discussions on whether the early clamping of the umbilical cord can affect the neonate negatively. This claim has been proven wrong. The needed stem cells for treating the sick child are a component of the umbilical cord blood. <sup>50</sup>

#### **4.2 Bone marrow**

It has been known in practice that savior children go under bone marrow aspiration to save their severely sick sibling. This practice is acceptable to a limit. It should not be over used and the donor child's best interest must be kept in mind. Bone marrow donation is known to be not an overly invasive procedure. The harvesting of the bone marrow is safe and usually causes mild discomfort after it has been performed. The overall risk is low and the savior child would go under a close assessment prior to getting the parents' consent. Usually this procedure does not need a court approval. The health and wellbeing of the savior child should be an important consideration in all decisions about that procedure. HFEA and the Infertility Treatment authority restrict the use of tissue coming from a savior sibling to the donation of umbilical cord blood and bone marrow only. It is ethically acceptable to conceive a child for specific reasons if it

acceptable to have it on other exiting children. Therefore, it is not allowed to harvest solid organs or non-regenerating organs from the savior sibling.<sup>51</sup> The hard tissue donation is controversial in other courtiers, but the loss of a non-regenerative organ is not in the best interest of the donor child. Therefore, there is a worldwide increasing hesitancy to use children as solid organ donors. Even in the cases of children donating organs, they are never used for donation of organs other than kidneys. Still, kidney donation composes a difficult borderline case, since humans can live a healthy life with one kidney, but such a life is never without risks.<sup>52</sup>

However, the health and wellbeing of the savior sibling should not be the only, or even the overriding consideration. The likelihood of having such a procedure should therefore not be enough for the ethics committee to deny approval for tissue typing PGD and approved selecting a savior child. A kidney donation between two young siblings would be more justifiable than the donation between two children growing up in different families. There is a potential psychological benefit for the donor sibling. Some children experience gratification out of this. They also feel guilt when being not allowed to donate stem cells or a kidney to their sick relative. Moreover, they have the advantage of growing and living in a less stressful family environment than when the sick sibling had died for not having a donor. The potential benefits and burdens should be balanced carefully, and the parents should make the decision that is in the best interests of both of their children. Finally, the decisions around such complex matters should be made on a case-by-case basis.<sup>53</sup>

#### **4.3 Solid organs**

World health organization (WHO) emphasized that no organ should be harvested from the body of a living minor for the purposes of transplantation. This means all minors including savior siblings.<sup>54</sup> It is more probable that the parental request for transplant of non-regenerative tissue from one child to another is likely to be refused by healthcare givers then becomes legally



challenged. The courts tend to apply the best interest test and are unlikely expected to allow such a donation. Law would protect tissue-matched savior children from exploitation by their parents who maybe desperate to save the other child, however this is not always the case.<sup>55</sup> Therefore, there should be some international interpretation of the law on this field of use of PGD upon a fear that tissue matched children will not be adequately protected. In the meantime, this is practiced in the United Kingdom through HFEA.<sup>56</sup>

#### **4.4 Frequency of donation**

Having the fact that the savior child was created and chosen because he/she is the best match for the sick sibling makes him/her the only and best choice in case the sibling needed another donation. This could subject the savior child to pressure due to the family's request or expectations. Parents should protect their children's health, but this does not apply to every single situation. In the savior child situation, parents are faced the struggle to protect the health of both the sick and the savior child. It is true that the savior child saved his/her sibling once but that does not mean that he/she should be used for the rest of his/her life. A couple of blood donations or bone marrow aspirations are acceptable. However, this should not be done extensively in a way that would harm the savior sibling or cause frequent suffering or pain. Savior children are not chosen with the intention of using their solid organs even when they are older.<sup>57</sup> The savior child is responsible of accepting and consenting for donation and other procedures when he/she is an adult. Prior to that phase, parents should care for the best interest of the savior child as well as the sick one. Sometimes this issue is taken to courts when parents insist on the donation. The courts evaluates the interest of the prospect donor and the prospect recipient. This is what is known as reviewing the parental decision test or the best interest test. The issue calls for the minor's right to assent in addition to having the parental approval.

A savior child holds the same rights and autonomy as any other person.<sup>58</sup>

### **5. Normative Ethical Criterion to Justify PGD for A "Savior" Child Through PDE**

The Principle of Double Effect was the primary operative principle used long time ago to solve issues of the professional practices of the medical field. The pre-Vatican II Catholic medical ethics dealt with specific topics concerned with physical interventions. With the help of the PDE, it gave precise absolute answers to those matters. Since then the PDE became commonly in use even by secular bioethics.<sup>59</sup> The PDE forces the question: is the action morally right or wrong? From a deontological view, if it is wrong, it is wrong. Nothing can justify it even it had good consequences coming out of it. It remains evil in itself. The act itself should not be morally wrong. This condition is the first condition. The second condition is that the bad effect must not cause the good effect. There are three probabilities of an act, it can cause the good effect then produce the bad one, it can cause both of the good and bad effects without affecting each other or it can produce the bad effect that leads to the cause of the good effect. The first two are acceptable, as they do not justify a wrong act through the consequences or the intention. The last one is not allowed because the act is wrong by itself. The way the action is named has an effect on its acceptance or not in the PDE.<sup>60</sup>

Roman Catholicism has a unified position towards this kind of issues related to artificial reproductive technologies.<sup>61</sup> The Catholic Church adopts the Canon Law that is sometimes referred to as the ecclesiastical law. The sources of these laws are the natural divine law and the positive divine law that are both contained in the scriptures and the tradition. The Pope is the only authority that has the power to abrogate laws made by his predecessors.<sup>62</sup>

The Catholic Church follows the principle of supremacy of the right to life when dealing with the artificial reproductive technologies.<sup>63</sup> God, who is the only Lord of life, has assigned mankind with the noble mission of safeguarding life. Without life, there cannot be any other

good. Life must be protected with the ultimate care from the moment of conception. That makes abortion and infanticide offensive crimes.<sup>64</sup> Ethicist Daniel Callahan states that God is the only lord of life so human beings do not have the right to take the lives of other innocent humans. To him, life starts at the moment of conception and taking the life of an innocent human is always wrong. This explains the strict position that the church follows towards PGD and IVF.<sup>65</sup> However, it should also support the use of savior children to protect two lives. There are situations where Catholics allow some action to save the human life through the application of the Principle of Double effect.

### **5.1 1st condition- A good moral object**

The act in itself – considered apart from its circumstances and consequences – should not be morally wrong. Two arguments can be weighed against this condition; one is the use of biotechnology upon human procreation and the other is saving the life of a sick child. Both are discussed from the Christian prospective.<sup>66</sup> A married couple may have respectable motives and generous sentiments to use the biotechnology of assistant reproduction. They seek the use of IVF and PGD to select a healthy child to save their other sick child. The act itself is the deciding moral factor which does not include the entirety of the conjugal life. The use of this biotechnology includes the use of masturbation to obtain the father's sperms. It also includes the discarding of the spare embryos that are not healthy and do not match the tissue typing of the sick child. Both actions are not seen as the expression and fruit of the conjugal union.<sup>67</sup> The Catholic Church prohibits IVF for no explained reason. There is a hope that the genetics field will make the church consider the use of IVF within the moral contexts of the health of the embryo and the sick sibling. In the meantime, the prohibition is within the context of the parental infertility. The reason is that assisted reproductive technologies lead to the separation in the

marital intimacy and procreation. However, Donum Vitae supports the prenatal diagnosis as it perceives it as moral because it provides a therapeutic procedure that benefits the future child. Besides, there is no disproportionate risk and there is a valid parental consent. Still, any abortion related to the prenatal diagnosis is totally prohibited. Supposedly, if the church teaching supports the prenatal diagnosis, it should support the Pre-implantation diagnosis on the same basis as it benefits the savior sibling and additionally his/her sick sibling.<sup>68</sup>

The reason that the church might not allow this is the difference between the two technologies as the PGD occurs in a petri dish and includes the use of IVF to fertilize the egg. The Catholic Church prohibits these steps in choosing the savior child. That would include the discard of the extra embryos that were not a good match. A human life is made of the existence of both the body and soul. There are many arguments about when does the soul enter the body. Some argue that this starts since the moment of conception.<sup>69</sup> According to the Church teaching and the Declaration on Procured Abortion, human life begins at conception and must be fully respected. An embryo is a full human with a soul not simply a potential human being as viewed by others.<sup>70</sup> Yet, the Church never revealed when the exact moment of ensoulment occurs. The church does not allow the lessening of the dignity of the human embryo. Embryos are viewed as laboratory materials treated with discrimination and disrespect. The church compares this to the discrimination that was practiced in history upon humans for their race, color and nationality.<sup>71</sup> Nevertheless, this is not considered a type of discrimination when parents try to save a sick child by having another child. The need is to have a tissue match that can help heal the fatal sickness of their child.<sup>72</sup>

It is true that PGD and IVF tend to select embryos, which are free from defects and have a specific tissue type. The church sees this as purely intrinsically evil as it is directed towards

qualitative selection and consequent destruction of the other embryos. The church sees this as a form of abortion that is absolutely prohibited.<sup>73</sup> However, Banking can solve the issue of excess embryos that are usually discarded. This would cover the problem of not respecting the human life at its beginning in the catholic teaching. It also gives these other embryos the chance for a prospective life and future.<sup>74</sup>

## **5.2 2nd condition- The casual priority of good consequences**

The bad effect must not be the cause for the good effect. This condition requires that the chain that starts with the act and continues with either a single or multiple effects must not have a link where it is found that the bad effect is causing the good effect. In this case, there are three possibilities: the first is that the act might cause a good effect that effect would cause a bad effect. The second possibility is that the act might cause a good effect and the bad one in the same time without having any of the effects causing one another. The third possibility is that the act might cause the bad effect, which will cause the good effect. The first two possibilities will pass the second condition of the principle of double effect. However, the third possibility will fail to pass the second condition of the double effect. The way of naming the act can give it a different interpretation when applying the principle of double effect.<sup>75</sup>

It is a reality that the process of choosing the savior sibling is successful. Many cases occurred throughout the world after the Nach case in which they were safe and fruitful. The view of PGD and HLA typing, as a good or bad effect, depends on the person's prospective to it. This effect definitely causes another good effect, which is having a new healthy life that has the ability to save another life.<sup>76</sup>

Healing a sick person is always a good deed that is demanded by the catholic teaching. Moreover, creating a new life with a future is better than not having a life at all. This life can

save another person's life, even though this life was not created in traditional means of marriage. However, having this allowed will save marriages and families. Having a dying child saved in this means would ensure that everyone in the family lives in a healthy happy environment. This included the savior child that was not conceived traditionally, the parents and the saved sibling.

The first and second conditions are corresponding to each other pretty much like the moral principles of beneficence and non-maleficence. The combination of the two conditions helps making sure that intention is good and the chain of actions do not include a bad effect to get to the good one. Catholics do not allow actions that are morally wrong to justify a good action.<sup>77</sup>

### **5.3 3rd condition- A good motive**

The agent must not intend the bad effect. This condition can be rephrased to 'intend as an end to be sought'. It shouldn't be interpreted as 'intended either as a mean or as an end' nor as 'the agent may not intend the bad effect either as an end or as a means to that end' as this renders the principle of double effect useless and not as beneficial as Catholics proposed it to be. This condition should be interpreted, as 'the agent may not intend the bad effect as an end to be sought'. All accepts this condition: deontologists, Catholic moralist and proportionalists.

Intentional actions are very controversial. This is a gray area that troubles many people while judging if an act was intended or not through the principle of double effect. It is viewed as having a blue print or a representation of both the means and the ends planned for the implementation of an action. So, to say that an action is intentional, it must match with the plan the person had in mind. In some cases, there are some actions that a person intends its effects because it is needed but the person does not desire that effect. That undesired effect is not what

he aims for but it is part of the process. Bad effects are then accepted because the good effect cannot come alone.<sup>78</sup>

It is true that this condition of PDE troubles many people when weighed against other issues except in this specific argument around the savior child it seems very clear. It is obvious that parents' main intention is to save their severely diseased child by having another child that they would care for and love too. The child is wanted and desired for itself beside being a savior.<sup>79</sup>

#### **5.4 4th condition- The proportionality of good and evil consequences**

The bad effect must not outweigh the good effect. Proportionalists agree that this is an important condition to reach to a conclusion regarding the act in view of the principle of double effect.<sup>80</sup> The Roman Catholic teaching explored the difference between kinds of assistant reproductive technologies and genetics using the Doctrine of Double Effect. However, differences between physicalists, proportionalists, utilitarians and other competitors raise many arguments and conflicts. The Principle of Double Effect can result in different decisions on savior children in a specific case, depending on how each group interprets it.<sup>81</sup>

This is considered the best condition that explains the need for the Catholic Church to accept the biotechnology that enables parents to have a savior child. The bad effect must not outweigh the good effect. Having two healthy children and a blissful family outweighs the use of assistant biotechnology that is resisted by the church. This shows that the entire process that started with choosing an embryo through PGD and HLA typing and ended with having transplantation from the healthy savior child to its sibling is a right decision taken for the best interest of the family.<sup>82</sup>

It is possible that the Catholic Church will start studying these issues in order to keep pace with the new biotechnology developments. It is also expected that it would allow using ARTs in the means of PGD and IVF to select savior children. This would be justified under the umbrella of the two siblings' benefit. Other issues, such as discarding the extra embryos, will also be solved by technology. It is recommended that they be banked for different uses such as adoption. The only issue that will remain is the separation of the unitive and procreative components of the marital intimacy.<sup>83</sup>

## **6. Conclusion**

The main concern with the savior child topic is whether it is ethical to use the PGD to create babies to save the others. It has been proven to be ethical and morally acceptable within specific limits. The thesis has been justified through discussing the Pre-implantation Genetic Diagnosis and the possible Recipients to the savior child. It has also been argued and concluded through the normative debate on whether a savior child is ethical. This has also been examined through the normative debate over how to use the savior child after its birth. Lastly, the debate has been assessed through the normative ethical criterion to justify Pre-implantation Genetic Diagnosis for choosing a savior child through the Principles of Double Effect. Even though the Church has absolute rejection to many procedures in this process however selecting savior children is justified under the moral absolutism. There are times where it seems justified to undergo these procedures. The moral object of saving the life of a child is beyond the other related issues.<sup>84</sup> All the mentioned concerns, whether they were scientific, ethical or religious, do not establish a sufficient ground to forbid parents to use Pre-implantation Genetic Diagnosis and tissue typing to save not only a sibling, but even any other loved one's. The practice of PGD and HLA tissue typing has proven to have the ability of creating a healthy new life besides saving



another life. It has proven to be successfully and beneficial on many levels not only to the sick recipient.

## **B. Privacy Genetic Databases**

### **1. Introduction**

Some call this time as the golden era of developing genetic biobanks. It wouldn't have been so without the experiences, the errors and achievements the of the very few developed biobanks around the globe. Through recording their involvements, evolving guidelines, debates and arguments around them; newer biobanks benefit along with the communities they are within. Having such a new field requires adjutant work form many professionals and specialists in order to work out through the practical, ethical and legal issues. Some of these issues are practical whereas others are still subjective while still having interactions and association between the two. Nevertheless, both types of issues have consensuses and of controversies around them. On top of the subjective issues comes a bundle of participants rights such as commercialization, benefits and sending feed back information to the participants. The other form of issues is related to confidentiality and access to data specially with third parties. On the other hand, Practical issues seem to mostly be dealing with the process of consent and withdrawing it. The second issue discusses the ethical ways to deal with samples regarding their collection, organization, coding, anonymization and disposing. Finally, some experiences became lessons though time and are used for teaching. The challenge with classic health research ethics is one of the very first basic issues that have been faced. The essence of research involving samples has features that differ from research involving directly human subjects leading to debates around the use of the existing guidelines. The other lesson was learned from the productive dialog of biobank where several guidelines existed for the past 20 years as reactions to the troubled birth and life

stories of different biobanks. These guidelines were the ethical justified and were made on local and global levels.

## **2. Overview over existing genetic data bases:**

Several biobanks have existed since the nineties and tried hard to lead the field of human genetic research. These biobanks made enormous efforts creating their policies, guidelines and databases while establishing the cornerstones of the bases of their practices. their success along with their failures were both extremely beneficial to future genetic biobanks.

### **2.1 The Iceland health sector database**

Iceland is considered the first country to establish its legislations on biobanks and databases by 1998. They picked specific solutions to the expected ethical and legal problems of genetic databases, however that raised several debates on many national and international levels according to Ragnhei haraldsdottir. He sees that all the ethical and legal issues that were taken into consideration weren't and are still not unique to Iceland only. Since 1999, all researchers and clinicians who worked in contact with human subjects, samples or data were concerned about the Icelandic legislation debate around biobanks. These concerns were raised by the nature of their medical work, ethical and scientific accountabilities. Some suggested using the general answers that are provided by the famous declarations to solve the ethical problems that can be encountered with genetic databases. Nonetheless, many ethical questions need to be answered while considering the scope and details of that specific biobank.<sup>85</sup>

The Icelandic Health Sector Database has received a good amount of criticism through the years that were not limited to its ethical and legal problems. The criticism also included the scientific value of its project as it was extensively questioned. This debate included over 700 newspaper articles, meetings and more than 100 radio and television programs. The idea was having an Icelandic gene pool that permits easy detection of disease-causing gene variants,

especially concerning multifactorial diseases. However, critics thought such a database would be biased. Such bias would lead to two unwanted results: families with inherited diseases would avoid participation to prevent discrimination and healthy people would be less motivated to participate. The main critics were from Iceland such as the Icelandic medical organization, the association of Icelanders for Ethics in medicine and science. From the international opponents was World Medical Association (WMA) as the Icelandic project legislations violated the WMA's commitment to confidentiality.<sup>86</sup>

### **2.1.1 Confidentiality and privacy**

Both the Data Protection Commission and the supreme court agree that the confidentiality and privacy are inadequate. They both came to the same conclusion that the bill's assertion that the database will contain non-personally identifiable health data does not hold.<sup>87</sup>

The Icelandic medical association tried to evaluate whether confidentiality is truly respected. This empirical problem tackles two questions the first whether individuals identifiable are really identifiable.<sup>88</sup> The second what does truly count as non-personally identifiable, as it is obvious that participant might always be identified with their DNA within a database that contains their genetic data.<sup>89</sup> Therefore, Ross Anderson - a computer safety expert from the university of Cambridge – was asked to evaluate whether the privacy provisions in Icelandic law are respected in the health database. On his conclusion, he showed that it is evident that there is a lack of competence at the security in the Icelandic project database computers. It was found out that the main leading cause for such problem was the existence of a key that permits the licensee of future adding of new information from the health care system to the database. This can be worked out and minimized but not reduced to a zero level. At least one employee would have the ability to add information and search and search the database. Kari Stefansson states that there's

no database that could be 100% secure which means participants can be identified. Therefore, an Act came out mandating employees of the data to bound to the obligation of confidentiality. Another important factor to be taken into consideration is the relatively small size of the country. Having personal information along with genetic information in such a small country makes it easy to identify a person.<sup>90</sup>

Some of the Europe's national data protection commissioners along with some legal experts whom are responsible for overseeing data-privacy laws, examined the legal consequences regarding breaking confidentiality. They informed the Iceland's minister of Justice that the bill might violate the European convention on human Rights and fundamental freedoms. European human rights law and recommendations demands informed consent as a requirement for the collection and handling of personally identifiable data. The Act shows clearly that the licensee must compensate any participant who suffers from violation of confidentiality in addition to other penalties that are set. Penalties are set as solution to deter violations however the protection is still not utter.<sup>91</sup>

The Icelandic medical Association and the Icelandic trade unions both dreaded that employers might attempt to attain data concerning their workers. These fears might be justified in the form of an empirical question. However, some argue that providing complete anonymity of the data is not the way to be used for protecting confidentiality. Doing such a thing would hinder the participants' future benefits. Therefore, it was proposed that Icelandic database uses a reversible third-party encryption system. Such a system would provide protection to the data by building strong barriers between the laboratories such as those of decode and the origin of samples and data. This independent third party would guarantee encryption of the data in direct collaboration with the Data Protection commission. Optimistically this might decrease the of

uncovering the encryption key. However, it is still does not eliminate the risk of indirect identification of individuals in a small population as the Icelandic one.<sup>92</sup>

### **2.1.2 Informed consent**

The argument goes around the fact that patients' rights were violated in the Icelandic project using presumed consent and not the informed one while transferring data from medical records to the health sector Database. It is ethically acceptable to not to require any consent of the research subject for empirical studies using anonymous data. However, this is not an epidemiological study and is not a public health project for which no consent would have been justified. It must be clarified that there is a big difference between the health sector Database and medical-records research. The information at the health sector Database are linked genetically to the participants' records. Genetic information is not restricted to the past like the information used for medical records research, but will probably provide information about the future.<sup>93</sup>

What seems ironic is that the Icelandic project had used an enormous amount of resources in order to create the database. This required time and money, retrospectively, decode have acquired more costs resulting from the delays. This has resulted due to all the objections to use presumed consent and the debates about it. Much time, money and effort would have been saved by using the informed consent procedure.<sup>94</sup>

Presumed consent was rejected due to several reasons on many levels. For a beginning, the presumed consent violates the person's autonomy. It was claimed that the Icelanders were not informed properly about the opt-out procedure. It is known that the presumed consent cannot grantee decisional autonomy. This also violates the European law and the international guidelines such as the Declaration of Helsinki. Informed consent was mandated in the 2000

version of this declaration as it includes medical research on identifiable human data and samples.<sup>95</sup>

Other downsides to the presumed consent were that previously expressed wishes of the dead are not considered. It also does not allow having a face to face meeting to discuss the consent and thereby, participants do not have the chance to ask questions. Using an opt-out model means that any information already processed cannot be retrieved and only new information will not be added beside the destruction of any remaining samples in the biobank. This conflicts with the rights stated in the Nuremberg code as it does not allow a meaningful withdrawal from the research. And since opting out is general, it becomes impossible to opt out from specific disease while opting in for others.<sup>96</sup>

Finally, and from the Icelandic experience, it appears that the community consultation cannot replace individual consent. As much as the community approval of a research project that concerns a group or the whole community is important. Nonetheless, a community consent cannot legally or ethically force members of the community to participate. Participation has to be informed, voluntary, and understood by competent individuals.<sup>97</sup>

In general, even when informed consent is collected, it seems to be insufficient in protecting vulnerable populations. therefore, some argue that informed consent takes advantage of vulnerable groups such as the elderly. Nevertheless, the informed consent is ethically and legally more appropriate to use than the presumed consent in the bio-banking context.<sup>98</sup>

## **2.2 The UK national biobank**

The UK biobank project is known as one of the largest biobanks in the world. It runs on a professionally managed scale with systems and procedures for all activities related to the process of sample collection, obtaining consent, storage and anonymizing of samples and destruction of

records upon withdrawal of consent from donors. Therefore, it would be truly instructive to examine the policies being followed by UK Biobank.<sup>99</sup>

All the debates around this project were influenced by the Icelandic experience. This project is extremely important to study and focus on because it was a well documented tentative attempt. This project had clearly defined the purpose of the biobank, better than the Icelandic one. It functions towards the public's interest while following a strict mechanism to comply with that purpose. Besides advancing research, it paid a lot of attention to the ethical aspect.<sup>100</sup>

The UK national biobank started several years later than the time it was planned to. The developers were eager to find solutions to the technical, ethical and legal solutions. They made benefit out of the Icelandic experience and tried to improve their experience, such as the concerns expressed about privacy and informed consent.<sup>101</sup> However, the critics of the UK biobank stated that the mistakes made by the Icelandic project have been transmitted to the UK national biobank. They use the issues around privacy and informed consent as an example, and state that it hasn't been total eradicated.<sup>102</sup>

### **2.2.1 Confidentiality and privacy issues**

The Confidentiality and privacy problems of the UK biobank seem similar to the ones of the Icelandic health sector database. One of the project's aims is to have the possibility to link the participants to their original data during the follow up appointments. Participants have the right to be adequately informed about the risks to confidentiality before consenting or data collection starts. It is recommended that more research should be done on encryption. The other recommendation is to have legal safeguards set to protect the participants.<sup>103</sup>

The provisions of the Data Protection act apply to genetic information processed at biobanks in the United Kingdom. The act mandates that the data must be fairly and lawfully

processed and processed in accordance with the data subject's rights. It also mandates that data must be used only for limited purposes and never be kept longer than it should be. In regards to shipping and transferring to other countries; adequate protection and extra safeguards must apply.<sup>104</sup>

According to the human Genetics commission; rigorous steps must be taken by all genetic biobanks to ensure that they prevent any unauthorized access or disclosure to their databases. Additionally, the national council for civil liberties believes that the current framework of law against the unauthorized disclosure of medical information is not enough to prevent adequate protection against the unauthorized disclosure and use of genetic information. Their concern is not only towards disclosing information to insurance companies; they are also concerned about disclosure to family members whether it was direct or indirect.<sup>105</sup>

However, it should be noted that the guidelines of the human Genome organization (huGo) suggests that access to samples is allowed to immediate family members. Nevertheless, healthcare givers are left in a huge dilemma when the DNA participant is unwilling to share beneficial information derived from his results with the family members. This leads to uncertainty whether to honor the participant's confidentiality or the benefit of the relatives. Some justify the disclosure to the family members under preventing serious harm.<sup>106</sup>

On its final protocol; the UK biobank does not allow family members to have access to participants' data even after the participant has passed away. In addition, the family have no rights to withdraw the samples nor the data. Therefore, and due to the contradictions between the regulations that biobanks have and the ones of the human Genome organization; GeneWatch recommends for further legal recommendation over this issue. The UK biobank makes sure that the access to the data stays to the minimum, therefore only few workers have access to the key



code. In addition, the biobank uses several safety measures such as encryption and coding data and sample beside using hacker-safe computers. Furthermore, the consumer's association and human Genetics alert recommends that genetic biobanks persons and the responsible bodies should use have the encryption and reverse encryption process be independent from the biobank users and owners. An extra advanced move towards protecting the participants and their data; the human Genetics committee has recommended that the government takes over creating specific legislations. This would ensure that insurance companies and employers won't be able to practice any form of genetic discrimination. The only downside is that these legislations will not be able to protect he participants when they move outside the United Kingdom where the exemptions of the Data Protection act apply.<sup>107</sup>

Some opponents suggested that all participants would receive precise information around the risks and the possible chance of having authorities such as the police of court having lawful access to the data. This has to be done before having the participants consent. However, the human Genetics commission states that this would discourage people from participating. Therefore, they suggested having legal means that would prevent authorities and other law enforcement agencies from having a lawful access to the participants' data.<sup>108</sup>

The Data Protection Act authorizes the access to the participants' data. The case of Stephen Kelly emphasis the need for having legal impediment or specific legislations to protect participants. Stephen Kelly was a prisoner who had agreed to participate in a study about HIV outbreak in prison. He was assured about the study confidentiality like all other participants however, Kelly's samples were used later in providing important evidence related to his criminal trial. He was convicted with the criminal act with the use of his genetic data that was part of the study. Hence, Gene Watch ensures that such a practice would of seeking justice through

participants' confidential data would discourage people from participating in research as their confidentiality is not respected.<sup>109</sup>

the debate about the confidentiality was less animated in the UK national biobank than in the Icelandic project. The reasons might be due to the kind of used consent where it was informed rather than presumed when it came to having access to the participants' healthcare records. Some participants believe that the risk still does exist but they tend to participate for the greater good that would result later.<sup>110</sup>

### **2.2.2 Informed consent**

When tackling the consent issue and the idea of the future use of the samples and its information; biobanks funders favor the use of the general consent. It is believed that this form of consent will achieve the maximum usefulness of the biobanks' samples and data. With that being hazy and yet clear to the public and participants; biobanks promise to provide the necessary ethical safeguards through the work of the ethical review committees while working on the regulations that are made by the oversight committee.<sup>111</sup>

Nevertheless, John Newton, the chief executive officer of the UK national biobank project states that once data had been given out under license for one research project, it could be difficult to control the further uses of the data. Therefore, the consumer's association and human Genetics prefers a more specific form of consent as they view the general consent as not being fully informed and ethically questionable. According to them, in order to study diseases, they need to be specified. Therefore, they see that all participants have the right to know what diseases they are giving sample for to be studied and hence receive a specific consent. This becomes a must specially while using the samples for commercial research. In addition, any other use that was not mentioned explicitly should require re-consenting the participant. the

human Genetics commission affirmatively recommends that all participants must receive thorough information about the research, its purpose, how the samples would be stored, how the data will be accessed and if there is any form of risk that would harm the participants.<sup>112</sup>

The experiences of these two genetic biobanks and other ones gave birth to consensus and arguments related to many subjective and other practical issues. These issues were extensively discussed through literature and anticipated to help future genetic biobanks.

### **3. Issues of consensus and of controversy**

#### **3.1 Subjective issues of consensus and of controversy**

##### **3.1.1 Participants rights**

Everyone agrees that participants have right to their own bodies and by products; the point instantly shifts from being a one of law and converts into one of right.<sup>113</sup> Since all human being own their own bodies in totality, they have the full right to decide and undertake to participate in studies and control the flow and generation of information from samples provided from their own bodies. Many debates tackled those rights including the commercialization debate, Benefit-sharing debate and finally Informing Participants about their research results.<sup>114</sup>

Commercialization of genetic research was another business that came out of the biobanks industries. Every now and then, the public receives new information about new commercial products that resulted from knowledge that was generated by research. The commercialization of genetics research has created opposed legal and ethical debates. This is happening due to internationally conflicted views towards the commercial interests and the public interest. The conflicting issue arises due to the inconsistency between the altruistic nature of the participation in a research and the opportunity for downstream users to commercially exploit the resulting knowledge. This knowledge would not have resulted without the altruistic willingness of the participants. Another fact is that researches are being rewarded with

intellectual property rights while on the other hand participants have no property rights on their samples or data. The conflict grows bigger with the fact that any monetary compensation is seen as ethically unacceptable while commercial exploitation of participation is not only acceptable but also desirable.<sup>115</sup>

The commercialization debate, focused on three areas: patenting rights and publicly funded research; the obligation to put data in the public domain; and, the permissibility of fees imposed on researchers using a repository. When it comes to genes, they are seen as products of nature therefore they are not supposed to be subject to patent law. However, without awarding patents, there's a worry that researchers and companies would lack an incentive to engage in scientific research and develop new products.<sup>116</sup> The principles of respect for autonomy and justice could be used as they play an important role in the analysis of some of the most burning issues relating to commercialization.<sup>117</sup>

### **3.1.2 Confidentiality and access to data**

Confidentiality might seem limited depending on the extent to which confidentiality is perceived as absolute or as overriding other principles or interests of all parties. However, all national and international guidelines agree that it's never absolute and that overriding it is the exceptional. Looking though literature, there were only few resources that reflected on the balance between confidentiality with other interests. Among the reasons that existed to justify overriding confidentiality were public safety and substantial harm to others. Another reason was consent of the sampled groups and the involved researchers. Finally, potential benefit if risks to confidentiality are proportional. The details of consent do not seem to be clear enough when it comes to confidentiality and therefore it goes under a lot of controversy. The usually asked question is whether consent is always sufficient? According to the WHO and the UNESCO

guidelines; they defend the fact that in undeniable situations, the consent appears to be insufficient. They consider consent to be deficient when information is being requested by third parties such as insurance companies, employers, state agencies who have the possibility of coercing individuals. The second question is; when can information be transmitted against the wishes of the donor? Guidelines were controversial around that question. Some accepted the traditional form of confidentiality that gives access to police, justice system or the state only when public safety is a concern. However, other guidelines gave more general exceptions to confidentiality such as for the prevention of crime or other forensic reasons. Nevertheless, others did not permit any form of access without the consent of the donor. The exception would be to prevent significant harm.<sup>118</sup> So how should prevention of significant harm' be interpreted? the understanding of what constitutes harm should be made more explicit as their interpretations can be made differently. Stephen Kelly case made is a clear example where confidentiality was violated in two studies. Hypothetically speaking, since the crime had already been carried out; the harm is irreversible and the punishment itself will not reduce harm that was done to the victim. Violating his confidentiality then adding 5 additional years to his imprisonment will lower the risk of him infecting others with HIV during those years but not afterwards during his liberty years of freedom. He also has the ability to infect other inmates. Some argue that such punishment would preventive others from doing similar crimes. However, this argument is weak and would only lead to have less prisoners consenting to joining research.<sup>119</sup>

Sharing data while assuring confidentiality is still a gray area. Seemingly guidelines vary from prohibition of samples leaving the country to the possibility of transfer of irreversibly anonymized data or even identified data. although the consent of the donor is generally a prerequisite, guidelines vary in the extent to which they require explicit consent to the transfer.

In conclusion, access should be granted to those researchers who are most likely to use the data and samples the most efficiently for the purpose to which the donor has consented. Another question is whether it should be mandatory to inform participants of the possible commercial uses of their samples or data. As usual, some guidelines do require that while others do not. Finally, should access by other researchers be limited according to the restrictions provided by patent law? Again, guidelines differ between explicit criticism and explicit acceptance of the present patent laws. The Protection of the participant's confidentiality remains the backbone of biobank research. It is crucial to find a balance between the advancement of science through global sharing of genetic databases and the protection of donors. There might be no single best answer, however its crucial to find a balanced process and the consequences of different protections, such as coding and anonymization, must be measured with scrutiny in order to guide further decisions.<sup>120</sup>

### **3.2 Practical issues of consensus and of controversy**

#### **3.2.1 Consent and withdrawal**

This is one of the most central and controversial ethical questions that are raised in the biomedical environment and genetic databases. Many ethical debates and international guidelines existed around issues related to consenting in the biobanking arena, there are two types of types of samples that create different arguments about consenting. Samples can be obtained and stored in biobanks for the purpose of research, while other samples were collected in advance for other purposes -mainly clinical- then stored and may be used later for research.<sup>121</sup>

Consent has a central role, however when it comes to biobanks, it's a tougher challenge for a long-term collection and conservation of samples or data. It harder to foresee the future research question, therefore the consent does not pronounce any future research on the samples and hence it is not informed. This makes it clear that the international guidelines on biobanks

lack consensus as regards the importance and relevance of informed consent in this traditional sense. Obtaining an informed consent is a norm that is agreed on internationally; while some have been advocating for global standards for taking consent, others have argued over the merits of respecting and integrating cultural, social and familial concepts into the consent as a way of adapting to the cultural equations being followed in a particular place.<sup>122</sup>

Hence there is a debate along the lines of informed consent or blanket consent that would indicate a clear agreement on part of the donor to collect the sample but would not be granting specific consent to use the samples for research in a particular area.<sup>123</sup> Thus depending on the field of research, one or the other type of consent is sought before collection of samples and starting the research. There are strong opponents and advocates of both types of consent.<sup>124</sup>

Since donors have the freedom of granting consent at the time their samples are collected, they also have the right to exercise the option of withdrawing consent. This right was stipulated in the Nuremberg Code and has since then been a very important part of classical research ethics. Some countries allow donors to request destruction their samples once they withdraw consent from future researches. The question is whether this could be done with genetic research. The fear is that allowing that would produce bias research results. Researchers state that the patients who withdraw are the ones who have experienced adverse effects; therefore, their data are extremely crucial to show negative effects of the medication being tested. Some argue that the right of withdrawal does not exist for research involving tissue samples or information as the donors are not directly burdened by the use of their data, detached body parts or their biological material. However, the other argument states that there is a form of harm such as violations of privacy or other non-physical harms that could arise from their material or data being used in research, therefore, participants should have the right to withdraw their data and samples too.<sup>125</sup>

The right to withdraw proves that consent to research is a continuous process rather than a one-time event, hence the research subject should be free to declare that they no longer wish to participate in a research project according to principle of autonomy.<sup>126</sup> However, should genetic data and material in biobanks be treated as the classical research? The leading statements on research ethics still exhibit the ambiguity regarding the application of the right to withdraw and could be interpreted differently.<sup>127</sup>

### **3.2.2 Dealing with samples**

Sample collection, organization, coding and anonymization form the basis for the successful operation of any biobank. Different biobanks follow different guidelines and therefore have distinctive requirements and various protocols and procedures adopted for the storage of samples and their record of characteristics. Patients and research participants, who provide genetic sample material, are increasingly worried about how their samples and data are being managed due to the sensitivity of genotype information.<sup>128</sup> The main concern is the unauthorized electronic access to the data files. The biggest risk is that their personal genetic information would be conveyed to third parties such as insurers and employers. Thereby and within this context, sample donors ask about the form of anonymization and coding that would be used for the storage and use of their samples and data.<sup>129</sup>

The argument starts by saying that there is nothing as non-identifiable samples. It is impossible to achieve complete anonymity for a human genetic data because DNA fingerprinting and cross-linking of different databases might permit identification of sample donors.<sup>130</sup> The opposite argument uses the (OHRP) definition of “non-identifiable”. To OHRP the genetic data and specimens are considered not to be identifiable when it cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.<sup>131</sup> Such



difference between the US regulations and different guidelines from other parts of the world regarding the notion of “identifiable” samples and information would cause issues whenever international research collaborations exists.<sup>132</sup>

Disposing samples and their associated data in a disciplined scientific manner is crucial to avoid the possibility of information leakage and survival. The issue still remains as to whether the donor should retain the right to destruction of the samples collected even after granting generalized consent or whether the same should be left up to the discretion of the researcher and biobank once they have obtained general consent from the donor. This challenging issue still exists due to the two interpretations of “withdrawal” that are incompatible.<sup>133</sup>

Implanting the confidence and trust of the public in such an industry has a paramount importance too. Any individual donor has the right to withdraw consent post submission of samples and that should always be respected. It has been predicted that the frequency of withdrawal is further complicated by the interactions between trust and withdrawal observed by some respondents. The trust is lost when participants are not offered liberal withdrawal options. Contrariwise, if withdrawal is certain, participants’ trust is increased, hence withdrawal would consequently be rarer.<sup>134</sup> Researchers express that by the time donors has permitted general consent, they shouldn’t claim for the future destruction of their samples. This becomes a matter of concern for biobanks where the samples have already been digitized and anonymized. Biobanks generally agree on the principle of withdrawal of consent while they haven’t established how this could be managed and executed in real.<sup>135</sup>

The group who fights for the full autonomy to withdrawing from research and destruction of samples, follow the traditional health research ethics as it is summarized in the Declaration of Helsinki and the WMA Declaration on Ethical Considerations Regarding Health Databases. On

the other hand, the group who believe that the withdrawal from an ongoing study should trigger the anonymization of the subject's samples and personal data are supported by the recent guidelines from the Council of Europe. The exiting guidelines for the researchers should clearly state the details of the samples destruction and timelines for the same that are in line with the consent taken from donors. Everything should be explained to the subjects in detail before they give consent to participate in a study, regardless which withdrawal policy is being used.<sup>136</sup>

These previously mentioned issues and other more derived from the experiences of existing biobanks were fruitful. They resulted in lessons that each new biobank considers and studies very well before starting.

#### **4 Lessons from existing issues in human genetic databases**

##### **4.1 A challenge with classic health research ethics framework**

Policy and guidelines makers must make clear while developing their work that there is a huge difference between research involving human subjects than the ones involving samples and data. When the differences were noted, ethical debates evolved around whether the framework of classical health research ethics needs to be changed. In 2008 the Declaration of Helsinki was updated and added a new paragraph with two propositions. There's a need to define what are considered as biological materials and data. The second proposition is to broaden the concept of consent. Such answers were needed to solve the problems related to feasibility of future biobanks. Therefore, the classical known framework had limits when applied immediately to biobanks. Hence, the Helsinki Declaration added a section that allows waiving consent for some type of research with identifiable samples or data. However, it did not state whether reversibly anonymized samples should be considered identifiable. Therefore, informed consent is no longer used as a gold standard for biobanks. The broadening the concept of consent and the definition of identifiable samples; is seen as a form of adaptation to expectation and not as conflicting

approaches. Having the old and new used together in a twofold framework provides a smoother consenting process. Hence, research participants would give a general consent to all future researches that entails reversible anonymized samples.<sup>137</sup>

The main problem with broadening the definition of identifiable samples and data; is that it does not require an approval from the research ethics committee when the research uses reversibly anonymized samples is declared to be research on non-identifiable samples. By that, the research is no longer considered a human subject research. The fact that biobanks require such diverse regulations owed to the binary choice between human subject research and non-human subject research should not be a condition to get away from rules and regulations. Therefore, ethic committees must improve and adjust their standards accordingly. Some IRBs are following that and creating approaches correspondingly. The best example would be the novel ethics approval mechanism exists for tissue banks in the United Kingdom.<sup>138</sup>

Such a general approval allows biobanks to acquire samples according to an approved protocol by the IRB. Then use allow researchers to get samples and use tissue with no need for a new approval as long as the activates are in the range of scope of the biobanks projects. That means that researchers do not have to seek individual approvals each single time. Researchers become automatically covered by the biobank's general approval.

By now it seems obvious that biobanks research has been a huge challenge to research ethics. All solutions are made as minor adjustments while maintaining the classical known framework. Through the history of biobanks, the lesson was learned that the classical framework cannot and should not be changed fundamentally. However, adaptation was needed in order to follow the classical values of research ethics along with the public's perception. Solidarity has been and yet still hard to be inflected according to the pure interest of biobanks' managers,

therefore, adaptation was the solution. Biobanks are seen as means to produce better healthcare to the community. Therefore, the need for altruism is justifiable. The concept of altruism shows obvious on the biobanks websites and related conferences. They invite the community to be nice and participate. The best example is seen through the UK biobank experience; when 354,271 persons participated.<sup>139</sup>

#### **4.2 Lessons learned from the productive dialog**

All the existing guidelines since the last twenty years are the result of the reactions of many troubled births and life stories at different biobanks. These issues occurred all over the world in Europe, North America and even in other international sites. These guide lines are the mirror of pursued values and principles on both local and global levels. These guidelines tend to solve the ethical and legal problems. It gets harder when trying to find a global solution that would balance and satisfy the western and eastern societies.<sup>140</sup>

Since the nineteen eighties; several frameworks existed that had different directions. Some gave full priority to autonomy of the patients and the research participants while others focused on solidarity with society and family. These two directions made it harder to find guidelines to focus on first then to agree upon later. Since then, the public started discussing biobanks along with the occurring controversy. The media had its share in facilitating the discussion and bringing it to the international debate level.<sup>141</sup>

Some argue that there is no history for the guidelines, as they are continuously changing and being replaced by new ones. Some of these old guidelines can be found posted online while others have no track as they were written over twenty years ago. Conversely, others view the history of guidelines differently; as the authoritative power keeps updating the guidelines to protect humans' rights since the era of the Second World War. This is viewed as a progression

more than having no history of guidelines. The changes that are continuously made are actually reassuring and show the richness of the work done over the guidelines. The ideas, the reflections and even the disagreements should all be seen as advancement in the field. It should be noted that what was written during the 1980s and until the beginnings of the twenty-first century is still valid. The drafts, the reflections should all be honored and viewed as enriching the field. Regardless the disagreements and the conflicting ideas; there is a lot of agreement on the basics. Its impressive to find that this degree of agreement on guidelines comes from different countries in different times and contexts.<sup>142</sup>

The birth of each biobank is accompanied with the development of more guidelines that are more specified to the scope of its work. These guidelines are influenced by many national and international bodies such as human rights organizations and international courts. Moreover, even several human rights-related concerns of the population had its own influence on the structure of some earlier biobanks. Therefore, biobanks are seen as a sort of trial and error: new ethical questions emerged and different biobanks created ethical governance frameworks that were tested in real-life scenarios.

## **5 Conclusion**

The pitfalls of some might create the success path for others. However, these pitfalls must be studied closely and carefully in order to achieve the required accomplishments. Some old challenges seem to be under control while other challenges remain challenges for even future biobanks. Some debated issues must be clarified to what extent are the controversial recommendations of international bodies are due to disagreement on fundamental ethical questions, while compared to a different evaluation of the empirical facts and the lack of a practical solution to the problems.<sup>143</sup> The very first human genetic biobanks seemed to suffer mainly with consent and confidentiality issues along with other practical and subjective issues.

Consent and withdrawal of consent, confidentiality, feedback of results, benefit sharing remain and dealing with samples are issues where empirical research of this type of issues is important to identify the most beneficial approaches for the future. Empirical research on different ethical frameworks seems to be still underfunded. Therefore, attention, funding and much more resources must be allocated towards those issues.<sup>144</sup> This would help create a smoother path for newer biobanks to develop. Nevertheless, and so far, the short history of biobanks made out several lessons. Biobank research is indeed a challenge to classical research ethics. However, the developed, argued and challenged guidelines on the local or international levels were a success in the lifetime of biobank regardless their functionality. the presence of the existing guidelines illustrates the richness of local and international approaches and the struggle to find shared solutions despite conflicting and overlapping ethical and legal guidance. This calls for more collaboration between national and international bodies to harmonize the guidelines. These guidelines were the huge steps towards the improvement and progress of more fixed guidelines that would be the corner stones of future biobanks. The construction of international ethics guidelines and the creation of standard operating procedures for biobank research is high priority task on the agenda of a global civil society and research community. Such a community would be responsible for protecting research subjects while maintaining respect for human rights and global justice.<sup>145</sup>

## **C. Privacy Bio-banking**

### **1. Introduction**

Biobanking was regarded as one of the top ten ‘ideas changing the world’ as published in the Times Magazine in 2009.<sup>146</sup> Bio-banks are one of the most important tools for the furthering of medical research and knowledge in the field of medicine and pharmaceuticals. Biobanking

includes the process of storing and cataloging a vast array of genes and tissue samples which is then used for research purposes as and when the need arises. The samples that are stored must provide the proper context to make their retrieval easy, convenient and targeted.<sup>147</sup> Therefore, this proper context and information has to be captured to enable researchers and scientists to make sense of and find the right samples for study and analysis. However, in order to have this ready and well managed by bio-banks for researchers, it has to be collected on proper ethical and legal bases according to international guidelines. This starts by having the participant or donor's consent. Consents can vary in type according to the policy that the biobank follows. It can also differ according to the underlying reason that led to the collection of the sample. Therefore, several issues and arguments arose around the notion of consent in the genetic bio-banking field. After obtaining the permission of working with the samples comes the issues related to storing and identifying those samples within the bio-banks. Bio-banks are faced with issues such as the anonymization and coding, destruction of the samples and data and even considering the ownership of samples. This is another bioethical issue that leads to one more ethical debate, which deals with the participants' rights. This would involve the several topics such as informing the participants about the results, benefit-sharing and Remuneration and public domain sharing, patents, and fees that result from<sup>[17]</sup> those researches research that involve genetic databases. Biobanks have the potential to change the world through the knowledge production they facilitate and socio-political transfigurations they imply. However, it has to be managed and regulated both ethically and legally in order to properly serve humanity.<sup>148</sup>

## **2. Ethical Issues regarding genetic bio-banking and possible solutions:**

Parts of the human body have served medicine since its very beginning. History shows that in the first half of the twentieth century, human body parts started to be collected not to only study their anatomy but also to create a structured research resource. This is similar to what is

known as bio-banks in our time. In those times, samples were gathered without informing people whom they originated from as tissue was seen as wastes. Healthcare professionals thought that such form of waste product belonged to them after having their patients undergo medical procedure that enabled its procurement. During that time, most bio-banks were almost too mundane and unproblematic to attract any major attention. However, by the 1990s, bio-banks became surrounded by more intense scholarly debates about ethical, legal and social issues that stressed on patient rights. This was explained by the sudden interest in tissue collections and the beginning of genetic research methodologies. The size of the biobanks –compared to small research labs- was another factor that led to these ethical, legal and social issues. With the increased interest in genetic susceptibility for multi-factorial diseases, Biobanks served as a fertile field for research than did small labs and with that increased the ELSI. These factors resulted in a new moral, legal and social landscape. Many discussions have arisen in this late century within the biomedical field around several ethical questions and concerns regarding genetic biobanks. Biomedical technology has undoubtedly been a driving force and an extremely useful tool for research purposes and the furthering of human knowledge regarding genetics, diseases. Yet, questions remain on some important issues that biobanks face every day.<sup>149</sup>

## **2.1 Consent**

One of the most central and controversial ethical questions that are raised in the biomedical environment and genetic databases are the issues around informed consent. Many ethical debates and international guidelines existed around issues related to consenting in the biobanking arena, there are two types of samples that create different arguments about consenting. Samples can be obtained and stored in biobanks for the purpose of research, while other samples were collected in advance for other purposes -mainly clinical- then stored and may



be used later for research.<sup>150</sup>

### **2.1.1. Consent to Use Samples**

There are several positions towards the use of consent in biobanks with two extreme positions and several intermediate positions. The first extreme is the use of the blanket consent. This solution was defended in the WHO publication where it stated that a blanket informed consent seems to be the most efficient and economical tactic to help avoid the costs for having to re-contact the participants prior to each single new project. However, WHO had some conditions such as that the consent form should specify that family members might request access to a sample to learn their own genetic status but not that of the donor. This would allow the use of a genetic sample in research in general including future unspecified projects.<sup>151</sup> The European Society of Human Genetics and Human Genome Organization (HUGO) both propose that type of broad consent.<sup>152</sup> The ESHG believe that it is difficult to predict all the possible research applications that a collection may be used for; therefore, it seems to be wiser to use a broader consent. By that, there will not be any need to re-contact the participants. However, the subjects should be able to communicate if they wish to withdraw.<sup>153</sup> An additional important query arises when considering the possible death of the sample donor. In such a case, would it be ethically right and morally responsible for a biobank to part with the samples taken in the interests of research and study? Some believe that the dead donors will not be harmed in any way if their samples are used for dissection and dissemination of knowledge. While others point out that even dead participants have reputations and blood relatives that can get hurt. Thus, when informed and specific consent is sought, the applicant expresses if the samples collected are to be destroyed after death and not to be used further, this makes the course of action clearer.<sup>154</sup>

On the other hand, comes the group who believe that consent must be provided in writing

to all proposed use(s) of the sample such as the Genetic Privacy Act (GPA).<sup>155</sup> Likewise come the American Society of Human Genetics (ASHG). They both encourage that biobanks do obtain informed consent for all studies involving identified DNA samples, including prospective as well as all retrospective studies. The only time it is not needed is when there is a waiver granted. Both organizations believe that DNA samples are the property of the person with whom they are taken. Therefore, the ASHG considers it inappropriate to grant a blanket consent for all future unspecified genetic research projects when the samples are identifiable.<sup>156</sup>

Additional to the two previous positions, there are several intermediate positions. These positions have been suggested by researchers and others who are involved in the Biobanking field as they believe that obtaining consent for each study is costly and would hamper research because it is expected that only a low percentage of research participants that can be reached after several years for new consent.<sup>157</sup> However, the blanket consent gives the implication of abuse to the research participants who provides samples for unlimited use and do not see the future risks, therefore, several ethical propositions have been suggested and fall in between of the two extremes.<sup>158</sup> The most accepted position at the North America is the “Multilayered consent”. This was suggested by the NBAC, the RMGA and the Tri-Council Policy Statement. Through the multilayered consent, participants have the possibility to give or refuse consent to a large number of options. It allows the research participants to from several options mentioned in the comprehensive consent form when the researchers intend to have secondary uses for the genetic material or genetic data. Another way to do it is to have a more limited consent form that has arrangements to keep in contact with the sample donor for the future uses of the sample or data. Whichever is used, the researcher should explain this clearly during an informed consent.<sup>159</sup>

This can be achieved by irreversibly anonymizing the samples. It would allow the

researchers to use identified samples for one defined study such as the one it was originally collected for. This option would help in not having to re-contact the participants again while having the ability to use the sample again. Moreover, this this can be done with or without the participants' permission to be re-contacted for other studies. With that option, participants have the right to authorize the use of their samples for research in some areas and to exclude others.<sup>160</sup> A second intermediate solution would be to use a form of semi-blanket consent. This can be done only if the other researches are going to be in the same overall domain or about the same condition that the first study was collected for.<sup>161</sup> A third intermediate strategy is to use a presumed consent or to use a form of opt out policy. According to the HUGO guidelines, they allow for a solution that seems similar to blanket consent only if the research participant have been notified and have the opportunity to object to further use of coded samples.<sup>162</sup>

It is central that consent be taken to study samples -whether informed or blanket- be taken at the very start of the process of collecting samples to have a clarity in the minds of the collector as well as the donor as to the possible future uses of the samples collected.<sup>163</sup> Thus, as discussed above, for the purpose of future research it becomes important to take broad general consent.<sup>164</sup> Specific informed consent creates a hassle when a new research question or theory arises and it becomes necessary to contact the donors and trace them down for an update. While many types of consent have been accepted yet the acceptance varied. Still, most ethical opinions agree that consent should not be construed. The literature does not show any form of agreement regarding the guidelines on consent to research involving biobanks. Yet, all intermediate solutions seem to depart to some extent from the classical doctrine of informed consent.<sup>165</sup>

### **2.1.2. Consent to Research Samples Obtained During Medical Care<sup>[L] [SEP]</sup>**

While it is taken for granted that samples collected and taken while treating a patient would obviously be subjected to tests and study to try and detect the exact nature of the condition that affects the patient, it becomes unclear which path to take in the unfortunate event of the patient's death and when a need arises for samples or tissue from that particular patient.<sup>166</sup> This situation demands slightly deeper introspection as the factors affecting the granting of consent have changed in this context. In a biobank, donors have been informed at least once that their samples would be utilized for research purposes whereas the same may not be the case for samples collected during administration of medical care to a patient.<sup>167</sup> Secondly, it becomes important to judge the state of mind and capacity of a person hospitalized for care to grant consent for the use of samples collected for medical and research purposes such as for a patient suffering from a severe head trauma or a neurological condition who might not be able to grant consent with full independent capacity.<sup>168</sup> Most importantly, even if one were to come up with a standardized procedure to obtain and record consent from patients in a hospital setting, the thousands and millions of samples that lie uncatalogued in medical institutions collected under vastly different circumstances and situations would be a tricky minefield to navigate.<sup>169</sup> In most cases it would be impossible to contact the patients again to obtain their consent for a specific purpose. There are only few international guidelines that addressed the issue of research use of samples taken in a clinical setting is a major worldwide problem. These samples are stored mostly in hospitals, universities and pathology departments.<sup>170</sup>

### **2.1.3 Collective Consent**

In biomedical research, the human genes can produce so much information about a person. This can have tremendous implications on the person's relatives and even his entire ethnic group. Therefore, the entire population would be seen as the "subject of research".<sup>171</sup>

Actually some biomedical research does focus on learning about the genomes of distinct populations or the frequencies of particular genes of interest in a specific population rather than the individuals whose genetic material is used.<sup>172</sup> Genetic testing and research may serve to identify a cluster of people within a larger population, and thereby they become a distinct group. Therefore, the burdens and risks would fall on the entire population or ethnic group rather than on the individuals who are participating in the research. Moreover, it becomes a greater issue when the genetic study encompasses a population that has a form of traditions where they believe in a collective form decision-making rather than the Western norm of individual choice.<sup>173</sup>

This all began twenty years ago when western researchers from industrialized countries started conducting research in non-western, developing countries. In these countries decision making usually revolved around collective consent rather than the individual considerations of well-being. At such communities, the leaders find it more advisable to consider the entire group's perspective. The Human Genome Diversity Project was targeted towards collecting genetic material from different distinct population from all around the world. By that time, it seemed that the research ethical guidelines were too focused on the individual to protect him and not on the community, which would not work for some communities.<sup>174</sup> Since then, commentators remained divided on the proper way to protect group interests. Some commentators believe that it is difficult and even impossible to seek collective consent for several reasons such as having to designate the appropriate representatives of groups and how to properly define the boundaries of a group.<sup>175</sup> Juengst has pointed out that the individuals of a specific community are the ones who define the boundaries of their group, however it might be harmful to redefine those boundaries through genetic research. Therefore, he believes in seeking the group's permission but only when there is a social structure for collective consent do exist.<sup>176</sup>

However, others recommend making the requirement for group involvement less stringent, such as through procedures of consultation. The purposes behind seeking permission and consulting a group range from the practical to the ethical reasons, which are requisite for ethical research. Therefore, the group consent is recommended when there is a need to protect the collective interests of that group. There are cases where the group interest differs and may conflict with the individual's interest. Additionally, the idea behind a collective consent may serve as a form of screening that helps in protecting prospective subjects. Some participants would not be able to properly apprehend the risks and benefits due to poverty or lack of education.<sup>177</sup>

Based on the principle of autonomy; many fought for the individual's autonomy, however, others who believe in collective consent argued that the procedure was essential in order to respect group identity or what is even called "group autonomy". One main reason to accept the collective consent is that in developing countries there are communities that are community-oriented and where people are vulnerable. Unlike the west where the individual has always been protected through awareness, constitutions and culture. Therefore, such protecting mechanism should be followed in genetic researching whenever the community is prone to exploitation due to poverty, and lack of education. In indigenous communities, the research consent language can sound complicated and scientific and it makes bioethicists wonder whether the individual person is clearly aware of all the implications of the research investigations. Hence, a collective approach was needed to safeguard all individual interests. After agreeing on using collective consent, there are some points that need to be taken into account before applying this mechanism. As a beginning; it is important to identify the representative of a community. Afterwards, it is important to make sure that he/she adequately represents their community. It is a very delicate ethical issue to find the fitting community representative as there is a potential

for misrepresentation. There were cases where instead of protecting the interests of all members of the community, a wrong community representative might reinforce his authoritative powers and exploit the weaker members within the group. Henceforth and as a partial remedy, some have suggested having a third party such as an IRB. The IRB would serve as an additional gatekeeper although there are some questions whether a foreign IRB would have the ability to pinpoint the symptoms of misrepresentation.<sup>178</sup>

An inquiry exists around the idea of have both collective consent and individual consent coexisting in one population. This can be seen as two different situations: in communities where the individual's autonomy has the primary importance or where many members of a group are located far away from each other, there's a possibility for a widespread public consultation that can be followed by the individual informed consent. Conversely, settings where researchers have sought and obtained the consent for the leader, it might be a futile exercise to ask for individual consent. It seems that the more traditional the community was, the easier it is to define the representatives. Nevertheless, in such a case it is also more likely that community members will not be willing to depart from a decision made by the group leaders.<sup>179</sup>

To find a global consensus on collective consent for genetic biobanks, there is a need to study that aspect more on both the theoretical and procedural aspects of collective involvement. Educating the researchers and the IRB on the important cultural aspects of various research settings is one important step. It could help in creating or reforming the consent form besides choosing legitimate representatives where collective involvement is required and in detecting the symptoms of misrepresentation. Finally, it is always obligatory to work towards developing alternative solutions based on existing needs of the sitting. The solutions need to stem from a common drive in order to conduct an ethical research that protects and benefits all

stakeholders.<sup>180</sup>

#### **2.1.4. Withdrawal of Consent**

Since donors have the freedom of granting consent at the time their samples are collected, they also have the right to exercise the option of withdrawing consent for their samples to be used further in any study or research without their express permission. This right was stipulated in the Nuremberg Code and has since then been a very important part of classical research ethics. Moreover, in most countries it is allowed that donors can request for a destruction of all their samples once they withdraw consent from future researches. Plus, during the course of the experiment the human subject should be at liberty to bring the experiment to an end, if he/she had a physical or mental reason to that. According to the Nuremberg Code, the original understanding was that research subjects can walk away and no one can force them to stay in a study they do not wish to continue with taking experimental drugs or be hospitalized. The question being asked is whether this could be done when it is a genetic research and if subjects may withdraw not only themselves but also their biological material and personal data that they have already provided to the researchers and the biobanks. The fear is that allowing research participants to exercise the right to withdraw the data and the samples would produce bias research results. Researchers state that the patients who withdraw are the ones who have experienced adverse effects; therefore their data are extremely crucial to show negative effects of the medication being tested. Some argue that the right of withdrawal does not exist for research involving tissue samples or information as the donors are not directly burdened by the use of their data, detached body parts or their biological material. They relate that to the idea that the right to withdraw was originally formulated as a means of ensuring that research subjects remain free to limit their participation based on their immediate suffering in an experiment. However,



the other argument states that there is a form of harm such as violations of privacy or other non-physical harms that could arise from their material or data being used in research, therefore, participants should have the right to withdraw their data and samples too.<sup>181</sup>

The right to withdraw proves that consent to research is a continuous process rather than a one-time event, hence the research subject should always be free to declare that they no longer wish to participate in a research project even if their data and biological materials that are held by the biobanks. The principle of autonomy suggests that research participants don't need to give a reason for withdrawing from a research. Whenever this is not applied, then the research would not be ethical.<sup>182</sup>

The huge issue that is still bioethicists face is the meaning of withdrawal when it comes to genetic data and material in biobanks. Should it be treated as the classical research or differently? And to what extent have research subjects the right to control the use of their own health information generated during research. The leading statements on research ethics exhibit the ambiguity regarding the application of the right to withdraw. The Declaration of Helsinki could be interpreted in at least two ways. Article 22 states that the “subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal”.<sup>183</sup> After figuring out consenting issues, there's a need to consider the thing that biobanks is handling, which is the genetic material or samples.

## **2.2 Samples**

Sample collection, organization, coding and anonymization form the basis for the successful operation of any biobank. Different biobanks follow different guidelines and therefore have distinctive requirements and various protocols and procedures adopted for the storage of samples and their record of characteristics.

### 2.2.1 Anonymization and Coding

Patients and research participants, who provide genetic sample material, are increasingly worried about how their samples and data are being managed due to the sensitivity of genotype information.<sup>184</sup> The public's main concern is the unauthorized electronic access to the data files that uses their genetic data for illicit purposes, therefore, they ask for stricter control. The biggest risk is that their personal genetic information would be conveyed to third parties such as insurers and employers. Thereby and within this context, sample donors ask about the form of anonymization and coding that would be used for the storage and use of their samples and data.<sup>185</sup>

There are various methods by which the samples may be achieved. They could either identified or anonymized. Samples are considered to be identified if the information that allows identification such as the name and address are associated directly with the tissue. On the other hand, anonymization of samples may be achieved through different levels, first comes the unlinked anonymized. This method implies that the biological samples collected are stored together with the relevant related data such as donor age, characteristics and medical records. However, any data that has the potential to identify the donor is irreversibly erased.<sup>186</sup> Second is the linked anonymized where the procedure remains the same as unlinked anonymized with the difference that the information linking the donor to the sample is coded and made searchable and reversible. Thus, the individual donor might be identified if the coding for anonymization is reversed. Finally, are the coded samples, the method of data storage and retrieval involves the use of a code that is linked to the anonymized donor data. Thus, the method of storage used is the same as that for a linked anonymized sample with the difference being that the researchers would have the code access to retrieve identification information upon needs arising.<sup>187</sup>

The Declaration of Helsinki states that the "Medical research involving human subjects

includes research on identifiable human material or identifiable data”. This could mean that any research that uses non-identifiable samples does not need to meet the ethical and legal requirements of medical research such as IRB approval and informed consent. However, the literature shows that the definition of “identifiable” reveals that the meaning is anything but clear. A multitude of different terminologies exists in literature and every guideline uses a different vocabulary. This Communication barrier causes a huge issue for biobanks, researchers and participants.<sup>188</sup>

The argument starts by saying that there is nothing as non-identifiable samples. It is impossible to achieve complete anonymity for a human genetic data because DNA fingerprinting and cross-linking of different databases might permit identification of sample donors. the opposite argument uses the US Office for Human Research Protection (OHRP) the definition of “non-identifiable”. To OHRP the genetic data and specimens are not considered to be identifiable when it cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. This definition provides researchers with a simple means to escape the strict regulations.<sup>189</sup> Therefore, any form of future research in the US is authorized without the need for consent or IRB approval. It is important to note that such difference between the US regulations and different guidelines from other parts of the world regarding the notion of “identifiable” samples and information would cause issues whenever international research collaborations exists.<sup>190</sup>

### **2.2.2. Ownership of Samples and Data** <sup>[1]</sup><sub>[SEP]</sub>

Once the samples have been collected and anonymized and recorded for permanent storage, it becomes difficult to pinpoint the ownership of the samples whether it is the collecting biobank or the donor. As per the European Union Database Protection Directive which was formulated in

1995 to act as a guiding principle on the use of personal data, it clearly states that samples and the information generated out of the study of such samples is the property and right of the researcher that comes up with the results and analyzed data.<sup>191</sup>

The ownership of samples and data produced arguments. Different countries had different solutions and approaches to the problem. For example, Icelandic law states that the government has custodial rights to the whole sample set whereas the original donors would enjoy ownership rights. Contrastingly, a small minority in the US calls for depositories or the blood banks themselves to be designated owners of the samples to instill confidence by researchers and scientists of the stability of data sets created and research conducted.<sup>192</sup>

This declaration is to given by the participants at the time of agreeing for donating samples that they would be giving up ownership rights to the samples that have been collected from them. In many discussions, the issue of international transfer of samples and associated rights and information presents another challenge of unimagined complexities. While most respondents and researchers feel that science being a global human endeavor should not have any restrictions and boundaries on the flow and exchange of information, others put forth the point of protection of the right of the donor and preventing foreign countries from taking control of the samples and the research seems to be a relinquishing of said rights.<sup>193</sup>

Another argument is from the fact that genetic heredity and culture may be treated as a national heritage and needs to be protected as such along with other natural resources such as oil and gas, fisheries etc. Moreover, some sections also stated that national security could be a deciding factor in allowing the free cooperation and exchange of information regarding the samples and associated data. For example, studies conducted on an entire homogenous population might be used for targeted attacks on said population through the use of biological weaponry.

Though it's an exaggerated idea, it holds validity as an argument point. The opposing view to this states that scientific research falls flat on its face without the luxury of having comparison possible across countries and generations for research purposes.<sup>194</sup>

Others say that the topic becomes debatable when one considers that most biobanks are not funded and run by the government but are in fact expensive propositions that are managed by multinational corporations, the question of territorial integrity and sharing of information becomes difficult.<sup>195</sup> Thus instead of looking at a territorial perspective of the issue, it is important to note that the guiding factors should be the continued and productive research of the medical and scientific community in the interest of all of humanity.<sup>196</sup>

### **2.2.3 Destruction of Samples**

The destruction of the samples and the issue of withdrawal of consent are both related. It's important to dispose samples as well as the associated data in a disciplined scientific manner to avoid the possibility of information leakage and survival. The issue still remains as to whether the donor should retain the right to destruction of the samples collected even after granting generalized consent or whether the same should be left up to the discretion of the researcher and biobank once they have obtained general consent from the donor. This challenging issue still exists due to the two interpretations of "withdrawal" that are incompatible.<sup>197</sup>

It is important to implant confidence and trust of the public in such an industry which already carried with it a weigh of contention and public outcry, the rights and respects of the donor be given paramount importance. Any individual donor has the right to withdraw consent post submission of samples and that should always be respected. It has been predicted that the frequency of withdrawal is further complicated by the interactions between trust and withdrawal observed by some respondents. The trust is lost when participants are not offered liberal

withdrawal options. Contrariwise, if withdrawal is certain, participants' trust is increased, hence withdrawal would consequently be rarer.<sup>198</sup>

Researchers express that by the time donors have permitted general consent and participated in the process of collection of the samples, they shouldn't claim for the future destruction of their samples and withdraw from the study. However even agreeing to this destruction becomes a matter of concern for biobanks where the samples have already been digitized and anonymized. It becomes an issue when the links from the donor to sample have been stripped of identifying characteristics and rendered untraceable. This means that biobanks generally agree on the principle of withdrawal of consent while they haven't established how this could be managed and executed in real. Therefore, when the donor is not traceable anymore, withdrawal becomes an even more tricky procedure.<sup>199</sup>

Another issue that needs a mutually agreeable solution is the seeking of re-consent once a minor child comes of age and can be classified as an adult. The consent taken from the child's parents or guardians at the time of sample collection ideally needs to be validated once the child comes of age but there is yet to be agreement on this issue of how it needs to be approached and executed.<sup>200</sup>

The group who fights for the full autonomy to withdrawing from research and destruction of samples, follow the traditional health research ethics as it is summarized in the Declaration of Helsinki and the WMA Declaration on Ethical Considerations Regarding Health Databases. On the other hand, the group who believe that the withdrawal from an ongoing study should trigger the anonymization of the subject's samples and personal data are supported by the recent guidelines from the Council of Europe.<sup>201</sup>

Another argument is based on the person's "autonomy rights" after death in the same

context of withdrawing. Some use an extreme approach arguing that autonomy indicates ongoing control over samples, which means that samples shouldn't be used as the deceased subject is no longer able to control. Others argue that autonomy of the research participants as absolute which implies that decisions they made during their lifetime is binding for research after their death. Still some argue differently, point control rights over genetic information either to blood relatives who share genetic risks with the research participant, or a representative appointed by the research subject before death. However, being practical, disagreements between family members will occur. Additionally, it'd be hard to locate family members and legal representatives after the death of sample donors. These issues occur because present guidelines do not provide any help regarding how these questions should be decided. A suggestion or framework that has been recently discussed in Australia as part of deliberations on said topics. Public has pronounced that guidelines for the researchers should state, in a transparent manner, the details of the samples destruction and timelines for the same that are in line with the consent taken from donors. Everything regarding withdrawal from the research should be explained to the subjects in detail before they give consent to participate in a study, regardless which withdrawal policy is being used. After dealing with the samples issues and finishing the research, the public calls for the rights and shares of the research participants.<sup>202</sup>

### **2.3 Participants' rights**

The discussion takes an interesting turn when one considers that participants have right to their own bodies and by products; the point instantly shifts from being a one of law and converts into one of right.<sup>203</sup> Since all human being own their own bodies in totality, they have the full right to decide and undertake to participate in studies and control the flow and generation of information from samples provided from their own bodies. After the sequencing of the human genome had

started, there has been considerable interest and public discussion regarding the setting up of biobanks either by private corporations or through public-private partnerships to further the cause of scientific research into understanding and decoding the secrets of virulent viruses and human DNA makeup. It thus becomes important to initially decide and fix upon how the benefits derived from such vast investments would be shared and distributed between all stakeholders in the project.<sup>204</sup>

### **2.3.1 Public Domain Sharing, Patents, and Fees:**

The commercialization of genetic research is a growing business. Everyday new commercial products are introduced to the public from the resulted knowledge generated by research. The commercialization of genetics research has created opposed legal and ethical debates. This is happening due to internationally conflicted views towards the commercial interests and the public interest. Moreover, the altruistic nature of the participation in a research is inconsistent with the opportunity for downstream users to commercially exploit knowledge. Such knowledge would not have been there without the altruistic willingness of the research subjects. Another reason is that the researches are seen rewarded with intellectual property rights while the research participants have no property rights on their samples or data. Finally, any monetary compensation is ethically unacceptable while commercial exploitation of participation is not only acceptable but also desirable. It provides an incentive to do research. The commercialization debate, focused on three areas: patenting rights and publicly funded research; the obligation to put data in the public domain; and, the permissibility of fees imposed on researchers using a repository.<sup>205</sup> When it comes to genes, they are products of nature therefore they are not supposed to be subject to patent law. However, without awarding patents, there's a worry that researchers and companies would lack an incentive to engage in scientific research



and develop new products.<sup>206</sup> It has been proposed that data is put in a public domain where the public owns it rather than an individual researcher or institution. This is an alternative to a property-based approach. A public domain ensures that no person or other legal entity can establish or maintain proprietary interests within a particular legal jurisdiction. Yet this means that anyone may use or exploit this data, whether for commercial or non-commercial purposes. Foray argued that an open science model would counter the still dominant commercialization model. It is providing more efficient dissemination of information, encourages its widespread use, while minimizing the transaction costs. Before the biobank era, researchers collected samples, conducted research, and exploited the commercial benefits. However, biobanks had challenged this as they are research infrastructures that collect and store samples. They rarely conduct the research that leads to commercial profits, thus its unlikely for them to make profit of their holdings. However, biobanks are costly resources. Many Commentators agree about having researchers pay fee for the biobanks services but they question if biobanks can request fees that go beyond mere cost recovery to make profit. Such a practical query demands further research.<sup>207</sup>

The commercialization is a very controversial topic and the debate on patenting rights and commercial exploitation of genetic research is not easily settled.<sup>208</sup> There's a need to conduct on research to uncover the roots of these disagreements and their implications for policy. The principles of respect for autonomy and justice could be used as they play an important role in the analysis of some of the most burning issues relating to commercialization.<sup>209</sup>

### **2.3.2 Benefit-sharing and Compensation**

One of the important remarks regarding benefit-sharing is that there is no constant recurring patterns between the choices and the reason given for them. everyone agrees that there should be a form of benefit-sharing scheme but several questions arise along with that, such as

when, who, what and how? This calls for leaving the choice of benefit-sharing to the population was balanced by concerns that it might lead to exploitation. Exploitation could be internal by the governing council or external by both sponsors and/or researchers. Therefore, the public divided to groups where some base their argument on the concepts of reciprocity and benefits according to contribution. Others base their arguments on more general principles of fairness and justice. Yet others preferred practical approaches.<sup>210</sup>

Having access to free genetic tests was seen by some as a fair compensation, but it was also ruled out as inadequate. Therefore, sharing a percentage of the profits that accrue from research was seen as considerable and flexible for the population. This solution also raised the concerns of exploitation. It might be a slippery slope into financial incentives for participation in research. Another idea was to provide medical equipment to the community that would contribute to its welfare. Nevertheless, it would unlikely to reach everyone who contributed to the research. Finally, ownership of intellectual property rights was one of the most argued on choices. However, it raised the previous ethical questions on the ownership of the samples beside the worries of exploitation.<sup>211</sup>

Between the issues of undue inducement and exploitation, benefit-sharing comes across as a very delicate procedure. It remains hard to have a clear proposition for international guidelines. However, it is still seeming that the need for benefit-sharing is widely supported and require further in-depth global discussion.<sup>212</sup>

### **2.3.3 Informing Participants about Research Results**

General consents do not show a set of timeframe to use samples, therefore it seems that samples can be used for research with no boundaries as to their vintage. For that exact reason, there were several arguments around the topic regarding the nature and quality of feedback to be

shared with the participants of the study if there is any feedback to be shared at all. However, it seems to be a burdensome task to have to re-contact all the participants whose samples have been taken to be a part of a study that has been conducted and then share the findings of the studies with them. Another issue that arise each time a research is conducted is that it becomes impossible to contact the donors of randomized, anonymized samples that have been stripped of all identifying characteristics.<sup>213</sup>

Some people are concerned that the information that results from clinical or non-clinical research may not reach research participants, although it may be very beneficial for the subject. They see that the tests conducted or the research undertaken has some significance in terms of identifying new methods or prospective medicines of treating certain illnesses.<sup>214</sup> On the other hand, others question the truthfulness of the anonymization process if any important results would be reported to the subjects. Traditionally, scholars have analyzed this issue in terms of participants' right to know and right not to know, thereby came the value of informed consent. The data of this study is consistent with this perspective. Some suggested that this approach could be complemented with disseminating to the public information about the research results. It can be achieved through posting them on the repository's website. There's a need to visualize the feedback of research results. This entails rethinking the role of researchers, and their obligations towards research participants.<sup>215</sup> When surveyed, many subjects are willing to inflict duties on researchers beyond the mere creation of general knowledge. They believe that beneficence requires that information potentially of use to participants ought to be passed on to them, this trend is counteracted by the views of others who believe that returning research results is not a biobank's duty and that it's more harmful than being good to share the results.<sup>216</sup>

In developed countries where clinicians have proper training in genetic counseling, participants indicated that genetic counseling is beyond the scope of conducting research and that clinicians must be responsible for conveying research findings to subjects. On the other hand, come participants from regions with poor health care systems who believe that the repository is ultimately responsible for handling genetic information. The contribution in research seems invaluable to those communities. This shows clearly that policies differ according to the country and this causes a bigger issue when having an international research.<sup>217</sup>

Using technology, there are new opportunities for making links between researchers and participants. Kohane and colleagues have developed the “informed cohort” model and personally controlled health records. This could allow researchers to communicate with participants without violating anonymity.<sup>218</sup>

Implementing the research participants’ right to know remains controversial. It’s still important that researchers re-think their relationship with participants. However, the debate goes on biobanking and the sharing of research results challenges the traditional view that researchers are not required to share research findings with participants.<sup>219</sup>

### **3. Conclusion**

Since biobanks play a central role in era of genetic research and new biotechnology, it was essential to go through its ethical ramification. Consent was and will remain the heart of ethical practice in this context. Many types were suggested but varied ethically according to its use. Literature didn’t hold any form of international agreement regarding the guidelines on consent to research involving biobanks.<sup>220</sup> This called for studying the mentioned forms of consent on both the theoretical and procedural aspects. Moreover, the focus on consent issues in genetic Biobanking included the notion of withdrawal too, as it varied from withdrawing from small researches. The main problem was caused by the vague existing ethical guidelines. Educating

researchers, IRBs and the public about their rights and responsibilities was one important step in achieving an ethical approach. After figuring out all issues and arguments around consenting, biobanks start faced the issues with storing, anonymization, and coding the genetic samples. Regardless the form of anonymization being used, its clear that there is nothing as non-identifiable samples due to the existence of the genetic material. Hence, guidelines and extra attention was being concentrated towards figuring and agreeing on the ownership of the samples in order to solve another issue such as withdrawing and destruction of the genetic samples. Public trust was a critical point to keep in mind while solving this issue domestically and globally.<sup>221</sup> And after the conduction the research came the need to understand the rights of the participants. The commercialization debate remained extremely controversial, and this area demanded further research and investigating in the future.<sup>222</sup> Benefit-sharing was widely discussed worldwide and supported by the public. However, the need to have a unified form of guidelines around it remained an issue.<sup>223</sup> Finally, several arguments opposed each other around the nature and quality of feedback that must be shared with the participants of the study if there is any feedback to be shared at all. This called for researchers to re-think their relationship with participants.<sup>224</sup> Looking at the big picture, it showed that the base of all existing problems was the classical ethical guidelines at hand. Those guidelines were meant to be for smaller researches and not for huge databases and genetic biobanks. Therefore, there's an urgent need to update or even form new ethics guidelines that would serve as the backbone for biobanks in a genetic context.<sup>225</sup>

## **D. Privacy Big Data in Healthcare**

### **1. Introduction**

As a result of the continuous evolving innovations and transformations of the web technologies, mobiles and sensing devices and other technologies; gigantic amounts of data are

being created and produced daily on an extraordinary rate. Traditional technical methods are struggling in operating and saving processes when faced with such massive data. Hence, the concept of Big Data has created a revolution that promises not only to solve those issues but to change how human's lives on every single aspect of life. Big Data ensures solving the issue of preserving the unlimited amounts of data like no other traditional database could. This inelegant analytical technology has the potential to facilitate the optimization of any process while empowering insight discoveries to improve the course of decision making. Accordingly, that can be achieved through the use of algorithms that extracts values from the massive amounts of data. This is machine learning at its core. Traditional machine learning methodologies were based upon multiple conventions where data is expected to fit into memory to complete a process which is difficult for the mean time and impossible in the near future.<sup>226</sup> However, the great practicalities and approaches of Big Data comes with a whole big package of challenges and ethical matters such as the privacy issue. And when considering what Big Data should offer to healthcare sector and biomedical research filed; privacy issues become profound and more sensitive due to the presence of the genetic element. This necessitates a closer study of the ethical aspects and challenges that are ahead of Big Data in the healthcare context.<sup>227</sup> Henceforward, the privacy concerns prevail as the most distressing ethical issue related to the utilization of Big Data technologies in the healthcare sector. Moreover, and since Big Data is an industrial technology, it would serve healthcare insurance companies more than other healthcare parties. However, this demands tackling the privacy issues that seem to be specifically unique within the healthcare insurance business in the era of Big Data.<sup>228</sup>

## **2. The Concept of Big Data**

### **2.1. Understanding What is Big Data**

Some say that “Big Data” is a meme and a marketing term for the future trending technology which will allow decision making with a better understanding to the world. Largely speaking, Big Data is the process of analyzing big datasets. It has been referred to as Big for several reasons; whether it was in terms of quantities and variables or for the procedural abilities it has. Big Data can manage enormous quantities of electronic data whether it was in gegas, teras or even petabytes. It can accept that in terms of entries, events and personal data. On the other hand, another explanation is related to the level of artificial intelligence that is acquired by Big Data. It has technological performances that makes it able to accomplish a human’s analytical work in computational means. This ability is combined by the massive and complex amount of information it holds. Therefore, Big Data deserves such a name since its features are incomparable with the existing computing technologies.<sup>229</sup>

Humans generate, capture and use massive amounts of information every day. Data keeps growing by the second, growing at fifty percent per year or doubling every two years according to IDC the technology research company. Such data isn’t only streams of data, but also entirely newly generated ones. Whether it was through online purchases, social media uses, handling financial possessions, business and medical diagnosis, all are entangled in data. There is an innumerable number of digital sensors spread around the world. Those digital sensors can almost be found automobiles, electrical meters, industrial equipment and shipping crates. Different sensors can measure and send different information such as location, movement, vibration, temperature, humidity, even chemical changes in the air. The industrial internet was created through the linkage of the communicating sensors to computing intelligence.<sup>230</sup>

Big Data is also fueled by the improved access to information move. This can be seen in the governmental data progressive migration to the web. For example, in 2009, Washington started the web site: Data.gov, which is a web site that allows all kinds of governmental data to be reachable and available to the public. This adds a lot to the sensitive information that is available for artificial analysis usage. This means that Data is not only becoming more available but also more comprehensible to the computers.<sup>231</sup>

A big portion of the Big data is streamed in the wild as a word, image or a video that has been gathered through sensors. This type of data is not usable in traditional data bases and therefore is called unstructured data. However, Big Data is able to analyze such data due to rapidly advancing techniques of artificial intelligence like natural-language processing, pattern recognition and machine learning. Two known examples are the experimental robot cars Google's search and ad business. Both two examples face a lot of challenges while using a bundle of artificial-intelligence tricks along with parsing vast quantities of data and making decisions promptly.<sup>232</sup>

Since some believe that knowing everything is better, Big Data has been catching the attention of the modern society. In all where such data is needed to be saved and used for many purposes medical, non-medical and research requirements. With all the attention its getting, obviously Big Data has its own captivating idea where it can deliver high expectation of the digital past pace world that no other existing technology is able to achieve.<sup>233</sup>

Nevertheless, this idea of Big Data seems elusive for many people since it has no definite definition that have been agreed on until now. So far it has been described as having these four characteristics; volume, velocity, variety and veracity. These features are not what



really attracts the world to the spark of Big data, but it is the idea of it as a valuable natural resource of readily collected public and private information to be used.<sup>234</sup>

Some believe that personal data is the oil that liquefies the internet. Every person sits on his own immeasurable reserve. The reserve is seen as the names, address, pictures, preferences and locations that are all information that are provided to companies through our internet-enabled smartphones and computers. Companies can then target advertising options depending on geo-locations and personal preferences.<sup>235</sup>

With every emerging new technology comes the need to understand its potential moral issues. The ethical foresight might affect the expected uses and regulations of Big Data. there are many issues on the social level such as the social justice, social profiling, the right to access big data, collective rights and the trust issues that might occur between the data subjects and the data users and even the processors. On the other hand, there are the classic known issues as privacy and confidentiality, informed consent, research ethics, ownership of the data and the anonymity issues.<sup>236</sup>

Big Data wasn't dedicated to serve bio-medicine and healthcare only. The very beginnings of Big Data were within social media, google, Wikipedia and loyalty cards points used at merchants. Another use was the collected data through smartphones whether it was related to geolocations or health habits.<sup>237</sup> All these different kinds of data were used to explain individuals' attitudes towards disease outbreaks, epidemic tragedies and vaccinations.<sup>238</sup>

## **2.2 The Individual's Privacy through Big Data Technology**

Privacy concerns have been the foremost raised issue when talking about Big Data. Therefore; data protection became a primary requirement whenever companies or governments deal with the individuals' information. It deals with the public's expectation of privacy, the

ethical and legal issues related to it when technologies such as big data is able to collect, diffuse and analyze personal information.<sup>239</sup>

When personal identifiable material is gathered, stored to be used –whether it was in a digital form or else- privacy concerns are elevated. The reason behind that is that there is no disclosure control or at least a proper one regarding the privacy of such information. Hence, there's a need to discover how manage privacy is controlled and managed though the application of Big Data.<sup>240</sup>

Data privacy is a wide issue as it related to many fields where digital data is in use, such as healthcare, genetic material, financial transactions, geolocation, cookies, web surfing behaviors and criminal justice investigations. Big Data has been a great help in all those fields and more however, there are complex ethical challenges that need to be treated first. This is not an overestimation of privacy; examples can be seen in real life incidences where Big Data was used for non-medical purposes such yet trampled over individuals' privacy.<sup>241</sup>

Loyalty cards had a notorious story back in 2012 when Target's analysts predicted that a teenage girl was pregnant through her purchases' history. She was sent a series of pregnancy product coupons to her house which made her father upset just to realize that his daughter was pregnant for real. This story was cited several times throughout literature. That was one of the very first incidents that showed that disturbing strange face of Big Data.<sup>242</sup>

The fact that such personal information is available and visible for unknown, untrusted others is pondered as a fundamental privacy invasion. Although such information might not be used to harm an individual nor be communicated beyond that database, nonetheless social harm is a possibility and a dreadful concern to almost everyone. Apparently, no consent is fashioned to use any behavioral or health information when a person signs a loyalty card with a departmental

store. Although pregnancy is only diagnosed through a urine or a blood test through the measurement of the hormones, yet the history of someone's shopping list was able to predict pregnancy. Regardless the fact that shopping lists are not considered as biomedical data, nevertheless this raises the bar of privacy concerns even higher. Apparently, in the real world; personal information and health indications can be pretty much driven from non-biomedical data.<sup>243</sup>

Secondly, when it comes to social media, a biomedical study was executed using publically available information on a social media website. Freileld and his colleagues were successfully able to collect and identify many medications' adverse events that were related to twenty-three medical conditions through twitter. Freileld and his team used around seven million twitter posts where most tweets had references to a specific medical product. That study was performed in order to help pharmacovigilance gathering. Pharmacovigilance is the method used to collect and evaluate the adverse events of medical products. The US Food and Drug Administration and many other national and international drug regulators; mandate the compendium of adverse effects. The collection of such data is critically needed in order to understand the biomedical process and emphasize the reactions and their extent. However, reality shows that adverse events are either poorly reported or under reported. Hence, such limitation of data would pose risks on the welfare of the patients and moreover on the budgets of the healthcare systems. There is a necessity to improve pharmacovigilance, therefore; Freileld and his colleagues' manner seemed appealing to regulatory authorities, however such a method cannot be utilized and depended on. Improving pharmacovigilance is not the case here, what is catching is the fact that twitter users were and are still not aware of such gathering of their information. Many wonder if it is alright to use such information since it is publicly available.

Another point to consider is whether the usual private and public dichotomy are the same in online world. More importantly is whether the data users hold any responsibility towards the individuals whom data showed serious adverse events. Hence, the question raised is if there's a moral obligation that requires them to provide care or advice towards the individuals using tweeter subsequently to the discovery of the adverse events?<sup>244</sup>

These issues have been discussed thoroughly in the field of biomedical research. Codes and regulations were created to govern the rights of the participants when research is conducted over their samples or data. However, the current process does not cover Big Data when it comes to protecting the autonomy, privacy and the anonymity in biomedical research.<sup>245</sup>

For instant, informed consent is obtained prior to the beginning of any biomedical research as a requirement to protect the ethical aspects. This process is mainly expected to cover the autonomy of the research participants. Apparently, many arguments go on around the validity of informed consent and whether it is really protecting the research participant autonomy or just to cover the research and the researchers legally. Research ethics seem to still lack nuance when it comes to the requirements of informed consent. Nevertheless, this does not mean that research on social media could proceed without any form of regulation, whether it gathers social or biomedical data.<sup>246</sup>

Despite the fact that the twitter posts are not considered biomedical data and it is hard for users to predict that their posts would be used when they register and agree to consent. Social media users expect that that nothing beyond their posts would be public and that privacy is maintained online like in the physical real world. However, it is easy to be tracked and have personal data used that are extracted from the posts.<sup>247</sup>

Another area where data has been exploited and is expected to be used more often in the future; is the data generated throughout the use of smart phones and mobile devices. Simply and by carrying a smartphone; health data as well as geo-location detection can be generated and collected any much more. Nevertheless, such data collection is not mentioned at any clause of the telecommunication service terms. Such a thing is expected to be mentioned in the cell phone contract and patient consent. It is expected that if such a piece of information was mentioned; that people would opt out of the data collection. Apparently, this isn't avoidable unless the individual would stop carrying a phone.<sup>248</sup>

A study was performed to estimate how much time people consume over their smart phones, daily location and how that is linked to depression and its severity. On the basis of such data; symptoms of depression were detected where the results were more accurate than the ones resulting from the use of questioners. Researchers claim that they have created an objective measure of behaviors that enables them to detect depression without asking questions where such detection is done passively. With such created algorithm; it will be possible to screen a population and detect individuals at risk of severe depression and even give alerts of characters with a suicidal tendency. The Samaritans charity had introduced an application that could detect individuals with suicidal risk through analyzing their tweeter feedback. This application has raised many arguments and debates and hence it was stopped and withdrawn as it breaches privacy and raises stigmatization concerns.<sup>249</sup>

In regard to healthcare, when the Ebola pandemic crisis occurred in 2014-2015, smart phones' data were accessed in affected areas. This proved that such data could help predict and gather health information when an infectious disease and other health emergencies happen. The

mobile phones' data were exploited in the affected regions with Ebola for surveillance to help trace the mobility of individuals and the disease.<sup>250</sup>

Using mobile data even in an international health emergency had ethical issues on several levels. There were no policies that allowed the swift of such data from telecommunication companies in which the customers have an agreement with. Mobile data are not considered as biomedical data, nonetheless they were tremendously valuable to such a new uncontrollable pandemic occurrence. The data were way more accurate and beneficial than whatever available sets of data were at that time. It enabled the identification of the disease trajectories where health and governmental authorities were able to identify and trace the individuals in risk.<sup>251</sup>

### **3. Big Data in Healthcare & Biomedical Research**

Many medical fields are being affected by the revolution of Big Data such as epidemiology, genomics, genetics and infectious diseases. When it comes to biomedical research; Big data has proven that it is a major reason for its success and revolution. Biomedical Big Data is known as the emerging technologies driven phenomena that focuses on the analysis of the accumulating sets of data in order to improve the medical knowledge and clinical care. When it comes to healthcare; it is not a far future where each patient would have a virtual cloud related to him or her of health data. Such a cloud would hold billions of health facts including history, current diseases, treatments, monitored habits and even future health needs that would be predicted through algorithms.<sup>252</sup>

#### **3.1 The Possible Contribution of big data to healthcare**

As a prediction of the future for the possible use of Big Data in healthcare, there's a need to generate and collect an ever-greater amount of volumes of information about every patient. Such information would be gathered from inside and outside the clinic. Big Data can be very

helpful to the healthcare field in the near future as it has a huge potential to provide advancements in regards to prevention of diseases, diagnosis, treatments and even fostering healthy habits. Another reason to procure the technology of Big Data in healthcare and bioscience is that it is able to reduce the cost containment and lessen the medical errors. However, healthcare data has always had this inherent sensitivity to it. This sensitivity is due to the imbedded vulnerability and needs of the individuals' who the data belongs to.<sup>253</sup>

Microsoft HealthVault is one service that has been available in the United States for a while. It allows the patients to collect share and even store their own health information with different physicians or even share it with family members. Moreover, Microsoft HealthVault enables direct upload of data from compatible devices which measures the patient's heart rates, the peak airway flow, blood pressure and even the blood sugar levels. The New York Presbyterian Hospital is getting a contract with Microsoft HealthVault to exchange data. However, Microsoft HealthVault specifically reveals that it does not use such personal health information for commercialization without the individual's informed consent.<sup>254</sup>

Since healthcare started using the electronic healthcare system; a rapid increase and improvement in the quality of the patients' care has been witnessed. However, it is becoming extremely hard to manage and process the healthcare data due to the excessive increase of its volume just using the traditional processors. Therefore, and since there's a need to extract values from healthcare data; it is required to consider what Big Data could provide to the healthcare segment.<sup>255</sup>

Big Data holds a lot of promises to healthcare sector within its technology. Starting with the ability to provide better Evidence based care which is the new trend that medicine is shifting towards. Evidence medicine uses subjective decision making which results in the provision of

treatments that are based on the existing scientific evidences. Henceforth, Big Data will be able to contribute to such evidenced based care through the aggregation of data collections from miscellaneous sources. Simply the recurrent trends and similar patterns showing in the data will postulate enough evidence to help Evidence Medicine with the diagnosis and treatment of patients.<sup>256</sup>

Subsequently this would result in another benefit which is the improvement of the quality of patient care. In other words, Big Data would be able to improve the quality of care when it shows that the decision made regarding their health care was based on high volume data that is applicable to their condition and up-to-date data.<sup>257</sup>

The third expected benefit of using Big Data in healthcare is that it would enable more effective communication between the patients and their healthcare providers. This is not limited on a personal or a regional level; it is expected to involve patients and care givers on a global level. Patients and physicians who share an interest about a cure or preventive methods, will be able to communicate, discuss and exchange information. This could also facilitate the interoperability across healthcare institutes worldwide.<sup>258</sup>

The increased communication level will lead to the fourth benefit of Big Data in healthcare. Big Data will be able to increase the patients' participation in their own healthcare. This can mean several things; as patients have access to their own accurate up-to-date data, they feel more indulged and in control of their own health. Moreover, they would be able to make more decision regarding their care while understanding the different available choice. Eventually this will result in prevention care; where patient work on improving their lifestyle to prevent chronic diseases.<sup>259</sup>



However, the previous two benefits call for the refining of the public health surveillance and some view this as one of the Big Data benefits. With modern technology, humans are able to track, record and even send their health data to their physicians through wearable health monitors and sensors. Furthermore, the innovative tools are expected to increase the public health surveillance by recording and analyzing healthcare data. This would track disease outbreaks and prevent further transmission similarly to what had happened during the Ebola outbreak. Health surveillance is expected to increase the public health education and active response to health issues. However, the downside to such measure is the privacy invasion.<sup>260</sup>

With all the previous mentioned benefits, it would be expected that there will be an obvious evident reduction in the mortality rates. Since Big Data would ensure early detection, proper evidence based diagnosis and treatment with enhanced communication between patients and care providers, hence there will be an understandable reduction in both morbidity and mortality rates.<sup>261</sup>

Furthermore, Big Data will enable the reduction of healthcare costs which is one of main challenges that the healthcare industry is faced with. Apparently and unfortunately, the costs of healthcare delivery are growing annually almost everywhere around the world. Using analytical data along with the innovative technologies and tools would enable the cut of healthcare costs by 300 billion dollars per year in the United States of America according to a study conducted by Priyanka and Kulennavar. Apparently, the costs of healthcare in the United States were about 16.9 percent of the Gross Domestic Product in 2012. Furthermore, according to a survey that was carried out by a Health Research Institute; readily available health information is able to cut the costs of healthcare significantly. It also showed that patients would use non-traditional forms of healthcare that could be done home which cost less if proven to be accurate. Hence, such

reduction in the costs of healthcare was expected to be around 8 percent of the national healthcare expenditures.<sup>262</sup>

Finally, from an ethical business point of view, Big Data will enable the early detection of fraud and security threats that would occur in the healthcare sector. Since there is an ability to monitor patterns of claims and the irregularities would be easily spotted. This is a very helpful feature for the insurance companies' business.<sup>263</sup>

The fact that diseases are not all genetic related made scientists think about studying the other contributing factors such as environmental, social, behavioral and socioeconomic. This would enable humans to understand illnesses and how to prevent them in a better way. This might develop a more accurate phenotype category. Subsequently, this would be the point where biomedical research and medicine meet where they both use Big Data for welfare of humans their own advancement. The collaboration of the two fields would result in Precision medicine.<sup>264</sup>

The billion bits of data points would be gathered about individuals and put at bio-banks. Those biorepositories would carry information from medical histories, genetic sequencing, life streaming, behavioral and health habits, former and current diagnosis, imaging and laboratory results and the interactions with environment. These are considered medical resources however there are other non-medical resources such as the data streamed through mobile devices, social media interactions, internet researchers and merchant purchases. The collection of such information is extremely highly dimensional, unorganized and heterogenous; would require an analytical process that would also have the ability to handle complex data sets while running massively on several servers.<sup>265</sup>

Precision Medicine is the paragon of the Big Data Medicine. Then and for the possibility of such a kind of medicine to exist; all the previously mentioned forms of information will require interconnectedness along with permissible accessibility for several parties. Users of that huge amount of data would include different institutions, different regions, physicians, and researchers. However, such approachability is impossible with the existing data construction available today in regards to the methods that data are collected or stored.<sup>266</sup>

Knowledge Commons was suggested at the NRC report in 2011. This infrastructure would allow data collection and sharing. However, it requires a considerable reorientation to the informational system used by both clinicians and researchers. The reorientation would make every single visit to a clinician; a data collection acquisition. This must become a part of the routine clinical care that all patients would undertake. Looking at this from another point, this means that every clinical care routine would be also a research gathering consequence.<sup>267</sup>

Eventually, medicine and bio-science would become inseparable. Nonetheless the process does not end here, as all the gathered information must be converted into portable yet also utilizable data. The next step would be to facilitate the data flow but only to the meant users in order to protect it from being abused by others. Hence and to be able to have such a process; data architectures must work on designing a protected bio-depository that has the ability to carry, transport and share that enormous amounts of data crossing all institutional, regulatory and cultural barriers while being highly protected. The significant level of protection is produced by the sensitivity of the patients' personal information and patients' rights.<sup>268</sup>

Biomedicine has been lately focusing over the genomic relation of diseases and human genes. However, genomics alone cannot explain the complexity of the manifestation of diseases. Apparently, there are many variables other than the gene by itself, hence data driven techniques

are being investigated to get an understanding of illnesses. Big Data gave promising results in biomedical research and clinical decision making when used to identify who becomes ill and when. However, this requires having access to as much data to both healthy and sick patients. Therefore, there is a need to educate the population about that need and what advantages it would produce to the community.<sup>269</sup>

### **3.2 The Relevance of Big Data to Genetic Bio-banking and related Privacy Concerns**

The increased number of human's biological samples and data stored has led to the demand of increasing the data storage capacity. Such information is stored at facilities called bio-banks. Bio-banks have been part of the history of many cohort studies specially disease specific tissue banks. Current bio-banks are bio-repositories of humans' samples, their associated numerical data, statistics, images and tables. They provide a platform for generating knowledge. Epidemiologists, laboratory scientists, statisticians, bio-informaticians, social and clinical scientists, researcher, ethical and legal scholars are the infrastructure scientists who share the creation of the knowledge that occurs in a bio-bank. Therefore, and since bio-banks are the resource of information, this makes the health researchers and scientist legibly positioned to use the data and samples that are reserved in a bio-bank.<sup>270</sup> It is obvious that biomedical research is all about studying humans' data which contain very personal information. Hence, there is a vast threat to the privacy of the individuals' and the leakage of their sensitive information in case of inappropriate use of these data. therefore, several privacy protection methods have been developed in order to protect the sensitive information. Nevertheless, with the advancement of technology also attackers advance their methods to break the security of the protected data.<sup>271</sup>

The quality of the researches comes from the high-quality bio-banks as they are the resource of the health data and other genetic information and bio-markers. Whether these

researches were general, medical, genetic, disease-related or for personalized medicine.

However, this expansion on the level of large scale bio-banks has its own new set of ethical challenges.<sup>272</sup>

The process of storage at any bio-bank happens in four stages which starts with the extraction of the sample, storing the sample, sequencing the data of the sample and finally, using the sequenced data. A sample donor may have interests and securities in all and each of the mentioned steps. These disease-specific and population-based bio-banks are absorbed to the new consent procedures due to the need for practicing long-term storing of both bio-specimens and their related data. The different uses and types of research created the need to use more than the standard consent. There is a direction towards the broad consent and the dynamic consent as there are unspecified future research projects that are still unanticipated. However, there is a need to explore more how this would exist in the era of Big Data.<sup>273</sup>

Since it became much easier and affordable to get human genomic data as a consequent result to the dramatic reduction of the genetic sequencing prices. With the enormous collection of genetic data that are being reserved; the discovery of new treatments is enabled and effective diagnosis methods are developed. This allowed the birth of Precision Medicine Initiative which aims to use health records of one million patients and link it to their genomic data in the United States. This is still functioning in the means of bio-banks. New legislations are in need when such genetic information would be accessible by everyone and analyzed through Big Data.<sup>274</sup>

However, the expected success of the utilization of Big Data in bio-medical research is also full of concerns and uncertainties. The large scale of genomic data raises concerns related to privacy and confidentiality. regardless the used measures to remove explicit identifiers such as names; genomic data has its unique issue when it comes to privacy. Sensitive information can be

easily leaked such as identity, appearance, predisposition of diseases and more even after stripping the explicit identifiers. The harm goes beyond the individual who the genomic data belongs to; it has the ability to disclose information about others who share the genes. Therefore, privacy risk may disseminate to the blood relatives.<sup>275</sup>

The privacy risk might increase by time as the genomic data are irrevocable once they are public. The risk becomes bigger with the availability of other data that could be linked to the genomic ones. Additionally, the risk to privacy increased with the accumulation of knowledge and new understandings about the human genes. Finally, even with the creation of advance protection methods; attackers develop their invasion methods too. Hence, close monitoring and security advancement is in need.<sup>276</sup>

Like Internet advertisers, biomedical researchers would like to have access to quantities of genetic and health data through Big Data. regardless the fact that it is probable to identify people. Some researchers believe that using genome information to re-identify somebody in a research dataset is very low. However, privacy is right that must be maintained and protected in all circumstances. The GWAS policy of the NIH might be the starting point that directs bio-banks, bio-medical researchers, policy makers and legislators when thinking about utilizing Big Data and understanding the privacy right.<sup>277</sup>

#### **4. The Aspects and Challenges of Big Data in healthcare**

In the era of Big Data and even before that since technologies were incorporated in healthcare; the face of healthcare changed and new challenges had emerged. The medial field had to discover, understand and solve the ethical challenges specifically the privacy and confidentiality issues when hospitals started using electronic patient records. Since Paper-based patient records are being constantly and unremittingly uploaded to their electronic format, since then patients are able to access their own records via the Internet.<sup>278</sup>

That was by far the latest new technology that spread almost everywhere. However, now and as technology keeps bring up new additions, sensor networks for in-home patient monitoring are the forefront of new technologies that generate a massive amount of health data. This type of remote patient monitoring is becoming more practicable with increased coverage among patients. Consequentially, the combination of the two technologies is promising to improve the quality of patients' health and healthcare in general as medicine becomes more personalized. It also guarantees less medical errors and an evident reduction in healthcare costs. However, while there are these palpable benefits there is also challenges and issues associated with security and privacy issues that needs a lot of attention and work in order to make these next-generation health care technologies reasonable and acceptable to the society.<sup>279</sup>

There is no doubt that big data has positive influence on healthcare and humans. However Big Data is faced by major challenges before it can proceed to help the healthcare community. One of the major challenges is that there is a lack of provided information that enables decision making, planning and strategy and not a lack of data. this means that health data needs to be authenticated, processed and then incorporated to Big Data in order to extricate values and results from it.<sup>280</sup>

It appears that healthcare has the tendency to resist changes unlike other fields such as business. This might be explained by the lack of trust in technology and concerns of legal and ethical issues. Another reason might be the inadequate administrative support for Information Technology and the related recurrent practical changes that it usually has, where healthcare is not ready to accept any exposure that could endanger patients' privacy, their medical data or rights. Furthermore, the healthcare staff is knowledgeable and occupied by several skills but not the appropriate skills for the operation of the new Information Technology. Hereafter, it is found that

hospitals and medical facilities still utilize the paper based record system along with the electronic based one in case of a sudden failure in the later one.<sup>281</sup>

Moreover, it seems that there are two technical problems that arise from the healthcare systems side. The first is the proliferation of healthcare standards where it is found that different hospitals follow different standards. This can be observed in the expression of the codes of case reports, examinations, drugs and diseases and how they vary in different healthcare facilities. Consequently, have such incompatibility in healthcare standards would obstruct the interoperability over the diverse systems.<sup>282</sup>

The other challenge of Big Data is the fragmentation and dispersion of data which are stored in proprietary heterogeneous systems over different healthcare facilities. It has been determined that it is a difficult mission to extract and analyze data through Big Data from the integrated healthcare data because of the different schemes, systems design, metadata and standards that are presented in the hydrogenous healthcare systems.<sup>283</sup>

For an ethical point of view, Big Data is confronted by a range of different ethical challenges including the privacy and confidentiality of the data, the commercialization of the de-identified patients' data, controlling the accessibility to the patients' information, the governance and the ownership of the patients' data. all the previous factors, hinder a facilitated effective exchange of data between patients and their healthcare providers and between healthcare facilities and organizations. Accordingly, the integration of the healthcare data from several resources becomes a challenge. Hence, it becomes hard to access and have a complete picture of a patient in a timely manner in order to provide proper care.<sup>284</sup>

Finally, security and privacy issues are the major ethical challenge facing Big Data when trying to integrate miscellaneous sources of healthcare information to Big Data. this is the main



reason that discourages both patients and healthcare providers from sharing patients' health information in such a huge highly accessible data reserve. There are several threats such as the unauthorized destruction of the patients' data, the unauthorized usage of the patients' data and the improper disclosure of patients' data that has sensitive personal information.<sup>285</sup>

#### **4.1. The Challenges of Big Data in Healthcare**

Privacy matters have been one of the major legislative concern. This is not new to the law; however, new updates and changes must be adapted whenever new technologies are introduced such as Big Data. since earlier in the time; regulations for the protection of personal information have been established such as the Privacy Act in Australia in 1988, the European Union in 1995, the PIPEDA in Canada in the 2000.<sup>286</sup>

The United States had its own sectoral approach as it created several privacy acts for different areas. The HIPAA was developed in the year 1996 as a privacy regulation for healthcare. Gramm-Leach-Bliley was made for the financial sector in 1999 while COPPA was designed for the protection of the children's data in 1998. Furthermore, principles were also established such as the Fair Information Practices in the year 2000, and the OECD Privacy Principles in the 2010. These privacy principles are meant to address the rules that different organizations should follow when dealing and using with personal information. Hence, personal privacy must be protected based on based these privacy principles and laws.<sup>287</sup>

In the era of Big Data, a different scheme is introduced, the Personally identifiable information is being provided by the individuals themselves. Such provision may be done in order to gain some benefits and conveniences that are being provided through the web services and the information platform whether they were medical, social or even business related. The

privacy risk occurs when the Personally identifiable information is used alone or along with other information to enable the identification, contact or even locating an individual. The person's privacy maybe compromised once such information is made publically available. Since then, it is not controllable to manage who and how it might be used.<sup>288</sup>

Several anonymization techniques have been developed and used to allow maximum protection to the individual privacy while enabling beneficial usage of their data. De-identification and anonymization are the methods where personal identifiers are removed from the data so that the data can no longer be associated with an individual in anyway. Nonetheless, selecting and applying these techniques is not a very simple task in the context of Big Data as it is in regular data bases.<sup>289</sup>

What makes Big Data special is the same thing that is harming the privacy of the individuals; which is its ability to analyze data and extract sensitive information even from raw anonymized data. this becomes worse when dealing with genetic and health information. The major challenge lies in between keeping the data available and useful for organizations to use while maintaining the individuals' privacy.<sup>290</sup>

Perfect privacy is achieved by publishing nothing but this has zero utility benefit while perfect utility can be achieved by have the data available as received from the individuals; where no privacy is offered. Hence, this could only mean that as the privacy protection level increases; the utility of data decreases which is not what this industrial world want. However, work must be done in order to utilize Big Data while overcoming the privacy challenges.<sup>291</sup>

This means that much attention should be devoted towards efficient privacy-preserving computing. This requires the collaboration of several fields and professions to foster the future's development of a research roadmap and address the privacy challenge. The collaborative work

would enable suitable methodologies and tools for privacy-preserving big data storage and analytics processes that focuses on anonymity.<sup>292</sup>

Encryption is another used method to protect the privacy of individuals when using their data. it is believed to be the dominant practice for privacy protection in the meantime.

Cryptography can be used in the Big Data age in different forms and manners. Since the emergence of Big Data, clouds are used to serve because of their economical nature and accessibility feature. This could be explained in the ability of a patients to use the public key of their healthcare provider to encrypt medical documents, and deposit the encryption text into the online database for their own treatment while their privacy is strictly conserved. Therefore, clouds are being utilized to carry medical data sets which concerns the patients' privacy.<sup>293</sup>

However, medical records can only be accessed by authorized healthcare givers and not by the public. This make the public key encryption inconvenient incase the number of the authorized persons is sufficiently large due to the key management issue. Technically speaking, the Attribute Based Encryption is the tool to be used with healthcare data. it is a set of descriptive elements of the related parties that need to be entered such as doctor ID hospital ID and patient's ID in order to generate a secret key to encrypt messages. The decryption is allowed only when the set of attributes of the user key matches the attributes of the cipher text. Yet, with Big Data there are several challenges with encryption based privacy protection as there's a demand to have adequate privacy safeguard for all the users, at the same time. Moreover, there's a need to have all the encrypted data informative and meaningful for big data analysis and public usage. Therefore, there are several challenges with Big Data in the technology world which is translated into insufficient protection and privacy risks in the ethical and legislative terms.

Therefore, encryption is able to protect the privacy yet it is weak and vulnerable with traffic analysis attack against anonymous communication systems.<sup>294</sup>

The main ethical debate around Big Data in healthcare is how could it be employed for the common good while respecting the individuals' right to liberty; specially the right to privacy. Obviously, such a concern isn't new to healthcare and particularly the public health research field. Privacy and data security have always been a consistent concern that required continuous work and maintenance in the building of the new information infrastructures. However, in this case and regarding Big Data; the issues must be studied and tackled according to the new context. The intent is to figure out those ethical concerns and tensions that emerge with such a complex new technology. This is not something special to Big Data but it is a must whenever a new technology is used with threats to the individuals' privacy. Furthermore, applicable standards must be set according to the different uses of Big Data in the healthcare and bioscience. Nevertheless, there's a concern that such preoccupation with these procedural issues might lead to a perceptual form of blindness. Such conceptual blindness would shift the public and even the professional attention from the advantages of Big Data in healthcare and biomedicine.<sup>295</sup>

It seems that the public believes that big data is covered by the legislative actions that protects privacy such as The Health Information Technology for Economic and Clinical Act HITECH and The Health Insurance Portability and Accountability Act HIPAA. However, big data is amounts of information that is consolidated and linked to other data. Big data is not covered by HIPAA and is not protected by law like health data is; at least for now. Most provisional laws related to data are creating moves around the issues of privacy without having the actual efforts to define privacy while the need to that is extreme <sup>296</sup>

The main issue with the use of big data is that privacy can be breached in several ways. First, data could be gathered without the individuals being aware of that. There are several examples that have already occurred such as the Facebook emotional study and the cupid study. Second, individuals might be aware that their information is collected however information isn't available for them to know how it might be used and for what. This can be translated that patient might have no idea how their information is being used through Big Data and whether they might be benefited or harmed by it.<sup>297</sup>

#### **4.2 Big Data's Contribution to Health Insurance & the related Privacy Concerns**

Since Big Data has become the new trending technology in different life sectors; electronic healthcare records, online businesses, banking and other more; insurance companies became also interested in the numerous benefits it would offer. Big Data seems to have a huge influence not only over healthcare and bioscience research but also over healthcare insurance companies and the healthcare business in general. Thereafter, insurance companies are exhibiting a lot of attentiveness toward the analytical abilities of Big Data. Such a feature would improve their flow of work, detect fraud and increase profits.<sup>298</sup>

Usually, healthcare insurance companies have vast datasets that encompasses patients' information, doctor office's information and hospitals' information. When these datasets are brought up together into a one data stream, they form what is known as the electronic medical record. From these datasets, health insurance companies extract several information. They run these information through applications that enables an advance level of analytical performance since it uses methods such as predictive-modeling techniques and predictive modeling procedures.<sup>299</sup>

It is important to note that they disclose all patients' private information using a data encoding algorithm. Interestingly, the United States' Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) safeguards the security and privacy of electronic and paper-based health record but that does not include Big Data yet.<sup>300</sup>

Healthcare insurance companies use systems that use validation techniques to process medical claims and detect invalid bills. The downside to these systems is that they do such a process individually without considering the other claims involved in the single patient care event. Moreover, insurance companies still do not have a transparent method to show their clients the value they receive for paying additional charges and premiums. The currently used systems cannot adjudicate on issues that might constitute abuse and waste. Therefore, it is important for health insurance companies to have access to high level analytical systems where they can identify and understand errors, fraud, waste and abuse. Using systems that are linked to Big Data would enable uniform comparative measures to regulate the quality of healthcare provided to their clients.<sup>301</sup>

Moreover, insurance companies use a mixture of methods and rules such as the business intelligence technologies along with the business rules. With the use of Big Data these systems would generate alerts beside enabling insurance companies to identify errors, fraud, waste and any form of abuse. The alerts that are generated by artificial intelligence; are accompanied by relevant explanations that makes logical sense to the risk-compliance and claim-processing staff could rely on. Such systems need large volumes of free text data and codified data that are extracted from discharge reports and hospital claims in order to operate and present comprehensible alerts.<sup>302</sup>

Marketing departments within insurance companies managed to recognize customers who might be at risk of cancelling or leaving their insurance company through Big Data. hence, customers would have more customer service time to sorting out that customer's issues or might be offered discounts or lower priced premiums.<sup>303</sup>

Insurance companies concentrate over the success and failure percentages and feedback given by patients. They use the patients' discharge summary, medical reports and hospital bills to make a decision regarding medical claims and reimbursements. Therefore, health insurance companies are one of the very fortunate parties in the healthcare system, who benefited more since the establishment of Big Data technology.<sup>304</sup>

Health insurance companies are expected to use Big Data to tackle claims through profiling and predictive modelling using deferent variables within each claim which will be matched against the profiles of past claims. With many different variables, a human working manually might slip and miss areas of the claim unlike analytical computerized skills.<sup>305</sup>

While the use of Big Data is a win win to Health insurance companies, it compromises the privacy of patients and might even lead to unaffordable health insurance rates. This can be explained through looking out at the different forms and types of data that are going to be available to health insurance companies to use through Big Data.<sup>306</sup>

Furthermore, Big Data has opened a gushing stream of information since it gathers social media data, daily life recorded episodes through monitors, and other sources of demographic data. it might also involve looking at other partner agencies' data involved in a claim. Moreover, the speeded-up discoveries of biomedical research and the genetic sequencing which include a lot of sensitive information about individuals and their blood relatives, also make the privacy challenging. Combing that amount of information with the available electronic record that the

insurance company hold for every patient and with the analytical assistance of Big Data could reveal a lot of sensitive harmful information. This makes the security challenge more projecting than ever and privacy issues become at the focal point as patients' vulnerabilities continue to grow.<sup>307</sup>

The different forms of data mentioned above require focused to be and careful protection. Otherwise, the disclosure of such information could lead to serious implications and privacy breaches. Such privacy breach would negatively impact the patients leading to different types of discriminations including insurance discrimination.<sup>308</sup>

Once data generated by wearable sensors and genetic tests become more utilized; more data would become available to health insurance companies. Genetic discrimination would become a variable that has major consequences not only on individuals experiencing the discrimination but also their blood relatives. The presence of the abnormal gene in one family member makes all other family members potential to that kind of discrimination unless protective privacy measure were taken.<sup>309</sup>

It has been reported that several institutions had engaged in genetic discrimination including military, schools, adoption agencies, blood banks, health care providers, health and life insurance companies. The reported instances of genetic discrimination were related to asymptomatic individuals moreover to their asymptomatic relatives. With such profiling and discrimination, most of the society does not know about the existence of institutions that would undertake the related complains and help with correction of misinformation such as the state insurance commissions.<sup>310</sup>

Healthcare insurance companies have complex problems around ethics and privacy. Some believe that it is efficient and even fair to have individuals who demonstrate unhealthy life



styles such as being over weighted or smoking, to pay higher rates of health insurance percentages than others. Regardless of the proven scientific facts that show that the genetic makeup that a person is born with is the bigger decider on their health status. This becomes peculiar and unreasonable when more genetic mapping and sequencing is becoming more common, accessible and affordable. Yet, genetically unlucky individuals are expected to pay more for healthcare insurance due to genetic profiling and discrimination.<sup>311</sup>

It is totally understandable to have discounted health insurances for people who exhibit healthier changes in habits and lifestyles. However, it remains unethical to ask others to pay more as they have a less healthy lifestyle or acquire genetic predisposition of a disease. That shouldn't be the case if one day; insurance companies were not prohibited by law to have access to those clients' genetic analysis through Big Data technology. The exact opposite is expected; where Big Data technology would enable healthcare insurance companies and healthcare providers to make a distinction whether the present illness is caused due to bad choices, or when it's down to genetic factors beyond the individual's control. Therefore, there is a need to have safeguards to make such distinction and allow insurance that is fair as possible. This is a place where ethics and law need to collaborate to ensure a fair nondiscriminatory health markets if privacy turn out to be over-rated one day in the age of Big Data.<sup>312</sup>

Since 1996 the Privacy Genetic Act was made to protect individual's privacy while prohibiting insurance companies and others from using genetic information to discriminate their clients. It was against the law for health insurers to ask for, require, or obtain genetic information about applicants or the individuals that they cover. Later this was updated through history GINA was introduced in 2003 and with the latest update in 2008. The Genetic Information Nondiscrimination Act also continued as the GPA in prohibiting insurers from denying coverage

to a healthy individual or charging that person higher premiums based on a genetic predisposition that the insurance company found about. However, GINA allows insurance companies still have the right to ask for the minimum amount of information to make a decision regarding a test treatment, or procedure related to genetic.<sup>313</sup>

The Insurance business representatives argue that they should be allowed to access and make use of genetic data. their claim is based on the idea that GINA is causing unfairness in the insurance rate. On the other hand, the National Human Genome Research Institute believes that the existence of legislations such as GINA, is curtail in order for patients to feel comfortable having genetic diagnostic tests and for the biomedical research to continue advancing. Therefore, GINA is an important act for the evolution of personalized medicine.<sup>314</sup>

Although the Genetic Private Act and The Genetic Information Nondiscrimination Act do not address or mention its effect on insurance companies and Big Data when dealing with genetic data. Nevertheless, both acts imply to any party that maintains or furnishes private genetic information as part of their business and uses it for discrimination. Clearly this should include both insurance companies and researchers using Big Data.<sup>315</sup> Then it would make sense that the effect of such an act would require Big Data not to hold genetic information and any health insurance company to erase all information that were obtained without consent. If the GINA was to be applied to Big Data one day, it would protect both privacy and autonomy but would partially disable the intended industrial vision of Big Data.<sup>316</sup>

It is obvious by now that Big Data is a tool that can bring a numerous benefits and positive changes to the health insurance industry. This can be understood in terms of improved customer service, further cost-effectively priced premiums and a noticeable decrease in harm caused by fraud. On the other hand, such an industrial technology has its own exclusive set of

ethical challenges particularly in regards of privacy and discrimination and the health insurance sector. With promises of creating privacy protective technologies of the patients' data; the technology industry is keen on showing that Big Data isn't dangerous but can actually provide support, resourceful services and respectable marketing. Nevertheless, even if Big Data was forced by law not to acquire any genetic data; with its analytical powers and along with the use of other personal data it is expected that insurance companies would still be able to get conclusions like genetic testing information.<sup>317</sup>

## 5. Conclusion

The basic goal of Big Data is to economically extract values from very large volumes wide variety of data to help the technological industry and other industries where privacy matters for a limited extend.<sup>318</sup> However, in healthcare where patients' privacy matters the most; it is expected that Big Data would provide benefits to patient and healthcare in general and furnish evidenced based care and Personized Medicine.<sup>319</sup> This has all to be done with the highest levels of privacy protection to patients. Nevertheless, what makes Big Data special is the same thing that is harming the privacy of the individuals; which is its ability to analyze data and extract sensitive information even from raw anonymized data.<sup>320</sup> Therefore, until being resolved; security challenges and the privacy concerns will remain the reasons to hinder the adopting of Big Data in healthcare. The healthcare privacy challenge in Big Data requires a collaborative work of technology experts, ethicists, healthcare providers and legal representatives.<sup>321</sup>

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## **Chapter 6: Conclusion**

Since Genomic Medicine is a field that deals with sensitive genetic information, medicine, and research, it is essential to view it through HIPAA as it is not explicitly engaged there. When it comes to Genomic Medicine and Genomic Research, the sharing and the availability of genetic data for researchers need to be accessible across populations. Hence it must to be protected by a rule that can be shared across geographical boarder that would ensure the privacy of the genomic data.

The Omnibus Final Rule is one of HIPAA's rules which deliberately defines genetic information as health information protected by the Privacy Rule. For genetic data to be protected by HIPAA, it must follow the definition of protected health information. Hence, it must be individually identifiable and maintained by a covered entity or a business associate. This rule prohibits both use and disclosure of genetic information for underwriting purposes by health plans and insurers, including employer-sponsored health plans. This was made as a set forth in the Genetic Information Nondiscrimination Act. However, it seems that there's no special focus on the restriction for the use and disclosure of sensitive information regarding genetics. HIPAA has made all protected health information safeguarded by the same exact standards. Therefore, covered entities are permitted to use and disclose protected health information for treatment, payment, and health care operations. This original approach to protecting individual privacy presents an ethical challenge for Genomic Medicine in which Data Analytics functions across populations. The Omnibus Final Rule defines Gen. Info as health info, but lacks focus on disclosure of genetics info. The following sections summarize the chapters in the dissertation.

The first chapter was dedicated to the Healthcare Insurance Portability and Accountability Act which is a landmark bill that was shaped to improve the portability and

accountability of health insurance coverage. All information of the first chapter were gathered from the US Department of Health and Human Service, and Federal registries. HIPAA was enacted in 1996, effective by April 2003. Additional sections were added through the years including the Privacy rule, the Security Rule, the Enforcement Act, HITECH, ARRA, and the Omnibus Final Rule. The rules of HIPAA were committed to the protection of health information whether that was in a clinical or research setting. It ensures the security safeguards of electronic, physical records, access and sharing of the different forms of patients' data.

The second chapter is divided into four sections: literature that focuses on privacy in terms of consent and its relationship with law; privacy in terms of consent within a multicultural community; consent and its relation to decision making; and consent and its relationship with substitute judgment. There is a substantial amount of interdependency among the areas of law, medicine, and ethics. This can be clearly observed in HIPAA regulations, even though not all aspects of HIPAA are based in ethical practices, the general thrust of the HIPAA's regulations is coherent with the ethical practice of medicine.

Ethics principles are developed by theorists who attempt to codify their moral insights. However, different cultures differ on the specific meaning of autonomy and consent due to major differences in cultures, religions, and the formation of relationships in societies. HIPAA and its set of privacy rules were developed for the Western society to protect the fundamental right to privacy and autotomy of all patients whether they were Americans or citizens. The adoption of HIPAA rules has exceeded the borders of America as it has established its usefulness in the medical field. Such legislation is necessary to ensure the best quality health care, patient control, security, accountability, and other rights. Nevertheless, the adoption of HIPAA in other societies

requires bioethicists and policy makers to make similar regulations that protects privacy with respect for the culture definition of autonomy and consent.

Due to some illnesses, some patients lose capacity and the ability to make decisions. In other occasions, the patients' decisions contradict with their best interest. Decision-making ability falls along a continuum, with no natural threshold for adequate decision-making capacity. From a legal point of view, someone else should take over the decision-making process. Still, privacy and the best interest of the incapacitated patient must be maintained while undertaking that process. Hence, a health care power of attorney for an individual, can get access to that patient's medical record to take medical decisions. This is covered and permitted by the HIPAA Privacy Rule at 45 CFR 164.524. Yet, decision making for an incapacitated patient can be extremely problematic.

From an ethical point of view, when a patient loses capacity and the ability to consent; the patient's right to autonomy must be maintained. An assent can be obtained to interventions decided on by a surrogate or court. According to HIPAA Privacy Rule at 45 CFR 164.510(b), this is not considered a violation of privacy. Whenever a patient is incapacitated, a health care provider is allowed to share the patient's information with a surrogate or a designated power of attorney. Advance directives and substitute judgments could both conflict with the patient's best interest. Hence, the existing standard used approach and several suggested approaches remain unhelpful. The modified reasonable person approach was suggested with the combination of the use of tools that measure the quality-of-life considering the incapacitated patient's previous expressed preferences.

The third chapter dealt with privacy within clinical ethics. This was elaborated under two sections: privacy and abortion; and privacy and mandatory vaccination. Abortion is a better

example to understand how religious pluralism might agree on same moral ethics. The Doctrine of Double Effect in Catholic Christianity was studied using abortion as an example to show that both Orthodox Judaism and Sunni Islam schools agree on saving the mother's life. However, they do not match on the indirect method. The second part of the chapter dealt with several arguments have occurred around the legislations on mandatory vaccination. Some argued the overall benefits to the community, while others argued the right to privacy and autonomy. This religious based debate interferes with another public debate on the right to autonomy and the privacy of abortion. It's been argued that since abortion is a medical procedure, hence it is covered by the HIPAA Federal law. This means that the Federal law suppresses any state law. Some healthcare facilities eliminate the abortion procedure or place some restrictions on the practice. This is a form of interference between the patient and their physician. Moreover, it is a violation of the woman's right to autonomy, which interrupts the HIPAA privacy law. Therefore, whatever the decision was that was weighed by the double effect rule, ethically it shouldn't interfere with the privacy and autonomy of the patient under religious consideration.

Several public arguments around vaccination and privacy arose again with the execution of HIPAA. However, the Privacy Rule was able to maintain a balance between the protection of the patient information and allowing traditional public health activities to continue. Under the 45 CFR § 164.512(b), HIPAA permits disclosure of patients' information without authorization, to a public health authority that is sanctioned by law to control or prevent a health hazard. This must be achieved with the minimum required amount of information. Moreover, once the protected health information has been disclosed, it can be stored conveniently to conduct the public health activity. The storage must be complying with the State and Federal laws.<sup>1</sup>

The fourth chapter was assigned to privacy within research settings. Two sections were allocated to discuss privacy and research on children; and the relation between privacy and research benefit sharing. HIPAA has already dealt with issues related to research on children. the subpart D of the 45 CFR part 46 was dedicated to deal with children as human research subjects. These are considered additional requirements that research investigators must meet along with the other HIPAA and research regulations. Institutional review boards make sure that subparts A and D are met when research includes children. <sup>2</sup>

Regarding research benefit sharing, it is very well known that federal regulations that protect research participants' health information has already mentioned data benefit sharing. <sup>3</sup> Healthcare organizations are commanded to de-identify all their patients' records before any data sharing occurs. <sup>4</sup> Hence, many health organizations trust using the Safe Harbor Standard of the HIPAA Rule. <sup>5</sup>

The fifth chapter was made of four sections devoted to study privacy within Genomic Medicine. Privacy was studied in relation to PGD for the making of Savior Siblings; Privacy and Genetic Databases; Privacy within Bio-banking; and Privacy and Big Data in Healthcare. Arguments are heated around the PGD technology and whether the use of Pre-implantation Genetic Diagnosis to create babies to save the others is ethical. Discussions included the autonomy of the savior child, the conflict of interest and the best interest of both siblings. Others discussed the morality of using the savior child's stem cells, bone marrow and donated organs. Finally, the Principles of Double Effect was examined to justify the PGD use for choosing a savior child.

In the United States, different states have different laws and statutes regarding the content of informed consent regarding PGD. HIPAA governs confidentiality as a federal law along with

other state statutes. It necessitates the complying institutes to include additional notifications and explicit written authorization regarding privacy protections. The fact that both PGD & Organ donation is both regulated in the United States is an indication that savior children is legal and moral under law. <sup>6</sup>

In 2008, the Genetic Information Nondiscrimination Act was signed into the American law. This law protects patients' genetic information. Any genetic information is considered as individually identifiable health information" which is also known as "protected health information. Hence, any genetic information is considered private and is covered by HIPAA. GINA is included in the Final Rule which is a modification to the HIPAA Privacy Rule. In 2013 GINA was published in the Federal Register, and covered entities and business associates were required to comply with it according to 45 CFR 164.502(a)(5)(i).<sup>7</sup>

The United States has always valued the autonomy right. It has also protected the procreative liberty; however, such a right is not considered as an unlimited one.<sup>8</sup> Proponents of selecting children with reprogenetics state that disagreeing with the choice of using the technology is not an adequate reason to prohibit it. These reproductive rights have been supported by the right to privacy.<sup>9</sup> All the mentioned concerns, whether they were scientific, ethical or religious, show that there are no grounds to forbid reprogenetics for legit reasons.<sup>10</sup>

HIPAA & GINA protect the privacy of patients, their genetic data and the right of not being discriminated against in health plans and employment based on their genetic data. This does not include the parents' privacy rights regarding the use of PGD or HLA technologies for the choosing of a savior sibling.<sup>11</sup> However, having such laws as HIPAA to govern the different causes to use PGD; passively indicates the right to use such technology.<sup>12</sup>

The practice of PGD and HLA tissue typing has proven to have the ability to create a healthy new life besides saving another life.<sup>13</sup> It has proven to be successful and beneficial on many levels not only to the sick recipient.<sup>14</sup>

Through studying the very first genetic biobanks, knowledge was gained to create consensus and controversies about several related subjective and practical issues. Consent, withdrawal of consent, confidentiality, feedback of results, benefit sharing and dealing with samples were some issues that were discussed to benefit future biobanks. Biobank research is indeed a challenge to traditional research ethics. Human research in general followed several guidelines such as HIPAA to protect the privacy of the research participants.<sup>15</sup> The developed, argued and challenged guidelines on the local or international levels were a success in the lifetime of biobank regardless of their functionality. The presence of the existing guidelines illustrates the richness of domestic and international approaches and the struggle to find shared solutions despite conflicting and overlapping ethical and legal guidance.<sup>16</sup> This calls for more collaboration between national and international bodies to harmonize the guidelines. These guidelines were huge steps towards the improvement and progress of more rigid guidelines that would create the cornerstones of future biobanks.<sup>17</sup> The construction of international ethics guidelines and the creation of standard operating procedures for biobank research is high priority task on the agenda of a global civil society and research community. Such a community would be responsible for protecting research subjects while maintaining respect for human rights and global justice.<sup>18</sup>

Privacy plays a significant role in international tissue banking and research. Therefore, discussions were developed around the general ethical rights and the underlying legal concerns related to privacy in genetic bio-banking. Additionally, authors argued the use of informed

consent and the De-identification methods to ensure privacy. Finally, different countries were viewed to compare their ethical principles, codes, laws, and legislation to direct, regulate and control this concept of privacy in genetic bio-banking. Achieving a legislative level of global harmonization in privacy laws in genetic bio-banking and bio-banking research is a collaborative mission. It cannot be obtained in trivial steps nor through independent bodies. Each country should work its share starting by revising its own laws, codes, and regulations related to privacy in bio-banking and bio-banking research.<sup>19</sup> These laws need to be based on ethical standards and norm, as this might be the only common groundwork that countries would share. This would ease the development of harmonization. Then, and only then, harmonization can be pursued.<sup>20</sup> This global project is the pre-step for proper global research projects. However, and while just checking and reviewing three different countries from different continents; it was found that some do not have any robust legal framework to regulate bio-banking and bio-banking research in order to ensure proper privacy protection and confidentiality level. Other countries seemed to have its level of confusion and gaps within its developed legislation and laws. Moreover, some countries would seem fully developed and ready for harmonization.<sup>21</sup> Yet, while studying their rules and regulation in bio-banking research and data sharing; issues appear which require such countries to consider revisiting and revising their legal frameworks before considering harmonizing Privacy Laws to Enable International Biobank Research.<sup>22</sup> The HIPAA Privacy Rule maybe a good base to establish those rules and regulations for the International Biobank Research and Data Sharing.<sup>23</sup>

The promising practicalities and approaches of Big Data come with a big package of challenges and ethical matters such as the privacy issue. When considering what Big Data should offer to the healthcare sector and biomedical research filed; privacy issues become profound due



to the presence of the genetic element. The privacy concerns become overwhelming for communities when Health Insurance Companies are added to the privacy equation. Privacy matters have been one of the significant legislative concern. This is not new to the law. However, latest updates and changes must be adapted whenever new technologies are introduced such as Data Analytics. Since early time; regulations for the protection of personal information have been established such as the Privacy Act in Australia in 1988, the European Union in 1995, the PIPEDA in Canada in 2000. This shows the complexity of privacy under Big data environment<sup>24</sup>

The United States had its own sectoral approach as it created several privacy acts for different areas. The HIPAA was developed in the year 1996 as a privacy regulation for healthcare. Gramm-Leach-Bliley was made for the financial sector in 1999 while COPPA was designed for the protection of the children's data in 1998. Furthermore, principles were also established such as the Fair Information Practices in the year 2000, and the OECD Privacy Principles in 2010. These privacy principles are meant to address the rules that different organizations should follow when dealing with and using personal information. Hence, personal privacy must be protected based on these privacy principles and laws.<sup>25</sup>

It seems that the public believes that big data is covered by the legislative actions that protect privacy such as The Health Information Technology for Economic and Clinical Act HITECH and The Health Insurance Portability and Accountability Act HIPAA. For now, HIPAA has the Privacy Rule and the Security rule to protect patients' sensitive information. The Privacy Rule protects the privacy of individually identifiable health information, while the Security rule protects the electronic form of protected health information. However, these rules do not cover Data Analytics due to the massive number of identifiers and the use of decryption and de-anonymization processes. Big data is amounts of information that is consolidated and linked to

other data. Hence, Big Data Analytics is not covered by HIPAA and is not protected by law like health data is, at least for now. Most provisional laws related to data are creating moves around the issues of privacy without expending the actual effort to define privacy; to which the need is paramount.<sup>26</sup>

The main problem with the use of Data Analytics is that privacy can be breached in several ways. First, data could be gathered without the individual being aware of that. Second, the individuals might be aware that the information is collected; however, information isn't available for them to know how it might be used and for what. This can be translated that individuals might have no idea how their information is being handled through Big Data and whether they might benefit or be harmed by it.<sup>27</sup>

The primary goal of Big Data Analytics is to economically extract value from huge volumes wide variety of data to help the technology industry and other industries where privacy matters for a limited extent.<sup>28</sup> However, in healthcare where patients' privacy matters the most; it is expected that Data Analytics would provide benefits to patient and healthcare in general and furnish evidenced-based care and Personalized Medicine.<sup>29</sup> This has all to be done with the highest levels of privacy protection for patients. Nevertheless, what makes Big Data Analytics unique is the same thing that is harming the privacy of the individuals; which is its ability to analyze data and extract sensitive information even from raw anonymized data.<sup>30</sup> Therefore, until being resolved; security challenges and the privacy concerns will remain the reasons to hinder the adopting of Big Data Analytics in healthcare. The healthcare privacy challenge in Data Analytics requires a collaborative work of technology experts, ethicists, healthcare providers and legal representatives.<sup>31</sup>

Privacy Protected Big Data Analytics is powerful, yet the use of Big Data in healthcare is at its infancy stage. When it comes to highly sensitive data; when all the technical precautions are taken, patients' privacy remains the most vulnerable. Solutions will not be created overnight, since the advancement of decryption, de-anonymization and quantum computing technology. IT security will be compromised considerably, as it may be used, when fully developed, to go through firewalls and decrypt information in seconds. When combined with artificial intelligence, it will do wonders, both good and bad. Hence, the privacy of anonymized health data will be exceptionally challenging to be guaranteed.<sup>32</sup>

All the available technologies have made it easier and cheaper more than ever to understand and sequence genomic data. Privacy should always be respected whenever such genetic information would be used for clinical or research practices. Laws and policies existed to protect individuals' privacy within these settings in terms of protecting their genomic information. However, further measures are needed to ensure privacy due to the distinctive nature of genetics and the powers of artificial intelligence.<sup>33</sup>

HIPAA is required to realistically manage privacy protection of genetics in times when sciences collaborate to hasten answers for the wellbeing of mankind. Regardless, and while being aware of the good intentions of all efforts, breeches and harms are definite results along the way. Hence, HIPAA should have a sounder revision to its final rule to focus on the privacy of genetics and its related fields.<sup>34</sup>

When it became attainable for social and behavioral researchers to identify health issues with the help of artificial intelligence, HIPAA might broaden its umbrella to cover those research fields.<sup>35</sup> The necessity comes from the fact that these results are related to the individuals' health but the privacy there isn't protected. The data for most social/behavioral researches come from

open sources as Facebook or twitter, but it managed to identify major health issues.<sup>36</sup> The limitations to HIPAA's Privacy rule will require HIPAA to consider revising its approach to population protection instead of individual protection.

Recommendations:

- Start by educating the public on both the health and digital security measures. And allow them to engage in national and regional debates by having access to the emerging issues. The topics must be comprehensible and relatable to the lay person level.
- Ensure that laws and policies are updated accordingly with the development of science and new technologies. This calls for the development of venues such as meetings, conferences and research funding in the field of genomic analytics to ensure that proper regulations are developed as needed.
- A Call for Global efforts to work on policy harmonization.
- Leaders and policy makers need to be aware of the updates in medicine and technology. They must be assisted by experts, researchers and academics to protect their societies and countries from biological weapons.

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