Organizational Ethics for Sponsorship and Governance in Catholic Healthcare

Alex Garvey

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ORGANIZATIONAL ETHICS FOR
SPONSORSHIP AND GOVERNANCE IN
CATHOLIC HEALTHCARE

A Dissertation
Submitted to the Center for Healthcare Ethics
McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By
Alex Garvey, M.A.P.T.

February, 2015
ORGANIZATIONAL ETHICS FOR
SPONSORSHIP AND GOVERNANCE IN
CATHOLIC HEALTHCARE

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ABSTRACT

ORGANIZATIONAL ETHICS FOR SPONSORSHIP AND GOVERNANCE IN CATHOLIC HEALTHCARE

By
Alex Garvey, M.A.P.T.

May 2015

Dissertation supervised by Professor Gerard Magill

Catholic healthcare in the U.S. is distinctive in its organizational structure insofar as it typically has Sponsorship as well as Governance oversight, reflecting the Catholic social tradition and organizational ethics to engage both patient care and the public good. Sponsorship deals with the mission and identity of Catholic organizations to ensure that they implement the Catholic social tradition. Governance deals with organizational ethics to ensure that the organization’s values (reflecting its mission and identity) influence all aspects of the institution. Because these are intricately connected, the dissertation deals with them in an integrated manner, hence the combined focus upon Sponsorship and Governance oversight. To express this integrative approach the analysis refers to organizational ethics (implementing the perspective of the Catholic social tradition) for Sponsorship and Governance in Catholic healthcare.
This oversight is explained with regard to specific issues. There needs to be enhanced oversight of current issues as well as intense oversight of emerging trends. Enhanced oversight requires more attention to current issues that Catholic healthcare typically engages insofar as they have changed slightly, reflecting revised Church teaching or changing secular awareness. These issues relate both to patient care (such as end of life care or withdrawing futile life-sustaining treatment) and to the public good (such as rationing, minorities in research, vaccinations, or antibiotics). Intense oversight requires more vigorous attention to deal with emerging trends that are pivotal for Catholic healthcare, reflecting the changing landscape of healthcare itself. These trends also relate to patient care (such as quality and safety) and to the public good (such as community benefit programs and conflicted organizational partnerships).
DEDICATION

To my Father, Denis, who was a kind and gentle Spirit
To my wife Tricia for her friendship and love
And our son Finbarr, may he shine.
ACKNOWLEDGEMENT

Be yourself. Everyone else is already taken. (Oscar Wilde)

The completion of this work is the collimation of a life’s journey. On my travels, I have been supported both intellectually and spiritually by a wonderful family and great friends. Many are with fond memories and all remain close to my heart.

I would like to begin by thanking my dissertation Director, Dr. Gerard Magill, for his kind guidance, continuous encouragement and ongoing support. His keen vision was invaluable to me. He provided constant insight and advice during this entire process, especially when I was questioning or doubting. Thanks also, to Dr. Hank ten Have for his openness, engagement and for our great discussions. I appreciate all the Staff at Duquesne Department of Healthcare Ethics, particularly Ms. Glory Smith. Her kind demeanor, warm smile, and willingness to go above and beyond encompasses the true Spiritan Tradition.

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Thanks to my many friends who have seen me through the great and often difficult moments in my life. Especially Fergus Garvey, Patrick Handrahan, Noel O’Connor, Jim Nero, John Mullet, Charles Kiley and Bert O’Connor. I appreciate you for often knowing me better than I know myself. Gratitude is due to my brothers, Sean and Fergus, we have sojourned.

Finally, a special word of thanks to my beautiful wife Tricia. Her friendship, companionship and patience over these many years have been remarkable. She has stood with me and allowed me to be. For our son, Finbarr and the unconditional love he shares. I would like to remember my parents, Denis and Treasa, in a special way, for instilling in me a sense of love for our poor, may they rest in peace.
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Intensive Oversight of Patient Care and the Public
Chapter 1. Introduction.

There has been significant discussion of the meaning of Religious Sponsorship in Church Canon Law from a Catholic perspective and of Board Governance in organizational literature from a secular perspective. Also, there has been significant discussion of the Catholic social tradition in religious discourse and of organizational ethics in secular discourse. However, there is no literature on the crucial connection between these four topics (Sponsorship, Governance, Catholic social tradition, and organizational ethics) that in reality function in an integrative manner in Catholic healthcare.

This dissertation seeks to address this substantive gap in the literature. Because these distinct topics are intricately connected, the dissertation deals with them in an integrated manner. The analysis explains that in Catholic healthcare Sponsorship and Governance work together to implement the Catholic social tradition through organizational ethics across their institutions. To express this integrative approach the analysis refers to organizational ethics (implementing the perspective of the Catholic social tradition) for Sponsorship and Governance in Catholic healthcare.

The thesis can be explained in this way. First, the main point of the study is that Sponsorship and Governance Oversight can resolve controversial ethical challenges in Catholic healthcare. Second, this dual oversight integrates the Catholic social tradition (focusing on Sponsorship & institutional mission) with organizational ethics (focusing on Governance & institutional values) to combine patient care and the public good. Third, the ethics thesis can be expressed in this manner. The ethics thesis is this: Sponsorship and Governance Oversight can resolve controversial ethical challenges in Catholic
healthcare by integrating the Catholic social tradition with organizational ethics to combine patient care and the public good.

Catholic healthcare in the U.S. is distinctive in its organizational structure insofar as it typically has Sponsorship as well as Governance oversight, reflecting the Catholic social tradition and organizational ethics to engage both patient care and the public good. Sponsorship deals with the mission and identity of Catholic organizations to ensure that they implement the Catholic social tradition. Governance deals with organizational ethics to ensure that the organization’s values (reflecting its mission and identity) influence all aspects of the institution. Because these are intricately connected, the dissertation deals with them in an integrated manner, hence the combined focus upon Sponsorship and Governance oversight. To express this integrative approach the analysis refers to organizational ethics (implementing the perspective of the Catholic social tradition) for Sponsorship and Governance in Catholic healthcare.

This oversight is explained with regard to specific issues. There needs to be enhanced oversight of current issues as well as intensive oversight of emerging trends. Enhanced oversight requires more attention to current issues that Catholic healthcare typically engages insofar as they have changed significantly, reflecting revised Church teaching or changing secular awareness. These issues relate both to patient care (such as end of life care or withdrawing futile life-sustaining treatment) and to the public good (such as rationing, minorities in research, vaccinations, or antibiotics). Intensive oversight requires more vigorous attention to deal with emerging issues and trends that are pivotal for Catholic healthcare insofar as they can threaten the continuing viability of an organization, reflecting the changing landscape of healthcare itself. These trends also
relate to patient care (such as quality and safety) and to the public good (such as
community benefit programs and conflicted organizational partnerships). A summary of
the analysis is presented here to provide an overview of the argument.

Hospitals are centers of healing where hope is expressed and life-changing events
unfold. Catholic hospitals have a rich tradition of healing. In the United States today
approximately one in six hospitals is Catholic. Catholic healthcare in the U.S. is
distinctive in its organizational structure from secular healthcare insofar as Catholic
healthcare typically has sponsorship oversight and governance oversight. Governance is
accountable to sponsorship, reflecting the mission and identity of religious congregations
that founded the hospital facilities. In contrast, secular healthcare typically only has
governance oversight. This structure of sponsorship and governance raises distinctive
issues for Catholic healthcare from the perspective of ethics. Hence, this dissertation
discusses organizational ethics for sponsorship and governance in Catholic healthcare.
However, the argument pertains also to all nonprofit healthcare organizations insofar as
organizational ethics for Governance can be presented as the duty to combine patient care
with public trust through organizational integrity and responsibility.

The argument is developed in the following manner. The meaning of Sponsorship
and Governance oversight is explained within the broader context of the Catholic social
tradition and organizational ethics. Broadly speaking, Sponsorship deals with the mission
and identity of Catholic organizations to ensure that they implement the Catholic social
tradition, whereas Governance deals with organizational ethics to ensure that the
organization’s values (reflecting its mission and identity) permeate across all aspects of
the institution. Because these are intricately connected, the dissertation deals with them in
an integrated manner, hence the combined focus upon Sponsorship and Governance throughout the analysis.

First, the Catholic social tradition upholds the dignity and sanctity of the human being in relationship with the community in a manner that establishes the right to basic healthcare. Discussion of this perspective typically engages issues of patient care. Also, the Catholic social tradition emphasizes the public good in healthcare, inspiring an approach that fosters public trust and institutional integrity. Discussion of this perspective typically engages issues related to the institution and policy in healthcare. Sponsorship and Governance oversight reflects and rejuvenates the Catholic social tradition by focusing upon Catholic mission and identity in healthcare to foster both patient care and the public good.

Second, the analysis adopts the phrase of “organizational ethics for Sponsorship and Governance” to express this integration of patient care and the public good – here organizational ethics is inspired by and integrates the Catholic social tradition. Recently, the American Society for Bioethics and Humanities integrated the concepts of clinical ethics (typically aligned with patient care) and organizational ethics (typically aligned with institutional systems and policies to support patient care). This analysis makes a similar integration, but from a broader perspective: the dissertation refers to organizational ethics to integrate patient care with the public good. That integration more accurately reflects the Catholic social tradition’s emphasis of each of these crucial components of healthcare. In other words, the dissertation title, “Organizational Ethics for Sponsorship and Governance in Catholic Healthcare” emphasizes the integration of
patient care with the public good as a Sponsorship and Governance oversight responsibility.

The dissertation explains this responsibility by discussing both current issues and emerging trends that require Sponsorship and Governance oversight of patient care and the public good in Catholic healthcare. Chapter 3 and 4 address current issues that need enhanced oversight, chapter 3 dealing with issues related to patient care and chapter 4 focusing on issues related to the public good. Chapter 5, 6, and 7 discuss emerging pivotal trends that require intensive Sponsorship and Governance oversight, chapter 5 dealing with issues related to patient care, chapter 6 focusing on issues related to the public good, and chapter 7 discussing conflicted organizational partnerships.

The need for enhanced oversight in current issues related to patient care is especially pertinent to end of life care (chapter 3). On the one hand, patient autonomy is respected as a function of human dignity and sanctity, ranging from consent regarding advance directives to the determination of death. On the other hand, this respect justifies the withdrawal of futile life-sustaining treatments while prohibiting assisted suicide and euthanasia. There is a need for enhanced Sponsorship and Governance oversight in this arena to hold a fine balance between what the Catholic tradition permits and what is forbidden in light of recent changes in Catholic teaching about when artificial nutrition and hydration may be withdrawn.

Also, the need for enhanced oversight in current issues is especially pertinent to the public good (chapter 4). This oversight of the public good is more complex than for patient care insofar as Sponsorship and Governance have a less direct control than of hospital care of patients. Nonetheless, in organizational ethics reflecting the Catholic
tradition’s oversight of the public good is indispensable. Hence, the chapter discusses issues that need enhanced Sponsorship and Governance oversight of issues related to the public good in order to provide leadership in Catholic healthcare that fosters sound public policy. Several illustrative issues are discussed where new data regarding policy or science challenges leaders to remain updated in their approach: the role of rationing in healthcare, the protection of minorities in research, the place for mandatory vaccinations in public health, and the dangers of antibiotics from a global perspective.

In addition to the need for enhanced Sponsorship and Governance oversight of current issues in patient care and the public good (chapters 3 and 4) there are emerging trends that are pivotal for healthcare and require intensive Sponsorship and Governance oversight. One pivotal trend that deals with patient care is the issue of patient care quality and safety (chapter 5). Another pivotal trend that requires enhanced oversight with regard to the public good is the issue of community benefit programs (chapter 6). Moreover, there is yet another pivotal trend that integrates the issues of patient care with those of the public good: organizational partnerships between Catholic healthcare and other-than-Catholic institutions are conflicted because they involve practices forbidden by Catholic teaching (chapter 7). There needs to be effective Sponsorship and Governance oversight of these conflicted organizational partnerships. The analysis of these emerging pivotal trends clarifies how intensive Sponsorship and Governance oversight of these issues is needed in Catholic healthcare to properly engage policy requirements and industry practices.

Briefly, the analysis uses organizational ethics to shed light on the need for enhanced Sponsorship and Governance oversight of current issues and the need for
intensive oversight of emerging pivotal trends. As mentioned above, the approach to organizational ethics integrates patient care and the public good as required by the Catholic social tradition. The analysis of each chapter is explained in more detail in the following sections.

Chapter 2 explains the meaning of sponsorship and governance oversight within the context of the Catholic social tradition in a manner that adopts the lens of organizational ethics to integrate patient care and the public good.

The Catholic social tradition upholds the dignity and sanctity of the human being in relationship with the community in a manner that establishes the right to basic healthcare. Human dignity refers to the notion that humans have inherited worth because of their existence, and that this worth is irrespective of social rank, utility, achievements, intellect and other such determinants. A relational concept of inherent human dignity conveys the point that dignity is best understood and respected in interdependent relationship.¹ In Catholic social teaching this focus on relationships is because “men [and women] are by nature social beings”.² The Catechism teaches that humanity is inherently social and that the individual person by nature requires a community of other persons to fulfill his or her personhood.³ Catholic Social Teaching holds there is one social moral order to which all belong. This stance reflects the nature and dignity of human persons and their authentic human development as individuals and as community together.⁴

As a result, the concept of a right to basic healthcare is explicit in Catholic social thought.⁵ This right is met through the requirements of distributive justice. The Catholic understanding of distributive justice refers to the obligation of society to provide its
citizens with a means to ensure that all can have access to a sufficient level of basic human goods, including healthcare.\textsuperscript{6}

The Catholic social tradition inspires an approach to ethics that shifts from individuals and communities to organizations. This focus combines the duty of patient care (of individual and communities) with a duty of public trust that fosters organizational integrity.

Public Trust is an unwritten agreement between two or more parties where both parties will perform a set of agreed upon activities without fear of change from either party.\textsuperscript{7} Today there is much concern about the public’s trust in healthcare accompanied by significant decrease in confidence in the healthcare system.\textsuperscript{8} While most Americans trust their personal physician, almost three quarters of the population consider them not to be a trustworthy source of healthcare information.\textsuperscript{9} In healthcare there is an urgent obligation to ensure that trust is re-established and maintained.\textsuperscript{10} Traditionally Catholic care for the sick and the needy was termed charity or social justice, reflecting a general view of cohesion and unity,\textsuperscript{11} an appreciation of mutuality,\textsuperscript{12} and a philosophy of solidarity.\textsuperscript{13} Pope Leo XIII’s encyclical \textit{Rerum Novarum} introduced a theological foundation for this principle of solidarity,\textsuperscript{14} explaining that higher levels of society should not take on tasks and functions that can be accomplished better at lower levels,\textsuperscript{15} thereby respecting the dignity of all involved.\textsuperscript{16}

Organizational ethics has traditionally combined the ethical principles of solidarity and subsidiarity. These principles appear in both secular and religious discourse about healthcare ethics. The Catholic tradition in particular provides a robust analysis of solidarity and subsidiarity as integral components of the principle of organizational
integrity, inspired by the Gospel and human experience.\textsuperscript{17} This integration of solidarity and subsidiarity to uphold the public’s trust provides a moral compass that reflects the mission and values of organizations in Catholic healthcare. Adopting this moral compass is crucial for organizational leaders to address the ethical challenges in healthcare. This means including all relevant stakeholders in decision-making while empowering those at different and appropriate levels across the organization.\textsuperscript{18}

The integration of the Catholic social tradition with organizational ethics inspires the integration of Sponsorship oversight (that deals with the Catholic social tradition) and Governance oversight (that deals with organizational ethics). A brief explanation of these distinct but integrally related oversight responsibilities is needed.

The next section explores how Sponsorship is responsive to the Catholic social tradition that combines the need for patient care and the public good in healthcare. Sponsor is a term derived from the Latin word for "guarantor." By tradition, it refers to a person who presents another person for the sacrament of baptism or confirmation, taking responsibility for the latter's religious education and spiritual welfare. In institutional history in healthcare, sponsorship denotes a relationship between two organizations: one, the sponsor, lends its name to, and exercises oversight over another. In the past, the concepts of sponsorship and ownership were intertwined. Catholic congregations, for example, were understood to own the healthcare institutions they sponsored. Today, however, many congregations sponsor institutions without having any direct ownership rights over them. Sponsorship in the Catholic sense has little meaning unless it is related to the mission and identity of the church. The church's mission is threefold: to teach, to sanctify, and to serve. Healthcare is one of the areas of service,\textsuperscript{19} including religious
congregations and lay leadership of its organizations.\textsuperscript{20} As religious communities decreased in size, to perpetuate their legacy they relied upon the laity to share in the leadership and charism of their founders.\textsuperscript{21} While the term “sponsorship” is not formally defined, in healthcare it is typically used to describe the official relationship between an apostolic work and the ecclesial entity under whose auspices the apostolic work is being conducted, including religious and laity alike.\textsuperscript{22} A standard canonical category that pertains to the meaning of sponsorship is that of public juridic person.

Within the Catholic Church, formally recognized groups and religious institutes are able to initiate and maintain apostolic works as part of the ministry of the church. Apostolic works are services provided to others in order to continue the ministry of Jesus Christ. Canon Law describes these groups and religious institutes as “Public Juridic Persons,”\textsuperscript{23} and their relationship to a specific ministry like healthcare is referred to as sponsorship.\textsuperscript{24} The term "reserved powers" is used to describe church ownership or canonical control of its institutional apostolates. A public juridic person that is usually represented by a board exercises a sponsored organization’s reserved powers, reflecting the requirements of the Catholic social tradition. In contrast, the organization’s board of trustees exercises the organization's ordinary administrative powers, reflecting the requirements of organizational ethics.\textsuperscript{25} Briefly, sponsorship in Catholic healthcare means that a Catholic organization as a public juridic person has reserved powers that give the sponsor exclusive canonical control over specified key areas of the organization, especially its mission and identity reflecting the Catholic social tradition.\textsuperscript{26}

In contrast to sponsorship oversight that deals with an organization’s mission and identity reflecting the Catholic social tradition, Governance oversight deals with
organizational ethics, integrating the focus on patient care and the public good that also characterizes that tradition. Governance must be responsive to the Catholic social tradition that integrates these crucial components of healthcare.

Hospitals deal with fundamental matters of human well-being; their services are not just a commodity in the marketplace. Historically, management of hospitals is the responsibility of a team of healthcare professionals, and governance is the responsibility of a volunteer board of community members. Traditionally these board members were called Trustees. Trustees were "entrusted" with oversight responsibility to ensure that hospitals stayed true to their purpose as a community resource, holding goods and services of the hospital in trust for the community. America’s healthcare delivery system has continued to evolve from mostly independent institutions into larger groupings. As these large systems developed, the role of governing boards also evolved. Now board members are responsible not only for thinking about the quality of care and community benefit, but also about strategic alignment to deal with local and regional competition, as well as the allocation of limited financial resources.

Today there are several basic duties for board oversight. The Duty of Loyalty to the institution maintains that board members should not engage in personal conduct that could injure the corporation’s reputation or financial well-being. There is a fiduciary obligation to act in accordance with the specific charitable purposes of the charitable trust, sharing in a common vision. The Duty of Compliance states that Directors are responsible for ensuring that their own conduct and the corporation’s activities are in compliance with state and federal laws and regulations, as well as reflecting the organization’s mission and identity. The Duty of Care requires the board to act with the
level of care that a prudent person would exercise under similar circumstances.\textsuperscript{37} Finally, there is a Duty to have Diversity to ensure that boards reflect the range of experience and expertise needed to perform their fiduciary duties effectively including, but not limited to, ethnic, racial, and gender differences.\textsuperscript{38}

Briefly, Sponsorship and Governance oversight functions in an integrative manner in Catholic healthcare organizations. Sponsorship deals with the oversight responsibility for the mission and identity of an organization that respects and rejuvenates the Catholic social tradition. Governance deals with the oversight responsibility for administrative success that honors organizational ethics. They function in an integrative manner to combine patient care and the public good in healthcare.

The dissertation explains this integrative responsibility by discussing both current issues and emerging trends that require Sponsorship and Governance oversight of patient care and the public good in Catholic healthcare. Chapter 3 and 4 address current issues that need enhanced oversight, chapter 3 dealing with issues related to patient care and chapter 4 focusing on issues related to the public good. Chapter 5 and 6 discuss emerging trends that require intensive Sponsorship and Governance oversight, chapter 5 dealing with issues related to patient care, and chapter 6 focusing on issues related to the public good. The distinction between enhanced and intensive oversight refers to the following. One the one hand, enhanced oversight requires more attention to current issues that Catholic healthcare typically engages insofar as those issues have changed significantly, reflecting revised Church teaching or changing secular awareness. For example, the 5th edition of the Ethical and Religious Directives in 2009 revised ERD number 58 to clarify when life-sustaining measures may be legitimately withdrawn. On the other hand,
intensive oversight requires much more vigorous attention to deal with emerging issues and trends that are pivotal for Catholic healthcare insofar as they can threaten the continuing viability of an organization, such as can arise by the changing landscape of healthcare itself. Specifically, the topic of patient care quality and safety requires intensive oversight because of new Medicare penalties that can accrue to an organization that incurs serious issues regarding patient safety resulting from the Affordable Act. The topic of community benefit programs requires intensive oversight because of the new and stringent reporting requirements in the IRS 990 Form that can endanger the tax-exempt status of healthcare organizations. The topic of conflicted partnerships requires intensive oversight because of the increasing need to integrate the delivery and financing of care, thereby requiring Catholic healthcare to partner with other-than-Catholic organizations to combine hospitals and insurance in an intricate manner.

Chapter 3 discusses enhanced oversight of patient care, focusing on end of life care. The need for enhanced Sponsorship and Governance oversight is especially evident in issues of patient care at the end of life. This chapter explains the need for this enhanced oversight by discussing the meaning of patient autonomy in end of life care and the legitimacy of withdrawing futile treatment. Sponsorship and Governance oversight in this arena must establish a fine balance between what the Catholic tradition permits and what is forbidden, reflecting changing Church teaching, such as on when artificial nutrition and hydration may be withdrawn.

Patient autonomy is respected as a function of human dignity and sanctity, reflecting the Catholic social tradition. This respect has to address changing interpretations of the traditional distinction between ordinary and extraordinary means,
emerging concerns about consent regarding advance directives such as in POLST forms, and ongoing science and policy changes over the determination of death.

There is consensus that not all life-prolonging measures are of benefit to the patient. Not every medical treatment that prolongs life is morally required. The ethical distinction between mandatory and optional measures reflects the traditional distinction between ordinary and extraordinary means. Sponsorship and Board oversight has to ensure that the decision about applying this distinction to treatment options focuses upon the patient and their proxy decision makers while also respecting the nuances and changes in Catholic teaching.

Advance directives are based on the principle of autonomy in that they allow our medical wishes to be known ahead of time. Hospitals, nursing homes, home health providers, and hospices receiving federal funds provide written information to each individual concerning decisions concerning care, including the right to refuse medical care and the right to formulate an advance directive such as a living will. Sponsorship and Governance oversight needs to be attentive to changes in advance care planning such as with POLST forms that can elicit some controversy within Catholic organizations.

While clinicians are familiar with the concept of death most would agree that to clearly define this concept has proven difficult. Defining death is primarily a philosophical task; clarifying the criteria for the determination of death is primarily a medical responsibility. In 1980 death was defined as the permanent cessation of functioning of the organism as a whole. This refers to the control of respiration and circulation, neuroendocrinology, as well as homeostatic regulation and consciousness. Death is currently measured in two ways, by cardiorespiratory or neurological criteria.
However, as the secular debate continues over the determination of death, Sponsorship and Governance oversight in Catholic healthcare needs to be especially attentive to “donation after cardiac death” to ensure that the retrieval of organs and tissues occurs after death has been appropriately determined.

Respect for patient autonomy, reflecting human dignity and sanctity in the Catholic social tradition, also justifies the withdrawal of futile treatments at the end of life while prohibiting assisted suicide and euthanasia. This topic relates the meaning of suffering with Church teaching about the circumstances in which withdrawing futile measures is justified to avoid the extremes of assisted suicide or euthanasia. Sponsorship and Governance oversight needs to be more attentive to recent nuanced changes in Church teaching about when life-sustaining measures become morally optional, distinguishing those interventions from assisted suicide and euthanasia.

Suffering is one of the most profound and disturbing human experiences. When medicine fails to address suffering, physicians do not deal properly with their patients. The relief of suffering is considered one of the primary aims of medicine by patients and the general public, and patients, families and physicians recognize the complex needs related to dealing effectively with it. Catholic teaching can be enlightening on this subject. Furthermore, the debate has been exacerbated with regard to patients in a persistent vegetative state (PVS), such as occurred in the case of Terri Schiavo in Florida that generated a revised version (the 5th edition) of the Ethical and Religious Directives for Catholic Health Care Services (ERD) in 2009.

On March 20, 2004 Pope John Paul II addressed participants in an international Congress on the “care for patients in that permanent vegetative state,” setting off a
vigorous debate. On November 17, 2009, the United States Conference of Catholic Bishops revised ERD number 58 to reflect the Pope’s stance, introducing a nuanced change in Catholic teaching about medically assisted nutrition and hydration, especially for PVS patients. The nuanced teaching clarified when futile measures including artificial feeding become morally optional, including for PVS patients. This nuanced teaching reinforced the opposition to assisted suicide and euthanasia in Catholic teaching.

Assisted suicide and euthanasia constitute the intentional termination of the life of a person who requests the deed to be assisted or undertaken by someone else (typically a physician). There seems to be an increased trend in the US to permit assisted suicide and the trend in Europe also includes euthanasia. In the Catholic tradition, the decision to withdraw or withhold treatment is based on the principle of autonomy, reflecting not only the human dignity of the patient, but also reflecting the patient’s relationship with God. However, secular discourse that justifies these actions also makes an argument based upon respect for autonomy of the individual patient. But this argument needs to be substantively repudiated through Sponsorship and Governance oversight, not least because illness places the patient in a vulnerable relationship with the physician, raising the specter of the patient as a victim being killed.

Briefly, there needs to be enhanced Sponsorship and Governance oversight of continuing developments around end of life care in Catholic healthcare. This enhanced oversight needs to be attentive to nuanced changes in Church teaching about when life-sustaining measures may become morally optional while at the same time avoiding any confusion with the secular shift to permit assisted suicide or euthanasia.
Chapter 4 discusses enhanced oversight of the public good. The need for enhanced Sponsorship and Governance oversight in current practice extends from patient care to the public good. This oversight of the public good is more complex than for patient care insofar as Sponsorship and Governance have a less direct control than of hospital care of patients. Nonetheless, in the Catholic social tradition oversight of the public good is indispensable and Catholic healthcare organizations engage in advocacy to influence public policy. The chapter discusses issues related to the public good to provide leadership in Catholic healthcare for sound public policy on controversial issues. Over recent years many several issues about the public good have become increasingly controversial from the perspective of social policy and regulation. Insofar as Catholic healthcare organizations advocate for public policies, Sponsorship and Governance oversight of these efforts is becoming increasingly important. Several issues can illustrate the need for enhanced Sponsorship and Governance oversight to influence changes in current public policy, including: the role of rationing in healthcare, the protection of minorities in research, the place for mandatory vaccinations in public health, and the dangers of antibiotics from a global perspective.

Distribution of limited healthcare resources involves the subject of rationing.\textsuperscript{57} While some forms of rationing are understood as morally justifiable others are not.\textsuperscript{58} Rationing is defined as the allocation of goods under conditions of scarcity.\textsuperscript{59} The Catholic Health Association guides this debate through its the document, \textit{With Justice for All: the Ethics of Healthcare Rationing}.\textsuperscript{60} Catholic healthcare has been proactive in setting out criteria as a guideline for evaluating healthcare rationing.\textsuperscript{61} Similarly, enhanced Sponsorship and Governance oversight in Catholic healthcare organizations is
needed to guide the debate on rationing, especially addressing the CHA document on rationing in the context of the recent Affordable Care Act.

Medical research involves collecting data about human beings. Based on the Catholic social justice tradition, attention is needed with regard to minority populations. There are many vulnerable research subject categories including children, prisoners, pregnant women, handicapped, mentally disabled, economically disadvantaged, educationally disadvantaged. In the U.S., federal regulations provide guidance about dealing with vulnerable populations such as minorities. These ethical guidelines constitute what is known as the “the Common Rule” – this pertains to biomedical and behavioral research that involves human subjects. The need to care for vulnerable populations in research is also acknowledged internationally. For example, The UNESCO Universal Declaration on Bioethics and Human Rights (2005) lists as a core ethical principle “Respect for human vulnerability and personal integrity.” Also, the CIOMS International Ethical Guidelines for Biomedical Research define “vulnerable persons” as “those who are relatively, or absolutely, incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.” Because Catholic healthcare organizations undertake considerable medical research, there needs to be enhanced Sponsorship and Governance oversight in accordance with regulatory developments, especially to ensure respect for and appropriate participation by minority populations.

There is clear evidence that vaccination programs can be highly effective. Vaccines are medicines that contain weakened or dead bacteria or viruses that weaken or destroy disease-causing organisms. For example, due to effective vaccination programs,
the last case of smallpox reported in the United States was in 1949, and the last case of smallpox in the world was in Ethiopia in 1976.\textsuperscript{67} Because of the ongoing threat to healthcare workers with regard to infectious and contagious diseases, there has been increased debate over the mandatory vaccination of healthcare workers. Catholic healthcare organizations can provide leadership in this debate both nationally and internationally. For example, the U. S. Center for Disease Control (CDC) estimates that the N1H1 virus resulted in an estimated 42 to 86 million cases of infection and caused between 8,522 to 17,620 deaths. The influenza vaccine is approximately 80\% effective in healthy adults, with the effectiveness being even higher when there is a close match between the vaccine and circulating strain of the virus.\textsuperscript{68} These data contribute significantly to the ethical debate of mandatory vaccination of healthcare workers as a matter of public health to more effectively deal with infections, especially when they effectively deal with infections as routine and serious as influenza.\textsuperscript{69} In this context, there is need for enhanced Sponsorship and Governance oversight in Catholic healthcare organizations to guide public health policy about the mandatory vaccination of healthcare workers.

Similarly, enhanced oversight is needed with regard to the use of antibiotics, especially to decrease unnecessary use and to maximize effectiveness. Because of the ability of bacteria to develop resistance, antibiotics can decrease or lose their effectiveness. For antibiotics to be used appropriately there needs to be restrictions of unnecessary use,\textsuperscript{70} and new more potent antibiotics need to be developed.\textsuperscript{71} As a result, there is cause for a widespread change of practice regarding the prescription and use of antibiotics.\textsuperscript{72} In this regard, enhanced Sponsorship and Governance oversight of
antibiotics in Catholic healthcare organizations can provide significant leadership for hospital policy and for public policy regarding this growing concern.

Briefly, the need for enhanced Sponsorship and Governance oversight in current practice extends from patient care to the public good. Enhanced Sponsorship and Governance oversight of the public good in Catholic healthcare can provide leadership regarding a variety of issues dealing with hospital policy and public policy where modifications in social trends can significantly impact the health status of communities and populations.

Chapter 5 discusses intensive oversight of patient care focusing on quality & safety. Just as enhanced oversight of patient care and the public good is needed to deal with issues that have changed based on revised Church teaching or changing secular trends (as discussed in chapters 3 and 4), there also needs to be much more intensive oversight of patient care and the public good to address emerging trends that are pivotal for healthcare (discussed in chapters 5 and 6). One of these pivotal trends that deals with patient care is the issue of patient care quality and safety.

Healthcare must be of high quality and be safe for patients. Iatrogenic harm is avoidable harm caused by the delivery of healthcare rather than by an underlying injury or disease. This problem of medical error has been recognized as one of the top four public health problems in the developed world. For example, 10% of admissions to acute care facilities are associated with an adverse patient safety event. According to The Joint Commission, leadership failure in healthcare organizations is one of the most frequent causes of sentinel events, thereby requiring much more effective organizational oversight to protect and foster patient safety. In light of the widespread awareness of
patient safety endeavors to prevent medical error as an emerging pivotal trend, there needs to be intensive Sponsorship and Governance oversight in Catholic healthcare to foster a culture of safety across the organization.77

There are two main types of errors: errors of execution and errors of planning. A slip or lapse constitutes an error of execution that occurs when the action is not what was originally intended. A mistake constitutes an error of planning where the action happens as planned but does not accomplish its intended outcomes because the original intended action was mistaken or wrong. Active errors transpire with the frontline staff and their effects are felt more or less immediately. Latent errors are typically removed from the operator’s control, such as occurs with poor system design. These errors pose the greatest threat to patient safety as they are linked to the failure of the system itself.78

Traditionally, organizational oversight delegated quality and safety to medical staff. There is now widespread recognition of the need for patient care quality and safety across the organization.79 Given the systemic nature of the problem, there is need for intensive Sponsorship and Governance oversight of this issue in Catholic healthcare. Prevention of harm and sustainable transformation to greater reliability can be related in a direct manner with oversight engagement and accompanying executive management. Intensive oversight is needed to engage the issue and to ensure that senior administrative leadership implements appropriate measures for evidence-based safety practices, including monitoring staff and caregivers.80

There are two general approaches to understanding and addressing injuries which reflect very different cultures and philosophies about mistakes and improvements.81 The professional sanctions model places practitioners in charge, being held personally
responsible for patient injuries. This approach blames and punishes individuals but does little to improve the delivery system.\textsuperscript{82} In contrast, the patient safety model recognizes that individuals make mistakes, but they do so typically not because they are insufficiently trained or sanctioned but because systems work against them.\textsuperscript{83} The patient safety model addresses medical error by seeking changes in the systems and processes that lead or cause individuals to make medical mistakes.\textsuperscript{84} There is a crucial shift from fixing blame upon individual professionals to fixing problems and implementing system-related change.\textsuperscript{85}

In the last decade, the root cause analysis (RCA) process has become the main tool used by hospitals to investigate adverse events and to prevent medical error.\textsuperscript{86} Root cause analysis is a process to identify the causal factors that underlie unexpected occurrences involving death or serious injury, focusing primarily on systems and processes rather than upon personal performance. It does not assign blame, but enables an understanding of the cause or potential cause of medical error, and promotes system-related change.\textsuperscript{87} The RCA approach, asks answer three questions: (a) what happened, (b) why did it happen, and (c) what do we do to prevent it from happening again? The product of the root cause analysis is a system-related action plan for corrective action.

To foster patient care quality requires an organizational approach that seeks to avoid medical errors in healthcare by fostering a culture of patient safety. According to the Institute of Medicine, the biggest challenge to patient care quality and safety is changing the organizational culture from blaming individuals for medical errors to one in which medical errors are treated not as personal failures, but as opportunities to improve the system to prevent recurrence and future harm.\textsuperscript{88} Professional and organizational
cultures in healthcare must undergo a transformation in the interests of promoting systems for safer patient care. Healthcare must come to see itself as a high hazard industry which is inherently risky. A culture of patient safety must be developed across each organization.89

Briefly, quality patient care is inextricably related with patient safety, hence this chapter has discussed patient care quality and safety. This is an emerging trend in patient care that is pivotal for healthcare across the U.S., a trend that requires intensive Sponsorship and Governance oversight in Catholic healthcare. Developing a culture of patient safety is very complex and requires astute and robust leadership. Catholic healthcare is especially well positioned to provide leadership nationally with regard to this emerging trend insofar as the focus upon patient care quality and safety reflects the integration of organizational ethics with the Catholic social tradition. To ensure that this system-wide organizational change occurs, intensive Sponsorship and Governance oversight is needed for the foreseeable future.

Chapter 6 discusses intensive oversight of the public good focusing on community benefit programs. As discussed previously, there are emerging trends that are pivotal for healthcare and require enhanced Sponsorship and Governance oversight. The previous chapter examined a pivotal trend from the perspective of patient care. This chapter examines another pivotal trend that deals with the public good, the issue of community benefit programs.

The Community Benefit Standard was developed over several decades as a requirement of the tax code for tax-exempt or non-profit status of hospitals or healthcare facilities. Hence, the American Hospital Association recommends that oversight of
system-wide involvement in community health needs and benefits is a core governance responsibility to be undertaken in cooperation with other community agencies. Although these programs have existed for a considerable time, there is an emerging trend in the U.S. that focuses upon community benefit to substantively engage communities that typically find themselves at the margins of society.

This responsibility fits well with the Catholic social tradition that requires Catholic healthcare institutions to have a prophetic role in service to the needy. Catholic healthcare emphasizes that within the marketplace where healthcare functions there are indispensable social responsibilities. Catholic healthcare commits itself to defend human dignity, care for poor and vulnerable people, promote the common good, provide sound management of resources, all being components of community benefit programs.

Given the national importance of this emerging trend that focuses on community benefit programs, and given its fit with the Catholic social tradition, there is need for enhanced Sponsorship and Governance oversight in Catholic healthcare to provide leadership for community benefit programs. This enhanced oversight means that the Catholic organization’s mission is carried out in a manner that extends from patient care in the hospital to addressing the public good through its community benefit programs.

Community benefit programs can be seen as a litmus test of organizational integrity. This litmus test pertains not merely from the perspective of compliance with tax-code for non-profit status, but especially from an organization’s mission which involves an ethical imperative to oversee community benefit. Developing plans and priorities as well as monitoring progress of community benefit programs not only
represent a basic indicator of effective Sponsorship and Governance oversight, but also constitute basic hallmarks of organizational integrity.

Briefly, community benefit programs constitute an emerging trend that deals with the public good as pivotal for healthcare across the U.S. The pivotal nature of this emerging trend requires intensive Sponsorship and Governance oversight in Catholic healthcare. Developing effective community benefit programs is organizationally complex and requires robust leadership. Catholic healthcare is especially well positioned to provide leadership nationally with regard to this pivotal trend insofar as the focus upon community benefit programs reflects the integration of organizational ethics with the Catholic social tradition. As with the emerging trend in patient care that focuses upon a culture of safety, this emerging trend that deals with the public good focusing upon community benefit programs requires intensive Sponsorship and Governance oversight for the foreseeable future.

Chapter 7 discusses intensive oversight of conflicted organizational partnerships. In addition to the emerging pivotal trends that focus on patient care (patient care quality and safety) and on the public good (community benefit programs) there is another emerging trend that is pivotal for Catholic healthcare in the U.S. – the increasing need to develop organizational partnerships between Catholic healthcare and other-than-Catholic institutions that involve practices forbidden by Catholic teaching. This clash of values means the organizational partnerships are conflicted. As with the trends focusing on patient safety and community benefit, the pivotal nature of this trend dealing with conflicted organizational partnerships requires intensive Sponsorship and Governance oversight.
Hospitals across the nation are being swept up in the biggest wave of mergers since the 1990s, a development that is creating giant hospital systems. Analysts predict that 1,000 of the nation’s roughly 5,000 hospitals could seek out mergers in the next few years. The reality is that instead of being paid on volume, rewarded for filling beds and performing more tests and procedures, hospitals are becoming responsible for more of the total cost of a patient’s care. This combination of the delivery of care (via hospitals) and the financing of care (via insurance companies) is referred to as integrated healthcare organizations. As a result, the incentive to keep patients healthy more than ever before reflects both the delivery and financing aspects of healthcare.97

In this fast-changing context, Catholic healthcare increasingly faces organizational challenges about survival. As a result, there is a pivotal trend to create organizational partnerships with other-than-Catholic facilities, some of whose values conflict with the Catholic tradition. This emerging trend is pivotal from the perspective of Catholic healthcare retaining its mission and identity. Hence, there is need for intensive Sponsorship and Governance oversight of this trend. Fortunately, there is a long-standing ethical principle in the Catholic social tradition that can provide guidance for this controversial issue: the ethical principle of cooperation.98

It is claimed that there is no more difficult question in Catholic moral theology than the principle of cooperation. The principle differentiates the action of a wrongdoer from the action of a cooperator.98 In the context of healthcare partnerships, the principle can differentiate between a Catholic organization (as the so-called cooperator) and an other-than-Catholic organization (that provides services prohibited by Catholic teaching) with which it cooperates. To understand how the principle of cooperation functions it can
help to explain another principle upon which it can be based, the principle of double
effect.

Double effect is applied in bioethics to distinguish between what one intends and
what one foresees and accepts but does not intend as a side effect. This marks the
difference between impermissible and the permissible.\textsuperscript{99} The principle of double effect
proposes that an action is licit if all four of the following conditions are met. First, the act
in itself must not be morally wrong. The bad effect must not cause the good effect. The
agent must not intend the bad effect as an end to be sought. Finally, the bad effect must
not outweigh the good effect.\textsuperscript{100}

The principle of double effect distinguishes between the direct (intended) and
indirect (unintended) features of moral action. To illustrate the principle a classic
example can be considered: the removal of a cancerous uterus from a pregnant woman.\textsuperscript{101}
First, the act itself must not be morally wrong. The removal of the cancerous uterus
involves the foreseen, unavoidable, and unintended death of the developing fetus.
Second, the bad effect must not cause the good effect.\textsuperscript{102} The hysterectomy does not abort
the fetus to cure the cancer; rather it cures the cancer while also bringing about the
foreseen but unintended side effect of the removal and unavoidable death of the fetus.\textsuperscript{103}
Thirdly, the agent must not intend the bad effect – the mother does not intend the death of
the fetus.\textsuperscript{104} Finally, the bad effect must not outweigh the good effect – the hysterectomy
is necessary to save the woman’s life, hence the condition of proportionality is
fulfilled.\textsuperscript{105}

As with the principle of double effect, the principle of cooperation provides a
moral compass when right and wrong intersect: for the principle of double effect, there
are two intersecting effects (one right, the other wrong) in a single action; for the principle of cooperation there are two intersecting actions, one right and the other wrong. The following distinctions clarify when the principle of cooperation can be used. Before these distinctions can be applied, there must first be a recognition that formal cooperation does not occur in which the cooperator intends the wrongdoing of the other.

Immediate material cooperation refers to an action of a cooperator without which the wrongdoing of the principal agent could not occur. Here the act of cooperation is so closely connected with the evil action that there is no other explanation for the cooperation than intending the wrongdoing. In contrast, mediate material cooperation is cooperation with an evil act that does not share the intention of the agent. Traditionally, mediate cooperation is morally licit under three key conditions, all of which must be met: duress, proportionality and avoiding scandal.

The distinction between proximate and remote action is important for the principle of mediate material cooperation. If the cooperator's involvement is remote, a lesser reason is required to justify the cooperator's involvement. But if the involvement is closer or proximate a stronger reason is necessary. Mediate material cooperation is proximate if the cooperator's act is close to the wrongdoing of the principal agent, and remote if more distant from the wrongdoing of principal agent. To explain the crucial role of this principle for enhanced Sponsorship and Governance oversight of organizational partnerships, different situations are discussed.

Austin's public hospital, Brackenridge, had a crushing $38 million debt. The city of Austin leased Brackenridge to Seton, a Catholic health system. The lease stipulated
that Brackenridge would retain ownership of its facility and that Seton would not identify Brackenridge as a Catholic institution. Seton agreed to permit surgical sterilizations to continue at Brackenridge. Seton tried to remove its personnel from any type of culpable cooperation. The Vatican found the details of the arrangement to be objectionable. The principle of material cooperation was at the core of the disagreement between Seton and the Vatican. If Seton had supported reproductive services it would have been guilty of formal cooperation which is always prohibited. Seton did not approve of the illicit procedures or want them to take place. Therefore, there was no formal cooperation by Seton. In 2001 they isolated a hospital floor and made it accessible only by a separate elevator. The so-called carve-outs were designed to guarantee that the sterilizations would be the responsibility of the city alone. Without this arrangement, Seton could have been seen as providing sterilizations and guilty of illicit cooperation.

In February of 1998, St. Vincent’s, sponsored by Catholic Health Initiatives in Denver entered into a partnership with a non-religious institution which performed abortions and tubal ligations. St. Vincent halted abortion services but allowed sterilizations to continue in a room, leased by Arkansas Women’s Health Center, which paid for rent and for supplies. The sterilization unit was seen as a way of remaining competitive in a very difficult market. The agreement was based on the principle of cooperation, which allows being connected with an act of wrongdoing in times of duress for the greater good. The source of duress was managed care; the greater good was the hospital’s financial health to keeps its doors open. This decision was based on the 1995 appendix of the ERD’s on duress. However, the Congregation for the Doctrine of the
Faith ruled that the argument of duress for an individual does not apply to institutions. The hospital had to close the Sterilization suite.

Briefly, this chapter reviewed an emerging pivotal trend in Catholic healthcare in the U.S. The examples of Seton and St. Vincent indicate that the debate about organizational partnerships stretches back for decades. Fortunately, the lessons they provide about how the principle of cooperation may or may not be used can guide Catholic healthcare in today’s environment where the delivery and financing of care are becoming increasingly integrated in large Catholic health systems. This merging trend of integrated healthcare organizations creates a pivotal challenge for Catholic healthcare today and requires intensive Sponsorship and Governance oversight.

Chapter 8 provides a brief conclusion to the dissertation. The meaning of Sponsorship and Governance oversight is explained within the broader context of the Catholic social tradition and organizational ethics. The Catholic social tradition upholds the dignity and sanctity of the human being in relationship with the community and emphasizes the public good. Sponsorship and Governance oversight in Catholic healthcare must address both patient care and the public good. The approach to organizational ethics that is adopted combines patient care and the public good, reflecting the Catholic social tradition’s emphasis of these crucial components. The dissertation title, “Organizational Ethics for Sponsorship and Governance in Catholic Healthcare” emphasizes the integration of patient care with the public good as a Sponsorship and Governance oversight responsibility.

A distinction was made between enhanced and intensive oversight to explain the following. Enhanced oversight requires more attention to current issues that Catholic
healthcare typically engages insofar as those issues have changed slightly, reflecting revised Church teaching or changing secular awareness. Intensive oversight requires much more vigorous attention to deal with emerging trends that are pivotal for Catholic healthcare, such as can arise by the changing landscape of healthcare itself.

The analysis explains the need for enhanced Sponsorship and Governance oversight of current issues related to patient care (such as end of life care) and current issues related to the public good (such as rationing in healthcare). Furthermore, the analysis highlights the need for intensive Sponsorship and Governance oversight of emerging trends related to patient care and to the public good, specifically focusing upon patient care quality and safety, community benefit programs, and conflicted organizational partnerships.

This concluding chapter also briefly explains the implications of the analysis for organizational ethics in Governance oversight in secular healthcare. The implications address the combination of patient care and the public good that defines organizational ethics in the analysis to enhance the public’s trust in healthcare and provide better patient care.
Notes


10 Mark Melconian, Blodgett, Linda, "Health-Care Nonprofit," Journal of the Center for Business Ethics Bentley University 2 (June 2012): 199.


31 Thomas Billings, "In the Service of the Board," Trustee 64 (February 2011): 6-7.


36 James Fishman, Improving Charitable Accountability (NY: Pace University of Law, 2003), 237.


70 The Infectious Disease Society of America, "Antibiotic Resistance: Promoting Judicious Use Of Medically Imported Antibiotics In Animal Agriculture" before the House Committee on Energy and commerce Subcommittee on Health, (July 14th, 2010)


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Chapter 2. Sponsorship & Governance Oversight and Organizational Ethics.

Introduction.

Chapter 2 explains the meaning of sponsorship and governance oversight within the context of the Catholic social tradition in a manner that adopts the lens of organizational ethics to integrate patient care and the public good. The Catholic social tradition upholds the dignity and sanctity of the human being in relationship with the community in a manner that establishes a right to basic healthcare.\(^1\) This tradition inspires an approach to ethics that shifts from individuals and communities to organizations. This focus combines the duty of patient care (of individual and communities) with a duty of public trust that fosters organizational integrity.

Organizational ethics has traditionally combined the ethical principles of solidarity and subsidiarity. These principles appear in both secular and religious discourse about healthcare ethics. The Catholic tradition in particular provides a robust analysis of solidarity and subsidiarity as integral components of the principle of organizational integrity. This integration of solidarity and subsidiarity to uphold the public’s trust provides a moral compass that reflects the mission and values of organizations in Catholic healthcare.\(^2\)

The integration of the Catholic social tradition with organizational ethics inspires the integration of Sponsorship oversight (that deals with the Catholic social tradition) and Governance oversight (that deals with organizational ethics). A brief explanation of these distinct but integrally related oversight responsibilities is needed.
While the term “sponsorship” is not formally defined, in Catholic healthcare it is typically used to describe the official relationship between an apostolic work and the ecclesial entity under whose auspices the apostolic work is being conducted. A category in the Canon Law of the Catholic Church expresses sponsorship in terms of being a Public Juridic Person. That is, the relationship of religious groups (referred to as public juridic persons) to a specific ministry like healthcare is referred to as sponsorship. In Catholic healthcare sponsorship means that a Catholic organization as a public juridic person has reserved powers that give the sponsor exclusive canonical control over specified key areas of the organization, especially its mission and identity reflecting the Catholic social tradition.

In contrast to sponsorship oversight that deals with an organization’s religious mission and identity, Governance oversight deals with organizational ethics integrating the focus on patient care and the public good. In Catholic healthcare, Governance must be responsive to the Catholic social tradition that integrates these crucial components of healthcare. Traditionally governance refers to Board members or Trustees whose multiple duties ensure that hospitals honor their purpose as a community resource.

Sponsorship and Governance oversight functions in an integrative manner in Catholic healthcare organizations. Sponsorship deals with the oversight responsibility for the mission and identity of an organization that respects and rejuvenates the Catholic social tradition. Governance deals with the oversight responsibility for administrative success that respects and implements organizational ethics. They function in an integrative manner to combine patient care and the public good in healthcare.
2.a. Catholic Social Tradition.

The Catholic social tradition combines the relation between dignity, sanctity, and community with the basic right to healthcare that belongs to everyone. Each of these are discussed in turn.

2.a.i. Dignity, Sanctity, and Community.

Catholic healthcare ethics supports a beneficence model of healing. In this model, healthcare delivery is geared, from a moral perspective, toward treating the total well-being of the human person. The moral foundation for this beneficence-oriented model of healthcare delivery is grounded in the belief that human persons are inherently valuable. Traditionally, within a Judeo-Christian moral frame of reference, human dignity is derived from and secured within the biblical notion of *imago dei*. It is this notion that grounds both respect for persons and the view that human life has sanctity from this Judeo-Christian moral perspective. Connected to this idea of human dignity is the primacy of rationality.

Historically, human rationality has been understood as a primary manifestation of the divine within the human species. It is through rationality that human persons express themselves freely. In healthcare ethics, the secular principle of autonomy—which is narrowly understood as “self-rule”—grounds respect for persons. Each principle, whether from a religious perspective or secular perspective, creates affirmative duties on the part of healthcare providers to provide a broad base of information in order for patients or their surrogates to free and informed decisions regarding the adoption of medical interventions. In the end of life context, one way in which the each principle is expressed
is through directive setting around one’s ideal plan of care given one’s values and preferences. In the analysis that follows, the concept of human dignity and sanctity are inextricably related and support a communal focus in health care, justifying the basic right to healthcare for all, as discussed below.

Dignity.

Human dignity is grounded in particular historical, cultural, and anthropological claims that help articulate the valued position that humans have put in creation. There are historical determines that give credence to the view that humanity itself is deserving of a special status within creation. The meaning of human dignity can be explained by considering its historical development and its role in medicine today.

The historical development begins with the physis-concept that helps to clarify how rational human nature is the basis of human dignity. The physis concept is grounded in pagan theology and philosophy. It generally claims that the whole cosmos, all of reality, is penetrated by the reason and rationality of God, the logos. Under this conception of human dignity, there is a practical link between one's human nature and one dignity. Then the essential ethical task of the human person is to live in accordance with the concept of “physis” or nature. In antiquity, the idea that nature is the basis for human work, happiness, and virtue seems to be common among many thinkers and traditions.

Cicero is often credited with being the first in antiquity to explicitly apply the concept of human dignity to human nature. In advising his son Marcus, Cicero develops a four persona theory. Persona refers to the roles or tasks that humans are, by nature, obliged to perform.
Firstly, he presented an ascending scale of dignity from inanimate objects through plants and animals and finally culminating in man; to maintain one's role within nature is to preserve one's dignity of persona. All humans universally hold the first persona it arises “from the fact of our being we all are endowed with reason and with that superiority which lifts us above the brute.” The second persona suggests that each person’s particular dignity is based on particular obligations, needs, wishes and circumstances and this must be respected. While the first persona represents universal recognition of the dignity of humanity the second persona claims that this must be respected. Regarding the third persona, Cicero claims that nobility of Birth, political office, wealth, influence, as well as their opposites depend on chance and are, therefore, controlled by circumstance. This third persona is still a topic in current discussions on human dignity. The fourth persona claims that humans are separated from non-human animals by the fact that humans have the capacity to reason. Reason is a common possession between God and humanity. So we must now conceive of this whole universe as one wealth of which both God and man are members.

The philosopher Immanuel Kant is perhaps best known for his work regarding autonomy; he did however understand its correlation with dignity. He argued that all persons are born with an "intrinsic worth" that he called human dignity. This dignity derives from the fact that humans are uniquely rational agents, capable of freely making their own decisions, setting their own goals, and guiding their conduct by reason. To be human, said Kant, is to have the rational power of free choice; to be ethical, he continued, is to respect that power in oneself and others.
Christian theology’s starting point of understanding human dignity is through the concept of the imago dei. The imago dei represents the symbolic interaction between the divine and the human, between the creator and the co-creator, and it provides, in part, a context for understanding the relational commands of inherent human dignity.\textsuperscript{12}

As Christian thought was influenced by Greek and Roman antiquity, it's not surprising there's a striking resemblance between certain elements of the Physis-concept and various Christian understandings, especially those of the Patristic and Middle Ages, providing the basis for inherent human dignity. The Stoic, Platonic and Aristotelian conceptions of rationality, clearly influenced the great Christian thinkers of the patristic age as well as those of the Middle Ages. St. Irenaeus refers to the human being as endowed with reason, which in this respect gives humans special closeness to God. Clement, like Irenaeus locates the rational power as that which equates the image of God in humanity. For Augustine, the human soul represents the resting place of God's image.\textsuperscript{13}

In his doctoral dissertation David Belde maintains that there are a wide variety of interpretations of the image of God throughout Christian history. He breaks them into five categories: the first account humanity represents the physical image of God. This so-called “anthropormorphites” was popular in the fourth century. Creation is good because it was created in the image and likeness of God and reflects the encounter between God and humanity that must show respect for the physical beauty of God's creation in which God's reflection is apparent. In other words creation as a whole gives visibility to the invisible God.\textsuperscript{14}

The second approach operates from the viewpoint that the Trinity is prototypical
the starting point for understanding God and the way in which God manifests in humanity. This is what Augustine refers to as vestigial trinitatis, situated in humanity by way of the rational soul, particularly its memory intelligence and will. So for Augustine the *imago dei* primarily represents the relationship between God and humanity and secondarily humanity's relationship with one another.

The third approach to understanding the meaning of *imago dei* was located in the idea that humanity has dominion over the rest of creation. Then being created in the image and likeness of God instills relationship with God, fellow humans, and nature. In this relationship dominion means to cultivate, to care for, and to preserve.

The fourth approach follows logically from the first three. This idea is that all humans are created in the image and likeness of God and the notion that humanity is invited to participate fully respecting the God's gift of creation provides the moral weight of the *imago dei*. The movements between encounter and relation, freedom in dependence, responsibility in hearing, and utility in difference marked the ethical locus of the *imago dei*. Then, the human person is the point at which creation is able to acknowledge gratefully the divine self-gift and respond by giving oneself in return. A fifth approach to understanding the meaning of the *imago dei* provides an explicit extension of the rational and social realities that emerge from the same.

Before we depart from the pre-reformation understanding of *imago dei* it is understood that there are major differences in the meaning of inherent human dignity between the pagan and Christian tradition. The pagan tradition generally understands human dignity as being part of the natural endowment of the person. In that essence, human dignity and the pagan worldview can be considered intrinsic, humanity *qua*
humanity has inherent dignity precisely because of those capacities. The implication of this view is that the person is important because of their capacity. That is concerning because inherent human worth becomes predictable on the possession of rationality.

This view would not be considered justifiable within the structure of Catholic Health Care Setting. In the Christian theology understanding, God imparts human dignity to the person. Then, it is only through God's covenant with humanity that humans have dignity. The implication of this worldview is that humanity is valuable irrespective of its capacities. The value of humanity is transmitted in God's invitation to relationship itself; inherent worth is not predicated on the possession of a particular capacity. This statement is vital to Catholic healthcare. The theological and philosophical concepts of dignity have the foundation to develop how this dignity is honored in healthcare. Arguably, the principle of autonomy heralds the concept of dignity.

When beginning to understand the principle of autonomy as we know it today most conversations originate with the philosophical constructs of Immanuel Kant. Most scholars agree that Kant’s moral thought represents a watershed in terms of its originality, especially in its understanding of morality as autonomy. Kant invented the concept of morality as autonomy. In his book the “Grounding for the Metaphysics of Morals” he holds that autonomy is the property of the fifth will attainable to all rational persons. Kant maintains that the goodwill is good not because of what it affects or accomplishes, not because of its fitness to attain some proposed end; it is good only through its willing, i.e., It is good in itself. Human dignity immures from the capacity that one has to follow the autonomous dictates of pure human reason. The dignity of humanity, writes Kant, consists just in this capacity to legislate universal law.
The critical essences of Kant's moral system emerge from the primacy of the autonomous will, the dignity of the individual, rational person who lives according to the dictates of their rational will, and freedom from the casual determinism of desire, passion, natural inclinations, and other heteronomous influences on the economists will.

Associated with this concept of autonomy is a strong reliance on the rational capabilities of the agent. Then autonomy is an ideal feature of the person conceived in the role of a moral legislator, i.e. a person reviewing suggested moral principles and values, reflecting and how they may conflict, and deciding which principles are most acceptable.¹⁹

In this sense, moral agents impose requirements on themselves. They are orators of moral law as well as been subject to them. For Kant they can be compared to autonomous states, bound to no higher authority, with the power to govern themselves in accord with their own Constitution, without needing approval of any further authority. So then rational agents with autonomy identify with the prospective from which moral judgments are made so that they see more requirements not as externally imposed, as in cultural norms. When they act from moral principle, they are governing themselves by their own standards. ²⁰ For the majority of people the feelings that motivate us are not always reflected in the actions we use to guide us and to explain our conduct. Kant conceded this when he repeatedly insisted that we do not know for sure what motivates us to act even we take ourselves to be acting for the best moral reason. But for Kant in so far as we take ourselves to be moral agents, we must conceive ourselves as capable of being moved by practical reason alone.
The meaning of human dignity can be explained not only in relation to its historical development as discussed above but also by understanding and its role in medicine today.

In the past quarter of a century the principle of autonomy and the philosophical constructs of human dignity have combined in the healthcare arena. Autonomy enjoys a privileged place in healthcare ethics today. It received a major boost in 1979 with the publication of Tom L. Beauchamp and James F. Childress' text *The Principle Biomedical Ethics*. This book was published by the time in which dramatic cultural and ethical shifts within medicine occurred, the book elevated the place of autonomy in bioethics. While it has taken some time recently the perspective has emerged in medicine that patients and physicians, not physicians alone, should both contribution actively in a shared medical decision making model.

The primary function of this shared decision-making model is to counterbalance autonomous decision-making would professionally undesirable and socially out modeled form of paternalism in healthcare. There was general buildup and dissatisfaction beginning around the model of paternalism. In 1980 nurse philosopher Sally Gadow claimed that if existential advocacy is to occur in the patient and professional relationship, then paternalism must be considered its opposite, for paternalism implies coercion and unwanted external limits of patient liberty. In 1984 Veatch argued that the rule of autonomy in bioethics was largely a reaction to paternalism, and its temporary triumph would not last.

By 1998 Edmund D. Pellegrino referred to autonomy's triumph over beneficence as irreversible and as the most radically reorientation in the long history of the
Hippocratic tradition. It seems that the cultural influences of individual liberty, right or wrong, leave no room even for softer forms of paternalism. Autonomy decision-making is a constitutive component of virtually all moral systems; the privileged position of autonomy in medical decision-making is here to stay.\textsuperscript{22}

Within the Catholic healthcare we have an active obligation to respect persons and their autonomy. Then to respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their personal values and beliefs. Such respect involves respectful action, not merely a respectful attitude. It requires more than noninterference in others personal affairs. It includes, building up or maintaining others capacity for autonomous choice while helping to allay fears and other conditions that destroy or disrupt autonomous actions. Respect involves acknowledging the value in decision-making rights of persons and enabling them to act autonomously.\textsuperscript{23}

Sanctity.

The concept of dignity is closely related with yet significantly distinct from the concept of sanctity. The meaning of sanctity can be explained in terms of the image of God, which has important implications from the practical perspective of health care.

While we explored different viewpoints of \textit{imago dei} in the previous section it is important to take a closer look at the foundational understanding and Church's teaching. The Christian understanding of the human person considers men and women to be the pinnacle of God's creation. We are made in the image of God. Whether taken as a literal or a mythic statement, this concept powerfully expresses the intrinsic value and dignity of each human being. The ancient Jewish sage, Ben Azzai, identified this proclamation as
the greatest principle of the Torah. Finally, on day six, “God said let us make humankind in our image and likeness” … God created humankind in God's image. In the divine image God created it. Male and female God created them’ (Genesis 1:26-27) men and women received the same blessing as the other animals go for to multiply, but to them is also given dominion or authority over the rest of the creation. At the end of the sixth day, God saw what he had created was “very good”.

The very beginning of the Bible makes this clear. The Jewish and the Christian understanding of the meaning of the human person as created by God in the beginning is one of portal goodness and of almost divine stature. In the Hebrew understanding life is a blessing and a gift from God. Each human being is valued as created Betzelem Elohim, in God's image. Whatever the level of her physical and mental abilities, whatever the extent of our dependence on others, each person has intrinsic dignity and value in God's eyes.

The two key words here are the Hebrew words “selem” and “demut” are usually translated “image” and “likeness”. The first word suggests an actual physical resemblance. People look like God. The second word corrects that impression, while adding to the impact by repeating that God creates us to be of almost divine stature. We are not photocopies of God, but in a very concrete way resemble God and are God-like.

This theme was also taken up by the second Vatican Council’s Gaudium et Spes which begins its discussion of “the dignity of the human person”: “for sacred Scripture teaches that man was created ‘to the image of God’ as able to know and love his Creator, and as set by him over all earthly creatures that he might rule over them, and make use of them, while glorifying God. What is man that thou art mindful of him, and the Son of
Man that thou does care for him? Yet thou has made him little less then God, and dost crown him with glory and honor.”

One of the implications for the proper understanding of the healthcare ethics stems from the Greek philosophical understanding of humanity's creation in God's image and likeness. Much of the early theology thanks in large part to Greek influences, tended to interpret this understanding in a very dualistic fashion. Since much of Catholic theology has depicted God as pure and perfect spirit, unchanging and completely indivisible, theologians have tended to emphasize only the spirit, soul, or minds of women and men in context of our created imaging of God. With this incorrect view only our souls are created in God’s image, not our bodies. There is no support for this dualism in the Hebrew Scriptures. In fact the Hebrew’s reject the idea of two creative forces, or God, one good creating spirit and light, the other creating evil and matter, darkness, and sin. This incorrect theology often emerges as an argument in the healthcare setting. It relates to the dignity of the person, and how healthcare professionals view situations holistically as opposed to placing value judgments based on traits.

Dualisms detract from the complete picture of humanity's relationship with God. David Kelly terms the Greek dualism of body and spirit as “anthropological dualism”. This dualism gives strength in favor to the Spirit and considers the body evil or the lesser part of the human person. Instead of seeing human beings as animated bodies or embodied Spirits, duelists see us as imprisoned souls. For the anthropological dualist, the human soul is reduced to its present diminished or sin filled state largely because of its imprisonment in material flesh. It strives to return to its original pure state of spirituality. The concept of two equally powerful creator gods’; the good who creates the spirit and
the evil who creates the matter was a Manichean understanding. This dualism has been used to create a framework where women have been subjected to male domination. The woman who has been identified with body has been forced into a subservient role to the man who was identified with spirit and intellect.\textsuperscript{30}

This view of sanctity based upon the image of God has several practical implications for healthcare ethics today, as follows. The basic paradigm of autonomy in healthcare is informed consent. This intimate connection between autonomy and decision-making in healthcare, which plays out in circumstances of consent and refusal, is fundamental to honoring the patient as a moral autonomous agent acknowledging that they are created in the image and likeness of God. Some commentators have attempted to reduce the idea of informed consent to shared decision-making between doctors and patients, thus rendering informed consent and mutual decision-making synonymous. However, informed consent cannot be reduced to shared decision-making.\textsuperscript{31}

This concept was born into the language of bioethics after the Nuremberg trials exposed horrific medical experimentations in German concentration camps. It did not receive a detailed examination until the early 1970s. In recent years, the focus has shifted from the physician's obligation to disclose information to the quality of a patient’s understanding and consenting. The forces behind this shift of emphasis were autonomy driven. The primary justification for the requirements of informed consent has been to protect a patient’s autonomous choice.\textsuperscript{32} There are five basic elements that inform consent as we know today. They are legal, regulatory, philosophical, medical, and psychological.\textsuperscript{33}
Part of the explanation for the shift from beneficent paternalism towards autonomy lies in historical events of the 20th century, some of which was directly related to research and more could be contributed to changes in the larger social environment. The atrocities revealed in the Nuremberg trials of Nazi doctors, as well as highly publicized cases of human subjects who were abused in the United States, began suspicion of the general benevolence of physicians and researchers. The late 1960s and early 1970s rules were times of great change within American society. There was growing activism among minorities and women and their assertion of individual rights challenged established social consensus on many fronts. The Vietnam War undercut credibility of many different authorities and individuality.

Autonomy, in the sense of freedom from interference, and even the stronger sense of self-actualization, gained ascendancy. In light of this atmosphere bioethics in America began to react against what it called termed “medical paternalism" over the next 20 years as, beginning from an academic scholarship base, and continuing through the Supreme Court cases and physician assisted suicide, a general agreement or consensus in American law, medicine, and ethics about the legal and ethical rights of foregoing life sustaining treatment began. While never achieving universal agreement this was the first time could be at least acknowledged.

This emerging consensus led David Kelly to develop his renowned three pillars of support: the distinction between ordinary/extraordinary means, between direct killing and allowing to die; and the right to privacy, autonomy and liberty. The first two pillars are rooted in the Catholic tradition and the third in American jurisprudence. These are explored further in chapter three when dealing with the traditional oversight of patient
care. For the purposes of the present chapter, it is sufficient to emphasize that the relationship between human dignity and sanctity includes a community focus that is found in supporting the basic right to healthcare.

2.a.ii. Right to Healthcare.

Organizational ethics has traditionally integrated two related ethical principles, the principle of solidarity and the principle of subsidiarity, with honoring the public’s trust. These principles appear in both secular and religious discourse in healthcare ethics. The Catholic tradition provides a robust analysis of solidarity with subsidiarity as integral components of the principle of organizational integrity.

In 1981, the then National Conference of Catholic Bishops’ issued its Pastoral Letter on Health and Healthcare and noted that health is integrally related to human flourishing on a personal and social level. This statement establishes an essential connection between good health and the common good as a function of organizational integrity and responsibility that honors the requirements of social justice. "A Christian steward is one who receives God’s gifts gratefully, cherishes and tends them in a responsible and accountable manner, shares them in justice and love with others and returns them with increase to the Lord." Such an understanding is in keeping with Catholic Social Teaching as it uses norms of judgments and standards for the orientation of action derived from Gospel and human experience.

The documents of contemporary official Catholic Social Teaching acknowledge there is one social moral order, or social justice to which all, including Catholic Christians, are called to work. The bases for this one order are the nature and dignity of
the human person and of authentic human development both as individuals and as community together.  

The Catholic tradition calls upon organizations to honor the principle of integrity by bearing the responsibility for assuring the right to healthcare as a practical realization of the basic principles of human dignity and the common good, each supporting care for the poor. Such organizational Integrity integrates the Ethical Principles which correspond to the healthcare systems Mission. This is best understood in the ethical decision process utilized and the integration of how the organization functions in light of its Mission. This Catholic understanding of organizational ethics, and its integrative components of Solidarity and Subsidiarity to honor the public’s trust, is developed in Catholic Social Teaching.

Implicit in Catholic social thought is universal healthcare. In the United States the Catholic healthcare system is the largest non-for-profit provider of healthcare. It enjoys a market share of approximately 12%. Each year, one in six patients in the United States is cared for in a Catholic hospital. This accounts for about one fifth of all admissions in 22 States. traditionally, the Catholic understanding of access to healthcare is seen as fundamental to the overall Common Good. This understanding developed during the papacy of Saint John XXIII where the theory was developed from a teleological language of goals to the deontological language of rights.

Inferring that the human person is the not the subject of an economic and social life but rather the purpose of it. Saint John XXIII wrote in Pacem in Terris the common good is actually defined by a notion of dignity that encompasses certain rights: Number #9 states: “Any human society, if it is to be well-ordered and productive, must lay down
as a foundation this principle, namely, that every human being is a person, that is, his nature is endowed with intelligence and free will. Indeed, precisely because he is a person he has rights and obligations flowing directly and simultaneously from his very nature. And as these rights and obligations are universal and inviolable so they cannot in any way be surrendered.”44 This enforces the strong emphasis on the relational aspect of justice.

Human dignity exists within interdependence relationships. Catholic teaching provides a second foundational aspect of human nature: “men [and women] are by nature social beings”.45 The Catechism teaches that humanity is inherently social and that the individual person by nature requires a community of other persons to fulfill his or her personhood.46 Then the concept of a social obligation or a right to healthcare is further developed in the 1981 “Pastoral Letter on Health and Healthcare.” This message from the United States Catholic Conference of Bishops declares that every person has a right to healthcare. With this in mind, the Catholic Church has never explicitly stated how such a right is to be guaranteed. Catholic social thought supports the, perhaps somewhat counter-cultural, idea that government is one of the best originations for protecting dignity and promoting the common good. The application of the principle of justice demand affordable and accessible healthcare for all. However to ensure that the poor, marginalized and vulnerable are protected any opportunity for free market coverage must be tempered with governmental oversight to ensure the requirement justice is fulfilled.47

All resources are scarce, particularly in healthcare. Whenever there is allocation of resources special attention need to be focused on the principle of distributive justice. The Catholic understanding of distributive justice refers to the obligation of society to
provide all of its citizens with a means to ensure that all can have access to a sufficient level of basic human goods. In countries that have a socially determined healthcare budget, such as the United Kingdom, cuts in one area can be justified on the grounds that the money will be spent on other, higher priority services. This closed system of funding provides a moral underpinning for resource allocation across a range of potentially unlimited demands. However, in the United States, there is no structure within which to affect a trade-off between savings in one area and benefits in another. Therefore it's difficult to refuse additional resources for patients, because there is no certainty that the funds will be put to better use elsewhere.

2.b. Organizational Ethics.

To understand the function of organizational ethics requires relating public trust with organizational integrity and responsibility.

2.b.i. Public Trust: Solidarity & Subsidiarity.

The public trust is fostered in organizational ethics by focusing on the reciprocity between the concepts of solidarity and subsidiarity in Catholic healthcare. Organizational ethics has traditionally integrated two related ethical principles, the principle of solidarity and the principle of subsidiarity, with honoring the public’s trust. These principles appear in both secular and religious discourse in healthcare ethics. The Catholic tradition provides a robust analysis of solidarity with subsidiarity as integral components of the principle of organizational integrity.

Catholic social thought was born of twin revolutions—one political, the other economic. The modern secular states in France and Germany stripped the church of its
property, limited its role in education and marriage and created the modern citizen, equal and alone before the state.\textsuperscript{50} These changes left people vulnerable. Catholic Social Teaching is grounded in the values and principles of Judeo-Christian religious experience, which reflects not only the Christian scriptures but also the Church's long lived tradition. It has evolved as each generation has attempted to live in society with reflective fidelity to those values and that religious vision. Today, an active commitment to social justice is recognized as essential to authentic Catholic faith. Directives are normally promulgated through a series of papal letters called encyclicals. An "encyclical" in Latin refers to a "circulating letter" which has become the widely accepted, commonly referred to as a crucial element of "Catholic Social Teaching."\textsuperscript{51}

However, Catholic social teaching is broader than just these encyclicals.\textsuperscript{52} While it covers a host of social concerns, there is a constant focus upon the obligation to care for the poor or underserved – this helps to shed light on the meaning of solidarity and of subsidiarity as integrative components of organizational ethics to honor the public’s trust.\textsuperscript{53} These reciprocal concepts, solidarity and subsidiarity, are designed to respect the public’s trust. Before discussing them, a brief consideration of an organization’s responsibility to honor the public’s trust is discussed.

**Public Trust.**

Today there is much concern and attention being focused on the issues of the public’s trust in healthcare. There is much to be concerned about, not just at the bedside but in the overall medical system. There has been a rapid drop in Americans expressed confidence i.e. Trust, in the people who run our healthcare. The decline has been
remarkable from a high degree of confidence in medicine, of 73% noted in 1996 to a record low of 20% in 1991. By 2004 the number had rebounded slightly to 32%. While most Americans trust their personal physician almost three quarters of the population consider them not to be a trust worthy source of healthcare information. Half of the population looks to other resources, outside the medical field, for medical advice and less that 40% trust hospitals as an earnest resource. With almost 75% of the population believing that neither hospitals nor insurers are prepared to meet the upcoming demands of healthcare the outlook remains bleak. Such lack of trust in our system brings with it worrying results, from decreasing health outcomes to increasing costs, from organization inefficiencies to an inescapable pattern of litigation.

Trust is a concept that can be defined in many ways and it comprises of key components. Chiefly, trust is an unwritten agreement between two or more parties where both parties will perform a set of agreed upon activities without fear of change from either party. One direct correlation can be made between the degree of publically perceived confidence in the Federal Government and the historic level in which people trust Healthcare. For example while crime prevention is not a major responsibility of the Federal Government the rising crime rates of the 1970 led the populous to conclude that if the Government cannot protect the people then there can be no confidence in them.

This condemnation was also extended to healthcare. Such erosion of public trust was witnessed again during Clinton’s administration. Chiefly, in regards to the Lewinsky and Whitewater scandals which dominated the press. Trust in Government, as with healthcare, symbiotically declined during this era. Ironically, during the same period overall health improved and life expectancy actually increased, thanks to new drugs and
medication, about 7 years, statistically a 10% longer lifespan.\footnote{57}

The media remains a dominant force in today’s society and has a direct bearing on people’s perception of Trust. In 1997 a young woman died from breast cancer and her father, who claimed that her HMO denied his daughter access to modern technologies, sued the HMO. The media carried the story. The backlash was immense. While the vast Majority of HMO members will never have such an experience, or even know someone who had, the fundamental value remains: People assume that the people who run a health plan would never do such a thing. The idea of letting someone die was so grievous that it dismantled their trust. The fact that this decision was made by individuals was catastrophic. This and other well publicized cases challenged the American trust to the extent that two thirds of the population, while individually never receiving any negative encounters with their own health plan, felt that managed care would in-fact permit people to die from lack of care.\footnote{58} There was no trust remaining.

Lack of trust is not confined to American hospitals or private owned intuitions. A recent British survey discovers similar findings. A report by an independent government watchdog group concluded that Trust in British public bodies is principally affected by two things: the quality of services; and how open and honest organizations are in their openness to acknowledge and learn from errors. The results were grim, with only one in eight (13 per cent) of the country believing that their local hospital, government or police admit when an error occurs and only one in four (22 per cent) believing that the organizations learn from their mistakes.\footnote{59}

In healthcare there remains a special obligation to ensure that trust is created and maintained. To meet and exceed the public’s trust, nonprofit healthcare management is
obligated to design policies and training to clearly disseminate the ethical standards of its organization. Trust is regarded as an integral aspect of healthcare, in essence, because it embodies collaboration, which is essential for the distribution of care and the environment of overall health. There are ethical and organizational benefits associated with the trust relationships which remain paramount. They include issues such as increased patient/physician engagement, overall satisfaction, reduced grievances and legal action, increased employee satisfaction and the creation of an atmosphere where the patients trust providers as expressed in the ethical principle of informed consent. Such understand certainly holds true from an organizational ethics prospective. Hospital’ nonprofit boards fulfill their fiduciary duty most significantly through effective governance of the organization’s mission and resources. This understanding places the standards of governance necessarily high and insists they operate within a similarly high context of trust. The primary fiduciary relationship is one which is based on this trust.

Generally, Americans have been worried about two main healthcare issues since the 1970. Chiefly, the amount of people who remain uninsured and the rising cost of healthcare. Trust declines when people believe that leadership are not addressing such major issues. The importance of leadership’s response to scandal is also paramount to the public’s perception of trust. In option polls the only company who has gained ground in the public’s perception of trust has been the US Military. Starting at a record low after Vietnam, the military leaders purposefully developed and enforced a code of ethics. This gave the impression that the military leaders were worthy of trust in their effort to bring ethical behavior to the entire institution. This sentiment was not shared with healthcare.

In response, healthcare Institution have begun to take measures in an attempt to
restore the public’s trust. These have included, eliciting patients feedback, empowering patients by educating on their rights and roles, working with staff to improve interpersonal skills and by focusing on ethical issues. It is the intent of this dissertation that such trust is best honored in organizational ethics through the concepts of solidarity and subsidiarity.

**Solidarity.**

The long Catholic tradition of care for the sick and the needy was termed charity or social justice, each assuming the meaning of solidarity. It is argued that when Catholic social teaching introduced the term solidarity it elaborated on a term that in the 18th century was used as an answer to the problem of the Industrial Revolution. It was defined as a sociological principle for social cohesion and unity. It later became part of Catholic thinking in the philosophy of solidarity, developed by the Jesuit economist Heinrich Pesch. This view considered a human being as being oriented to the community, and the community being oriented to every human being. Drawing on this mutuality, the duty to foster solidarity emerged. Pope Leo XIII's encyclical *Rerum Novarum* provided a theological foundation to the solidarity concept. In 1961, Pope John XXIII's encyclical *Mater et Magistra*, linked the idea of the solidarity of the human race with the Christian community. Later, in 1963 in *Pacem in Terris*, Pope John would argue that God makes deep demands on us to address the countless number of people who suffer in the world. In *Octogesima Adveniens* in 1971, Pope Paul VI describes solidarity as the effort of the Church at the service of the Gospel. Through these re-interpretations, solidarity, which was not a specifically Catholic concept from its origin, began a process of Christianization in the official social teachings of the Church,
receiving further expressions in Vatican II’s *Gaudium et Spes* in 1965 and the social encyclicals of John Paul II. The introduction to the *Compendium of the Social Doctrine of the Church* explains that solidarity emphasizes “the solidary humanism capable of creating a new social, economic and political order, founded on the dignity and freedom of every human person, to be brought about in peace, justice and solidarity.” The traditional concept of solidarity remains especially relevant today in the face of widespread poverty. Since 1980, about 5% of annual national income has shifted from the middle class to the nation's richest households. The Census Bureau reported that nearly one in six Americans was living in poverty in 2012. As a result, the number of Americans below the official poverty line was the highest in the 52 years the bureau has published data.

**Subsidiarity.**

The principle of subsidiarity holds that higher levels of society should not take on tasks and functions that can be accomplished better at lower levels. Again, this political theory has been adapted and developed through the Catholic Social thought. Subsidiarity respects personal dignity by recognizing in the person a subject who is always capable of giving something to others. Subsidiarity is also considered to be among the most constant and characteristic directives of the Church's social doctrine and has been present since the first great social encyclical of Leo XIII. Pope Benedict understood the principle of solidarity to be a unifying expression of Charity. A particular manifestation of charity and a guiding criterion for fraternal cooperation between believers and non-believers is undoubtedly the principle of subsidiarity, an expression of
inalienable human freedom. The recognition of solidarity and subsidiarity together are indispensable for organizational ethics in the Catholic tradition. That is, as integrity honors its responsibilities, it does so by respecting its integrative components of solidarity and subsidiarity to uphold the public’s trust in healthcare. If the principle of organizational integrity is to provide a hermeneutical filter to realize the ethical principles of human dignity, common good, and the care for the poor, then it can only do so by respecting the integral relation between solidarity and subsidiary.

Organizational ethics is a new frontier for healthcare ethics. The integration of solidarity and subsidiarity as functions of organizational integrity in healthcare to uphold the public’s trust highlights several related dimensions of organizational ethics. The first is the articulation of a moral compass for the organization, typically referred to as a mission, vision or values. Establishing and espousing a moral compass is a central task for organizational leaders. Solidarity highlights the need for the organization to function in the interests of all, providing a moral compass for everyone (in the organization and in its communities served) to flourish.

The second is the ability to identify the ethical challenges that arise from the organization and address the inevitable conflicts among basic values in a systematic manner. This aspect highlights the role of both solidarity and subsidiarity in the sense of including all relevant stakeholders in decision-making while empowering those at different and appropriate levels across the organization.

Finally, a robust organizational ethics matrix must incorporate management processes that lead to doing the right thing. This aspect highlights subsidiarity in the sense of empowering everyone across the organization, at every level, to assume
responsibility within their own realm of action for moral behavior. The first aspect (mission) and the second aspect (moral deliberation) should inspire and result in the third aspect (worthy performance) – this is crucial to avoid organizational wolves being hidden in the clothing of ethical sheep.\textsuperscript{82} In other words, organizational integrity, through its integrative components of solidarity and subsidiarity to honor the public’s trust, must assume responsibility for institutional mission, moral deliberation, and individual behavior and practices. Altogether, there should be responsibility for the care for vulnerable populations, of commitment to employees and of participation in community outreach.\textsuperscript{83}

2.b.ii. Organizational Integrity & Responsibility.

To foster public trust based on the Catholic social tradition, organizational ethics highlights the importance of integrity and responsibility across the healthcare organization. This section relates organizational integrity with organizational responsibility in healthcare (in contrast to the emphasis upon autonomous consent of individuals in clinical ethics).

Hospitals are complex and imposing institutions. They are vital to the communities they serve and to society as a whole.\textsuperscript{84} Catholic health care facilities form the largest not-for-profit health service sector in the United States, caring for nearly one-sixth of all U.S. hospital patients each year. There 620 Catholic hospitals across the country make up approximately 12\% of the nation’s 4,973 community hospitals. They employ about 533,152 full-time workers and 232,591 part-time workers.\textsuperscript{85} Hospitals, by dealing with the most fundamental matters of human well-being can never be understood
as just another commodity in the marketplace. In the competitive environment among organizations in healthcare today there is an increasing need for an organizational ethics strategy that can offer practical guidance for healthcare leaders. Organizational ethics is the articulation, application, and evaluation of the consistent values and moral positions of an organization by which it is defined, both internally and externally. This process of articulation, application, and evaluation needs to be developed and maintained. In organizational ethics there is a focus on the nature and function of the institution. These reflect the mission of the organization and its role in society. The organizational perspective takes its light, so to speak, not from patient care alone, but from the pivotal mission of the organization, including its obligation to all who are affected by its activity.

Organizational ethics can provide guidance for leaders by encouraging a sense of institutional integrity and decision-making that foster shared standards of ethical conduct across the industry. The principle of organizational integrity, with its integrative components of solidarity and subsidiarity to honor the public’s trust, must focus on the communities served in healthcare. Magill and Prybil emphasize this importance by calling on the principle of organizational integrity to inspire a virtuous organization that respects the resources entrusted to it by the community. The principle of organizational integrity provides a hermeneutical filter for the practical principles of solidarity and subsidiarity in service to the public’s trust. This can be illustrated by the image of an hour glass through which sand representing the abstract ethical principles falls from the upper to lower portions. Organizational integrity is a hermeneutical filter seen as the narrowing of the glass. The lower portion represents the practical realization of the principles. Also,
the lower portion of the glass might also be described as having a base with two pieces of glass molded together, representing solidarity and subsidiarity in service to the public’s trust. In other words, the abstract principles need the hermeneutical filter of integrity if they are to be realized practically - and in doing so, the practical realization of these principles must uphold both solidarity and subsidiarity together to honor public trust.\textsuperscript{92}

This hermeneutical filter helps to explain that the principle of organizational integrity is dedicated to upholding the organizational responsibility. Insofar as integrity upholds the responsibility of an organization, the organization can be referred to as a just organization.

In the Thomistic/Aristotelian tradition of justice, good habits of character described the conduct of human flourishing, individually and communally.\textsuperscript{93} From Aquinas, such virtue is understood as good habit or stable disposition inclining the person towards the good.\textsuperscript{94} This is important for how Justice is embraced. Aquinas maintains that "what is particular to justice among other virtues is that it orders a human being in those affairs which concern another" (II-II, 57, 1). Justice demands an equitable treatment of the other according to a universally recognizable standard of fairness (II-II, 57, 1 ad 2). Aquinas would then define justice as a "habit according to which one gives to everyone what is right (\textit{ius}) with a constant and perpetual will" (II-II, 58,1). This dissertation maintains that such an understanding extends the individual virtue of justice into a social dimension which is expressed through our healthcare organizations.\textsuperscript{95}

Aquinas identifies two species of particular justice that deserve attention: commutative and distributive justice. Both seek to preserve equality between persons by giving to each person what is due. Distributive justice is concerned with the rational
regulation of the distribution of the society’s worldly goods. That is what a person receives is not a matter of equal quantity but “due proportion”. In other words, it focuses on society as a whole and its relationship with its individual members. Commutative justice concerns the “mutual dealings” between individual citizens. Insisting, that people who are buying and selling view one another as equals and therefore conducts their transactions fairly.\textsuperscript{96}

Attributing justice to an organization means that the organization enables and supports fair activities on the part of its members and through its policies, embracing moral goodness and social betterment. However, such an attribution is not without its controversy.\textsuperscript{97} Some organizations have created structures in order to enhance flourishing of interpersonal relationships, meaningful work, learning and personal development among employees. Such structures can foster justice across the organization.\textsuperscript{98}

For this dissertation, justice refers to the ethical caliber of an organization that can be elicited from the integration of three distinct but related components of an organization: its basic identity, decision making processes, and practices. Organizational integrity integrates the ethical principles connected with an organization’s mission with its decision-making processes and its practices.\textsuperscript{99} In practice, this dissertation will explore pivotal issues that reveal the moral caliber of an organization: governance responsibility for patient care quality and safety as well as for community benefit programs. These reveal an organization’s integrity from the perspective of the responsibility of the board of directors.\textsuperscript{100}

The attribution of moral agency (through organizational integrity and responsibility) to healthcare institutions raises the issue of how can a healthcare
organization maintain its moral commitment in the face of challenges posed by social and economic changes in the delivery of healthcare. As indicated previously, organizational integrity involves a commitment to the integration of institutional identity, its decision-making, and its practices. In other words, operationally, organizational ethics focuses upon the integrity and responsibility of the institution.\textsuperscript{101}

The Tylenol tampering case, and their subsequent response, is a good example of this approach to the organizational integrity of the institution.\textsuperscript{102} The principle of organizational integrity, integrates institutional identity, its decision making, and its practices in relation to the communities it serves.\textsuperscript{103} In this manner, the principle of integrity fosters a just organization whose identity, decision-making, and practices are seamlessly integrated.\textsuperscript{104} This approach to organizational ethics, focused upon the ethical principle of integrity that fosters a just organization, provides a robust paradigm for Board Ethics in health care.\textsuperscript{105} This organizational responsibility of boards reflects a long tradition of social justice in the Catholic tradition.

In sum, the Catholic social tradition that emphasizes the role of justice helps to develop public trust in healthcare by emphasizing the importance of organizational integrity and responsibility. To pursue this further, the next section relates organizational ethics with sponsorship responsibility and governance responsibility in Catholic healthcare.

2.c. **Sponsorship Oversight.**

This section on sponsorship responsibility explores the contribution of organizational ethics by discussing the history of sponsorship in Catholic health care, the meaning of the public juridic person around which the legal meaning of sponsorship
revolves, and the role of leadership formation as a crucial requirement of sponsorship from the perspective of organizational ethics.

2.c.i. **History of Sponsorship.**

Sponsor is a term derived from the Latin word for "guarantor." By tradition, it refers to a person who presents another person for baptism or confirmation, taking responsibility for the latter's religious education and spiritual welfare. In institutional history, sponsorship denotes a relationship between two organizations: one, the sponsor, lends its name to, and exercises governance over, another. In the past, the concepts of sponsorship and ownership were intertwined. Catholic congregations, for example, were understood to own fully the health care institutions they sponsored. Today, however, many congregations sponsor such institutions without having any direct ownership rights over them. Sponsorship in the Catholic sense has little meaning unless it is related to the mission and ministry of the church. The church's mission is threefold: to teach, to sanctify, and to serve through governance. Health care is one of the elements of service.\(^{106}\)

The actual term “sponsorship” is not found in Canon Law. However, when placed within the Church’s context it should embody three elements: The use of one’s name, the exercise of certain governance responsibilities that arise from that use; and, some form of accountability with church authorities.\(^{107}\) Perhaps a good analogy to understand this process can be found within the History of Women Religious in the United States and their Colleges. Such academic institutions were individually incorporated; separate to that of their founding congregations. Catholic Colleges remain
protected by and answerable to American Civil Law while at the same time, due to their Catholic Identity, subject to the ecclesial code of Canon Law.

Congregational sponsorship of College and Universities became defined by such legal systems. Prior to their separate incorporation most Colleges were considered extensions of their founding religious congregations and thus derived their canonical status there. Such distinctions became a pressing issue when attention was given to “alienation” or selling of properties to which both Church and Congregation claimed to hold an interest.  

Vatican II intensified the debate and brought bishops, canonists and congregational leaders into dialog on how to find and maintain a delicate balance between and among secular and ecclesial claims on property. Then Religious congregations, faithful to the mandate of Vatican II, began to recognize municipal ways to respond to God’s call. However, for Catholic Higher education and the Congregation which founded them, a new tone for future dialog was emerging. Vatican II had boldly reaffirmed the autonomy of the human sciences, the primacy of conscience in Religious matters, the need for ecumenical dialog, and the importance of the laity. This vision began to gain momentum.

By 1967, twenty six Catholic educators led by University of Notre Dame president Fr. Theodore Hesburgh, CSC, gathered at what became known as the Land O’ Lakes Conference, to define the relationship between the modern American University and the Church, and between the Catholic University and American intellectual life. The statement which this conference issued helped to redefine the character of American Catholic higher education. This manifesto boldly affirmed the importance of
institutional autonomy and academic freedom for Catholic colleges, while simultaneously insisting on a Catholicism that was perceptibly present and effectively operative on campus.\textsuperscript{111}

This development was realizing the significant role that founding communities must continue to play within the ministry; the role of sponsorship began to emerge.\textsuperscript{112} Such an understanding was quickly embraced by religious communities who were involved in the health care ministry. As founding orders transitioned into supporting rather than controlling managers, new roles in areas such as governance and financial support and also sponsorship emerged. From such a transition Sponsorship became an unofficial but commonly used term used to refer to the overarching roles, responsibilities, and influence of congregations in independently incorporated institutional ministries.\textsuperscript{113}

Within Healthcare the desire of religious communities to perpetuate their legacy, as the laity become directly involved in their ministry, and the requirement of civil and canon law, created an environment where the lay faithful began to share in the leadership and charism of the founders.\textsuperscript{114}

Following the Second Vatican Council, the Catholic Church, moving away from almost exclusive reliance on the religious vocations, began to emphasize the dignity of the baptismal vocation.\textsuperscript{115} Interestingly, the Theology of baptism emphasized in Vatican II underscores the rights and responsibility of each person for the apostolic mission of the church by virtue of baptism. This right and responsibility cannot be given nor taken away by the church: it is an element inherent in the Sacrament of Baptism.\textsuperscript{116} While this reality was unfolding, the number of men and women religious began to dwindle. As a result lay people, who were answering their baptism call, increasingly assumed leadership and
decision-making processes in Catholic health care.

Over time, such sponsorship became more identified with the policy setting of the congregation's board of directors than with the actual delivery of health care services. Similarly to the path of Catholic Universities Health care organizations began to acquire "civil recognition" in the United States, incorporation under the civil law, distinct from that of their sponsoring congregations. This led to the creation of boards for the health care organizations, the memberships of which sometimes coincided with the memberships of the sponsoring congregations. Later a two-tiered structure developed. Sponsors began to distinguish between a congregation's members and its board of directors. It is during such time in which Health care truly began to formulate its understanding of Sponsorship.

While the term sponsorship is not formally defined in theology, canon law or civil law, today, in healthcare it is often used to describe the official relationship between an apostolic work and the ecclesial entity under whose auspices the apostolic work is being conducted. While various definitions have been proposed, a practical and helpful definition says: “Sponsorship is a reservation of canonical control by the juridic person that founded and/or sustains an incorporated apostolate that remains canonically a part of the church entity. This retention of control need not be such as to create civil law liability on the part of the sponsor for corporate acts or omissions but should be enough for the canonical stewards of the sponsoring organization to meet their canonical obligations of faith and administration regarding the activities of the incorporated apostolate.”

In 2006 the Canon Law Society of America defined the term to be: “Sponsorship of an apostolate or ministry is a formal relationship between a recognized Catholic
organization and a legally formed entity, entered into for the sake of promoting and sustaining the Church’s Mission in the World.” Yet another definition says, “Sponsorship is the legally protected authority in the corporation of the leadership of a public juridic person to control those elements of the corporation that correspond to the canonical order governing the relationship of a public juridic person to its apostolate.”

While sponsorship can be seen as a formal, legal relationship, such adjectives fail to capture the purpose of sponsorship, the experience of sponsorship, or the accomplishments of sponsorship. Rather, sponsorship should be considered a dynamic approach to providing ministry, particularly complex ministry, on an institutional scale such as in our Healthcare Systems, Hospitals or Universities. Then Sponsorship, by its nature, is an expression of our Catholic identity.

2.c.ii. Public Juridic Person.

Within the Catholic Church, formally recognized groups and religious institutes are able to initiate and maintain apostolic works as part of the ministry of the church. Apostolic works are services provided to others in order to continue the ministry of Jesus Christ. Canon Law describes these groups and religious institutes as “Public Juridic Persons.” Such originations, by virtue of their role in the church, have authority to perform certain public ministries, and are held accountable for them. The relationship between a public juridic person and a specific ministerial work is commonly referred to as sponsorship.

Today the term "reserved powers" is the current way of describing, protecting, and even camouflaging church ownership or canonical control of its institutional
apostolates. Under this arrangement, a public juridic person, who is usually represented by a board, exercises a sponsored organization's reserved powers, while another board, the board of trustees, exercises the organization's ordinary administrative powers. An understanding of sponsorship based on reserved powers means that the institute, or any other public juridic person, carries out its governance responsibilities through the reservation of some powers that give the sponsor exclusive canonical control over certain key areas of the organization sponsored.

From a Canon law perspective a juridic person, is an artificial person, distinct from all natural persons or material goods, constituted by competent ecclesiastical authority for an apostolic purpose, with a capacity for continuous existence and with canonical rights and duties like those of a natural person. Conferred upon it by law or by the authority which constitutes it and to which it is also accountable under canon law.

When religious congregations first began to consider reserved powers as an acceptable way to sort out authority, some congregations counted as many as fourteen of them to be essential. Congregations tended to set the number high because they did not want to relinquish control of their health care organizations. A well-known work by Cardinal Adam Maida and Nicholas Cafardi addressed the issue in detail in 1984. The original reserved powers included, in addition to those still in force today, approval of operating budgets, ratification of appointments of various officers, including but not limited to the health care organization's board members and CEO, and approval of the auditor. In time, as sponsors became more comfortable with the idea of sharing power, they reduced their lists of reserved powers to essential ones.

Over the years, the sponsors of Catholic health care facilities and educational
institutions have essentially honed their reserved powers down to five. According to a CHA booklet entitled The Search for Identity: Canonical Sponsorship of Catholic Health Care, sponsors typically reserve for themselves the right "1.) To establish the philosophy according to which the corporation operates, 2.) To amend the corporate charter and bylaws, 3.) To appoint or to approve the appointment of the board of trustees, 4.) To lease, sell, or encumber corporate real estate in excess of the approved sum, 5.) To merge or dissolve the corporation." Then, to facilitate coordination and reduce expenses, congregations began to form what had been separate health care institutions into "systems." This resulted in a further refinement of reserved powers, some of which were now located at the system level, rather than in the congregation’s general membership.

This sponsorship responsibility is closely related with Governance oversight in Catholic healthcare, as discussed in the next section.

2.d. Governance Oversight.

To appreciate the significance of governance oversight the responsibility needs to be situated within a historical context and related to its diverse duties, as follows.

2.d.i. History of Governance.

Nonprofit organizations in the United States educational, charitable, civic, and religious institutions of every size and mission represent the most widespread organized expression of Americans’ dedication to the common good. The creation of these voluntary, often grassroots organizations to accomplish some public purpose is a distinguishing feature of our national life. Since the 1835 publication of Alexis de
Tocqueville’s Democracy in America, they have been recognized internationally as a source of social cohesion, a laboratory of innovation, and a continually adaptable means of responding to emerging ideas, needs, and communal opportunity.\textsuperscript{129}

It is from within this non-for profit structures that our Board trustees found their humble origins. 19th century hospitals were functioning under a different philosophy that today’s modern Healthcare facilities. They satisfied a full range of purposes from social service, to medical care, to moral reform. Patients entered the institution for a variety of reasons, only some of the medical. Single girls, pregnant out of wedlock and ostracized from their communities, would seek refuge while awaiting the birth of their child. Their care was intimately linked to restoring social and moral well-being as well as physical health. The moral and social objectives of these diverse 19th-century institutions had a profound impact. Patient stayed for months and sometimes years as their moral and physical ills were tended to. Trustees often held a religious conception of suffering that they believe required as much attention as the physiological ailments. Patients learned moral lessons that trustees and administrators sought to impart about the moral value of work, the need to care for each other, and the righteous way to live, all of which are intrinsic to any meaningful cure of disease.\textsuperscript{130} Trustees were “entrusted “with the responsibility of ensuring that the hospital stayed true to their purpose.

The trustees were the responsible stewards of an important community resource.\textsuperscript{131} Potential patients either applied to lay trustees they knew, or offered a letter from a clergymen attesting to the moral character. The “truly worthy” that is those patients who were temporarily down on their luck, or who had swayed from the righteous path through “no fault of their own” were allowed into the charity institution. The
“unworthy poor,” those who were taught to be unreachable by the techniques our
message the charity institution sought to convey, were denied admittance. Trustee
conception of benevolence influenced the method of patient care within the late 19th-
century institutions. Although the institutions were often administered by specific
religious or sectarian orders, most trustees believed in moral obligation to admit poorer
patients regardless of race or religion. In fact, given their strong missionary zeal, many
trustees understood inclusion.132

In the decades surrounding the turn of the century, the significant reform
movement arose within medicine itself that held as its guiding principle the need to
standardize medicine. This began with the medical schools and the standardization of
their education. Reforms were on the way. Those who lived long-term in the hospital
eventually left and soon the only residential labor at the hospital was the physicians. This
increased physician admitting and control over patients. Scientific medicine made the
paternalistic trustees involvement in the provision of care unnecessary. The old model of
the trustee and house staff physician walking the charity wards surveying patient's
progress had, by the 1920s, been replaced by a new method of standardize care.

However many trustees remained committed to the charity nature of their
institutions. Trustees continue to worry that the standardized model of scientific medicine
advocated by physicians and reformers could not meet the needs of patients. Caught up in
the industrial models popularized by proponents of scientific management, trustees open
their hospitals to infiltration by ideas and practices that often undermined the very goals
this ought to promote. How to reconcile this conflict would plague trustees throughout
the century.133 The critical link between the values of a particular community and the
day-to-day operations of complex healthcare organization is provided by the governing body. Institutional trustees are accountable to a standard of fiduciary stewardship that embodies the complex set of expectations communities have towards healthcare and that, at the same time, requires a constant balancing of competing pressures. This form of governance, when properly observed, constitutes in itself the principal strength of our organization.¹³⁴

Today trustees of all corporations have a fiduciary responsibility to act in the best interest of the organization this serve. They're responsible for selecting, evaluating, and replacing Management and for determining levels of compensation. They provide the financial, legal, and reporting oversight. Trustees regularly review operating statistics, budget performance data, financial statements, and capital planning data. They approve and revise strategic plans. Ultimately trustees are responsible for policies and practices to ensure the highest and most consistent quality of care for patients. Coupled with these responsibilities, Catholic hospital trustees must struggle with the multiple dimensions of mission versus margin; that is performance with respect to the charitable purpose of the organization and financial performance.¹³⁵

It is important that non-for profit hospitals be governed well and boards do their job well. Hospitals deal with the most fundamental matters of human well-being; their services are not just another commodity in the marketplace.¹³⁶ Historically, hospitals have been managed by a team of healthcare professionals, and have being governed by a volunteer board of community members.¹³⁷ Traditionally these board members were called Trustees. Trustees were "entrusted" with the responsibility of ensuring that hospitals stayed true to their purpose. These boards of trustees focused on quality of
healthcare services, the alignment of services for community needs, strategic direction, and financial performance. The trustees have responsibility oversight for this important community resource. The goods and services of the hospital were held in trust for the community.\textsuperscript{138}

Often time’s titles are used interchangeably with little thought to whether they are indeed synonymous or actually reflect subtle distinctions (e.g., doctor versus physician, lawyer versus attorney, non-profit versus not-for-profit). So it is with the titles “director” and “trustee.” In the non-profit world, “directors” and “trustees” are often used interchangeably; intended to refer to the group of individuals responsible for the management of the activities and affairs of the corporation (e.g., “board of directors,” “board of trustees,” “board of governors”). Most state non-profit laws provide a common structure from which these individuals (whether directors, trustees, or governors) may carry out those responsibilities.\textsuperscript{139} However, this dissertation will use the term “Board of Directors” when discussing these organizational responsibilities. It is important to understand the entomological development and significance of this term.

While in some ways this was just a change in terminology, in other ways it suggests an important and noteworthy change in emphasis. Trustees are entrusted with protecting and advancing a specific community resource. Directors, on the other hand, are responsible for the oversight and direction of a large and complex system of care.\textsuperscript{140} This is especially relevant for nonprofit systems as compared to investor-owned systems for which public reporting requirements are somewhat more extensive.\textsuperscript{141}

America’s healthcare delivery system has continued to evolve from mostly independent institutions into larger groupings.\textsuperscript{142} Accompanying this development the
role of trustee also change and expanded. Increasingly complex medical institutions demanded leadership in strategic thinking, strong financial management, as well as legal and regulatory skills. As these large systems were forming, the role of governing boards also evolved. Now board members were responsible not only for thinking about the quality of care and community benefit, but also about strategic alignment and advantage, local and regional competition, and allocation of very limited financial resources.

Today's boards face an increasing set of demands that expand the scope of board accountability. Reform and the rapid pace of change in health care mean hospitals need greater guidance, more agile decision-making and updated strategic plans from their boards. While it might be difficult to achieve, effective governance in a for-profit enterprise has the advantage of being a recognizable commodity. Financial performance is the principal scorecard. If the stock price is rising, healthy dividends are being paid regularly, market share is increasing, pension obligations are funded, and company executives are not under indictment for accounting fraud, the board of directors is probably doing its job well. Such a scorecard might not be obvious for non-for-profit boards.

This dissertation maintains that success begins within execution of healthcare’s mission. The mission should be the not-for-profit organization’s guiding “polestar” in that it provides a measure of success which focuses the organization’s boards to ethically lead the ministry. Embracing this concept is of vital importance in developing a just Organization. It is the board’s responsibility to ensure that the identity of the organization is fully integrated with its decision-making processes and practices in order to foster a just organization. Nonprofit boards are guardians of cherished institutions; they bear
responsibility for our society’s most vulnerable members; they are the keepers of community dollars, aspirations and hopes. It is implied that within this oversight of the board the constant reliance of the principle of integrity will guide the organizational responsibilities. There are also legal obligations derived from trust law and enforceable by the state Attorney General.

2.d.ii. **Board Duties and Organizational Mission.**

All directors are legally bound by the board duties in the context of an organization’s mission, reflecting its charitable purpose, due care, and loyalty. The most dominant duties are the duty of loyalty, the duty of compliance, and the duty of care.

**Board Duties.**

The *Duty of Loyalty* to the institution maintains that Directors should not engage in personal conduct that could injure the corporation’s reputation or financial well-being. Since directors are in a position of trust and have access to confidential corporate information, they must resist any temptation to misuse their position for their private interests or personal gain. There is a fiduciary obligation to act in accordance with the specific charitable purposes of the charitable trust. Directors need to be extremely careful and forthcoming to avoid the appearance of personal gain by making a full disclosure of any potential conflict to the board.

Effective board oversight is not always easy to discern or to measure, and it is certainly becoming more difficult to recognize. Not every organization defines an optimal effective nonprofit board in the same way. For example, religious sponsors and nonprofit
organizations place more emphasis on mission then on the bond ratings. Senior managers and medical staff leaders may prefer a board that does not always demand expectations or that delegates more policy making onto them. Bond underwriters may prefer boards that do not argue for flexibility in bond covenants so the bonds can be sold more quickly.\textsuperscript{150} The board must share in a common vision.\textsuperscript{151}

The \textit{Duty of Compliance} states that Directors are responsible for ensuring that their own conduct and the corporation’s activities are in compliance with state and federal laws and regulations. The board is ultimately responsible for overseeing the condition and effectiveness of the corporate compliance program. Legal counsel plays a crucial role in educating the board about the status of their compliance with regulatory issues, accreditation guidelines, and local ordinance.\textsuperscript{152} The non-profit corporation exists to serve social purposes, as embodied in both internal and external norms. Compliance with these norms is not only central to the legitimacy of the non-profit corporation, but frames the duties imposed on its actors. The non-profit vocabulary of “mission” suggests the degree of compliance that non-profit fiduciaries owe to the organization.\textsuperscript{153} The duty of compliance therefore tracks and reinforces the non-profit’s mission; “to act with fidelity, within the bounds of the law generally, to the organization’s ‘mission.’\textsuperscript{154}

Recent non-profit cases bolster this point. Consider the MEETH (Manhattan Eye, Ear & Throat Hospital) case, involving a non-profit hospital in New York City that proposed to sell its facility to another hospital to be operated as a breast cancer ward and its additional land to a private real estate developer, the proceeds to fund diagnostic and treatment centers throughout the city. In reviewing the sale, as required by New York non-profit law, the court faulted the board’s decisional process required by the duty of
compliance. The court pointed out that the board had failed in its duty by seeking to “monetize the assets,” rather than to “serve the poor,” the hospital’s original mission.\textsuperscript{155}

Then the duty of compliance can be likened to the invisible “dark matter” of the corporate fiduciary universe, its existence inferable by imagining the universe populated only by care and loyalty as those duties are generally understood.\textsuperscript{156}

The \textit{Duty of Care} requires, a director to act with the level of care an ordinarily prudent person in a like position would exercise under similar circumstances. The judicial interpretation of what this duty of care means may result in a nonprofit director being held to a higher standard of care than a for-profit director.\textsuperscript{157} So, then the duty of care refers to the director’s obligation to exercise due diligence in making decisions involving charitable assets.\textsuperscript{158} Again, there have been several recent high profile cases in which this duty was neglected. The case of the United Way’s errors was highly publicized and damaging to their mission. After the CEO’s mismanagement of funds, the court found that the United Way board of directors breached its fiduciary duty of care by not staying sufficiently apprised of the organization’s affairs.\textsuperscript{159}

Finally, these duties are also reflected in having an appropriate diversity of the board. In the healthcare field and other sectors, there is general agreement that the membership of governing boards must include persons with a strong blend of pertinent experience and skills in order to perform their fiduciary duties effectively. It is increasingly recognized that the boards of nonprofit organizations also should include members with diverse backgrounds including, but not limited to, ethnic, racial, and gender perspectives.\textsuperscript{160} It is crucial to increase diversity in board and management leadership.\textsuperscript{161}
The IRS stated: “Very small or very large governing boards may not adequately serve the needs of the organization. Small boards run the risk of not representing a sufficiently broad public interest and of lacking the required skills and other resources required to effectively govern the organization. On the other hand, very large boards may have a more difficult time getting down to business and making decisions. If an organization’s governing board is large, the organization may want to establish an executive committee with delegated responsibilities or advisory committees.”

Board diversity is a pervasive concern. Today men continue to occupy most seats on U.S. firms’ boards of directors; yet U.S. firms lead most other countries, with 86% of U.S. firms having at least one woman on their boards of directors. In 2007 a survey discovered that, 86 percent of board members are white, non-Hispanic; 7 percent are African-American; and 3.5 percent are Hispanic/Latino with the balance from other ethnic groups. Among nonprofits whose clientele is 25 to 49 percent African-American, 36 percent have no African-American board members. Many faith-based system boards still include a substantial proportion of persons who are affiliated with the previous or current religious sponsors. With respect to race and ethnicity such information would raise basic questions about the ability of many boards to truly represent and respond to the diversity of the public they serve.

These board duties shed light on the governance responsibility of boards of directors or trustees in healthcare reflecting the organization’s mission, which is especially evident in Catholic healthcare.

Organizational Mission.

Catholic hospital trustees share the same governance and ethical responsibility
faced by trustees and other non-for profit hospital and system boards. Catholic hospital trustees have the same fiduciary responsibility, as other non-for profit boards, chiefly, to act in the best interest of the organization they serve. They provide the same types of financial, legal, and reporting oversight.

However, Catholic hospital trustees must also struggle with the multiple dimensions of “mission versus margin.” That is to say Catholic non-for profits have two bottom lines: performance with respect to the charitable purpose of the organization and financial performance. That is, the fiscal health of the organization and the physical and public health of the people in the community. Coupled with this demand, Trustees at Catholic institution face the same pressures their non-for profit hospital periods face in a rapidly consolidating healthcare delivery system. Proposal for joint ventures, mergers, acquisitions, sales, and closures all must be examined for their strategic wisdom and scrutinized throughout the endless variety of details they embody. Trustees must ensure that any changes in corporate organizations that they approve are consistent with the charitable intent of the organization, its mission, and serve the healthcare of the needs of the community.

Also, Catholic non-for profit hospitals enjoy tax-exempt status in return for filling a certain public purpose, and therefore also have a responsibility to all citizens and taxpayers to ensure that these public purposes are realized. Then the general ethical principles of trustees apply to Catholic hospital trustees, plus they must be faithful to their mission, ensure that patients and communities are well served, and act as responsible stewards of the institution.

Catholic healthcare facilities constitute a sizable portion of American Healthcare.
In 2013, there are 630 hospitals, 56 healthcare systems, with a presence in all 50 states. They provide acute care, skilled nursing, along with hospice, home health, assisted living and senior housing. Compared with nonfederal US hospitals in 2013, Catholic hospitals accounted for 14.9% of total beds, 15.6% of admissions, 14.9% of inpatient days, 14.5% of outpatient visits, along with 16.5% of Medicare discharges and 13.7% of Medicaid discharges. These percentages translated to over 19 million emergency room visits in the previous year. Catholic healthcare employed 13.8% of all nonfederal US hospitals broken down to 533,152 full-time employees and 232,591 part-time workers.\textsuperscript{168}

At the same time they experience their Catholic mission to be under pressure, among others by social groups like Merger Watch that fight faced-based restriction in providing certain services in, for instance, reproductive health care are in end-of-life decisions. Great pressure also comes from a strong market orientated society. Market forces, however, also encourage religious organizations to “sell” religion. Interestingly, while the ‘marketability’ and obviously sustained market share of Catholic healthcare remains solid. It does so in stark contrast to the people it serves. The number of uninsured Americans has increased more than 45 million a population that is 40% larger than the entire population of Canada.\textsuperscript{169}

Catholic healthcare facilities have 258 sponsors, primarily religious congregations of women and men, but including diocese and organizations of lay people. Of all religiously sponsored non-for profit hospitals, 94% are Catholic. Taken together, Catholic healthcare facilities are the single largest group of non-for profit healthcare facilities under a single form of sponsorship. Put Another Way, Catholic hospitals constitute the largest private sector effort to deliver healthcare services in the United States.\textsuperscript{170} Then,
given the size and the importance of Catholic healthcare on the American scene, it is useful to examine the special ethical challenges of those who are ultimately in charge of its governance, hospital trustees. It could be argued that trustees play a large role as the guardians of the hospitals moral integrity. This is expressed through their fidelity to mission, the standards for dealing with professionals and with and the population’s served.\textsuperscript{171}

Trustees must strike a delicate balance, learning the new skills of competition without unlearning traditional skills of compassion. In addition to the fiduciary responsibility that Catholic hospital trustees share what others, they have certain responsibilities their specific to Catholic healthcare. They must be faithful to the mission, ensure that patients and communities are well served, and act as responsible stewards of the institutional material and human resources.\textsuperscript{172} The source of these duties is the mission of Catholic hospital. Broadly speaking, that mission takes its inspiration from the healing ministry of Jesus Christ, the explicit tenets of Catholic medical ethics and social teaching, and a long tradition of spiritually motivated services to the sick and poor people by Catholic institutions and individuals.

While, not all trustees of Catholic hospitals are themselves Catholic, and perhaps do not identify with Catholic values as individuals, nevertheless, their fiduciary responsibilities trustees is to advance the values in the organization they serve.\textsuperscript{173} There is much with which trustees have been entrusted. There are public and private fiduciary promises, implicit in each trustees acceptance of appointments to the board, these lay the foundations for a set of more specific ethical and legal duties that non-for profit hospital trustees assume.\textsuperscript{174}
Mission and Identity in Catholic healthcare is as old as the church itself. From the very beginning, Catholics have been functioning as a moral source that empowered people to take care of the sick, the poor and the needy. However, in modern western culture many of these hospitals face problems when interpreting their religious identity against the background of growing pluralism and secularization. The notion ‘Catholic Identity’ covers different meanings: a formal one, in the sense that a Heath Care Organization is Catholic according to its statutes, and a normative one, in the sense that our hospitals take the Catholic tradition. This includes the ecclesiastical moral teaching, as a guiding frame of reference for its practices. However Catholic identity is not just following the moral views and prescripts of the Catholic Church, but is shown and developed by investigating how to connect contemporary society- and culture-bound practices of care, as well as ethical issues arising within these practices, with Catholic tradition. Understanding that healing can be a moral source for Catholic tradition, and Catholic tradition can be a moral source for this care.

In paraphrasing the now infamous conversation between Alice and the Cheshire Cat in Chapter 6 of Lewis Carroll's Alice in Wonderland: “If you don’t know where you’re going any road will take you there.” The concept of “where we are going “is summarized in a mission statement. The mission statement is the dominating concept in today's modern management theory. Though Catholic hospitals did not subscribe early to the influence of modern management consultants, it did have an impact mission statement from their very beginnings; they follow the teachings of the church. Recently this teaching has been expressed in the Ethical and Religious Directives for Catholic Healthcare Services. In addition to this statement of moral norms, Catholic hospitals have
sought to express their mission in a more succinct and more personal language for patient staff and professional persons affiliated with the institution.

Mission statements are often coupled with statements of Catholic identity which describe essential qualities and characteristics of the service and personnel of Catholic healthcare facilities. Our mission statement calls us to be prophetic, often defined as counter cultural, in market-driven commercializing. It is rooted in the ethical perspective of the common good which provides a framework on how we view healthcare. Being prophetic calls Catholic hospitals to commit themselves and reaffirm commitment to the poor, to those who suffer and to those on the margins of society. The governing board is the first stop for assessing and demonstrating the organizational, institutional integrity. It needs to ensure that the hospitals integrity and mission are demonstrated to the public and government agencies and that they are meeting or exceeding their community benefit and institutional integrity, responsibility as tax-exempt organizations.

The primary principle of the ethics of trusteeship can be stated as follows: trustees should use their authority and best effort to justly promote the mission of the non-for profit organization, and to keep that mission alive by interpreting its meaning over time, in light of changing circumstances. The mission of the organization governed by trustees is central to the ethics of the trustee role because it is the cornerstone of the entire trustee’s other responsibilities. The board exists to direct the organization, but the organization exists to pursue and fulfill a mission, a moral and social objective. Without the mission there would be no trustee role in the first place.

It is important to interpret this principle broadly. Fidelity to mission should not be interpreted to mean that the exclusive role of the trustee is to perpetuate the past or to
resist change. The true mission of an institution is rooted in the past and in the tradition of
the institution, but it also points towards the future. The mission is a dynamic thing, and
overriding purpose that changes with changing environment and circumstances, and
trustees are faithful to it when they adopt an open-minded orientation. And mission does
not interpret itself any more than it implements itself. It is in need of ongoing
interpretation and reflection, much as does the Declaration of Independence in American
political theory or the Constitution in American law.\textsuperscript{181}

While a Catholic hospitals mission is definitely greater than its mission statement
the mission statements can serve to communicate the ideals and goals of an organization.
Mission statements are an ideal expression of the institutions identity. They are a public
disclosure of something interior, and the act of disclosure confirms an identity already
present. It helps us to clarify what is important and what contributes to progress towards
institutions goal.\textsuperscript{182} In the daily struggles to achieve such goals is the governance of
every hospital which involves a delicate balancing of power. There is the legal authority
and responsibility of the board which also involves the hospital's obligation to the system.
This involves power in the medical staff credentialing, understanding nursing and
professional pathways, dealing with union contracts and engaging the numerous
regulatory bodies whose power to affect the daily operations and strategic planning of the
hospital is enormous.\textsuperscript{183}

In addition to all of these governance realities, Catholic hospitals have a clearly
defined relationship to sponsoring organizations that further shape the responsibility of
trustees. Traditionally religious sponsorships have taken three forms; that of religious
congregation, of the diocese, and that of laypeople. Trustees are also tasked with not only
working closely with the sponsoring organization but also understanding their particular Charism. In the U.S. most Catholic hospitals are sponsored by the religious congregation of women and men who establish them, or by their successor’s organizations. Many of these congregations were started by charismatic individuals whose founding spiritual intent included care for the dying, sick and poor. For example, the founding sisters of Bon Secours, who in the early 19th century, began healing ministry to bring healthcare to the home in an effort to “keep healing out of the hands of mercenaries”. They established hospitals with a special commitment to those who are poor and dying. Generations of women from this congregation have sustained decision and founded numerous Catholic hospitals.\textsuperscript{184} It is these values which inspire the mission of this organization. It is the Catholic identity that can be expressed as a means to an end in achieving the mission of the Catholic Hospitals.

Trustees at Catholic institutions face the same pressures to not-for-profit hospitals face in rapid consolidating healthcare delivery systems. Proposal for joint ventures, mergers, acquisitions, sales, and all closures must be examined for strategic wisdom and scrutinized true of the endless variety of details they embody trustees must ensure that any changes in corporate organization that they approve are consistent with the charitable intent of the organization and serve the healthcare of the community.\textsuperscript{185}

2.e. Conclusion.

As indicated at the start of the chapter, Sponsorship and Governance oversight functions in an integrative manner in Catholic healthcare organizations. Sponsorship deals with the oversight responsibility for the mission and identity of an organization that respects and rejuvenates the Catholic social tradition. Governance deals with the
oversight responsibility for administrative success that honors organizational ethics. They function in an integrative manner to combine patient care and the public good in healthcare.

The dissertation explains this integrative responsibility by discussing both current issues and emerging trends that require Sponsorship and Governance oversight of patient care and the public good in Catholic healthcare. Chapter 3 and 4 address current issues that need enhanced oversight, chapter 3 dealing with issues related to patient care and chapter 4 focusing on issues related to the public good. Chapter 5 and 6 discuss emerging trends that require intensive Sponsorship and Governance oversight, chapter 5 dealing with issues related to patient care, and chapter 6 focusing on issues related to the public good. The distinction between enhanced and intensive oversight refers to the following. One the one hand, enhanced oversight requires more attention to current issues that Catholic healthcare typically engages insofar as those issues have changed significantly, reflecting revised Church teaching or changing secular awareness. For example, the 5th edition of the Ethical and Religious Directives in 2009 revised ERD number 58 to clarify when life-sustaining measures may be legitimately withdrawn. On the other hand, intensive oversight requires much more vigorous attention to deal with emerging issues and trends that are pivotal for Catholic healthcare insofar as they can threaten the continuing viability of an organization, such as can arise by the changing landscape of healthcare itself. Specifically, the topic of patient care quality and safety requires intensive oversight because of new Medicare penalties that can accrue to an organization that incurs serious issues regarding patient safety resulting from the Affordable Act. The topic of community benefit programs requires intensive oversight because of the new and
stringent reporting requirements in the IRS 990 Form that can endanger the tax-exempt status of healthcare organizations. The topic of conflicted partnerships requires intensive oversight because of the increasing need to integrate the delivery and financing of care, thereby requiring Catholic healthcare to partner with other-than-Catholic organizations to combine hospitals and insurance in an intricate manner.
Notes


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Chapter 3. Enhanced Oversight of Patient Care: End of Life Care.

Introduction.

Chapter 3 discusses enhanced oversight of patient care, focusing on end of life care. This chapter focuses on the need for enhanced Sponsorship and Governance oversight in issues of patient care especially at the end of life. The point of enhanced oversight of patient care is for Governance and Sponsorship to give more attention that typically occurs in routine board matters to dilemmas in Catholic healthcare that are changing significantly, either because of evolving Church teaching or advances in science or health care. This chapter explains the need for this enhanced oversight by discussing the meaning of patient autonomy in end of life care and the legitimacy of withdrawing futile treatment. Sponsorship and Governance oversight in this arena must establish a fine balance between what the Catholic tradition permits and what is forbidden, reflecting changing Church teaching, such as on when artificial nutrition and hydration may be withdrawn.

Patient autonomy is respected as a function of human dignity and sanctity, reflecting the Catholic social tradition. This respect has to address changing interpretations of the traditional distinction between ordinary and extraordinary means, emerging concerns about consent regarding advance directives, and ongoing science and policy changes over the determination of death.

There is consensus that not all life-prolonging measures are of benefit to the patient. Not every medical treatment that prolongs life is morally required. The ethical
distinction between mandatory and optional measures reflects the traditional distinction between ordinary and extraordinary means. Sponsorship and Board oversight has to ensure that the decision about applying this distinction to treatment options focuses upon the patient and their proxy decision makers while also respecting the nuances and changes in Catholic teaching.²

Advance directives are based on the principle of autonomy in that they allow our medical wishes to be known ahead of time. Hospitals, nursing homes, home health providers, and hospices receiving federal funds provide written information to each individual concerning decisions concerning care, including the right to refuse medical care and the right to formulate an advance directive such as a living will.³ Sponsorship and Governance oversight needs to be attentive to changes in advance care planning such as with POLST forms that can elicit some controversy within Catholic organizations.

While clinicians are familiar with the concept of death most would agree that to clearly define this concept has proven difficult.⁴ Defining death is primarily a philosophical task; clarifying the criteria for the determination of death is primarily a medical responsibility.⁵ In 1980 death was defined as the permanent cessation of functioning of the organism as a whole. This refers to the control of respiration and circulation, neuroendocrinology, as well as homeostatic regulation and consciousness.⁶ Death is currently measured in two ways, by cardiorespiratory or neurological criteria.⁷ However, as the secular debate continues over the determination of death, Sponsorship and Governance oversight in Catholic healthcare needs to be especially attentive to “donation after cardiac death” to ensure that the retrieval of organs and tissues occurs after death has been appropriately determined.
Respect for patient autonomy also justifies the withdrawal of futile treatments at the end of life while prohibiting assisted suicide and euthanasia. This topic relates the meaning of suffering with Church teaching about the circumstances in which withdrawing futile measures is justified to avoid the extremes of assisted suicide or euthanasia. Sponsorship and Governance oversight needs to be more attentive to recent nuanced changes in Church teaching about when life-sustaining measures become morally optional, distinguishing those interventions from assisted suicide and euthanasia.

Suffering is one of the most profound and disturbing human experiences. When medicine fails to address suffering, physicians do not deal properly with their patients. The relief of suffering is considered one of the primary aims of medicine by patients and the general public, and patients, families and physicians recognize the complex needs related to dealing effectively with it. Catholic teaching can be enlightening on this subject. Furthermore, the debate has been exacerbated with regard to patients in a persistent vegetative state (PVS), such as occurred in the case of Terri Schiavo in Florida that generated a revised version (the 5th edition) of the Ethical and Religious Directives for Catholic Health Care Services (ERD) in 2009.

On March 20, 2004 Pope John Paul II addressed participants in an international Congress on the “care for patients in that permanent vegetative state,” setting off a vigorous debate. On November 17, 2009, the United States Conference of Catholic Bishops revised ERD number 58 to reflect the Pope’s stance, introducing a nuanced change in Catholic teaching about medically assisted nutrition and hydration, especially for PVS patients. The nuanced teaching clarified when futile measures including
artificial feeding become morally optional, including for PVS patients. This nuanced teaching reinforced the opposition to assisted suicide and euthanasia in Catholic teaching.

Assisted suicide and euthanasia constitute the intentional termination of the life of a person who requests the deed to be assisted or undertaken by someone else (typically a physician). There seems to be an increased trend in the US to permit assisted suicide and the trend in Europe also includes euthanasia. In the Catholic tradition, the decision to withdraw or withhold treatment is based on the principle of autonomy, reflecting not only the human dignity of the patient, but also reflecting the patient’s relationship with God. However, secular discourse that justifies these actions also makes an argument based upon respect for autonomy of the individual patient. But this argument needs to be substantively repudiated through Sponsorship and Governance oversight, not least because illness places the patient in a vulnerable relationship with the physician, raising the specter of the patient as a victim being killed.

Briefly, there needs to be enhanced Sponsorship and Governance oversight of continuing developments around end of life care in Catholic healthcare. This enhanced oversight needs to be attentive to advances in science or health care as well as to nuanced changes in Church teaching about when life-sustaining measures may become morally optional while at the same time avoiding any confusion with the secular shift to permit assisted suicide or euthanasia. There are two main sections in the chapter, on the significance of autonomy and the meaning of futile treatment. The first section of the chapter discusses autonomy in end of life care, focusing on the distinction between ordinary and extraordinary means, the importance of advance directives, and the
significance of autonomy with regard to the emerging science on the determination of
death.

3.a. Autonomy & End of Life Care.

To understand the significance of autonomy in end of life care it is necessary to
close three distinct but related topics that require Governance and Sponsorship
oversight in the Catholic tradition: the distinction between ordinary and extraordinary
means, the role of advanced directives, and the controversy over the determination of
death.

3.a.(i). Ordinary and Extraordinary Means.

The modern American consensus on issues of forgoing life sustaining treatment
are summarized by David Kelly in what he terms the “three pillar approach.” The first
pillar is based is the general agreement that not all medical treatment which prolongs
biological life is of human benefit to the patient. The ethical distinction between
mandatory and optional treatment has been provided by the Roman Catholic tradition in
its century’s old distinction between ordinary and extraordinary means of preserving life.
This distinction dates to at least the 16th century and was included in the important works
of Alphonse Liguori in the 18th century, and was emphasized and made popular by the
teaching of Pope Pius XII in the 1950s. This is a moral distinction, not a medical one, and
it relies on theological and philosophical understanding of the meaning of human life for
which the practical implications, if not the theological basis, have largely been accepted
in the US consensus. It is mostly a question of human benefit versus human burden. Not
every medical treatment that prolongs life is morally required.
The terms ordinary and extraordinary themselves are open to misinterpretation if
the distinction is understood as a medical one. It is a moral distinction and there are no
simple techniques or statistical criteria for determining the difference. This means that
they are usually thought of as medically ordinary maybe morally extraordinary. What
would be an ordinary or reasonable means, when used in caring for a person whose
chance of renewed health is great, would become an extraordinary in the care of a patient
who has little or no chance for recovery.\textsuperscript{20}

There is no moral obligation to preserve life at all costs. The Pontifical
Declaration on Euthanasia promulgated in 1980 states that correct judgment can be made
regarding means, if the type of treatment, its degree of difficulty and danger, it's expense,
and the possibility of applying it are weighed against the results that can be expected in
light of the sick person's condition and resources of body and spirit. \textsuperscript{21} One of the best
assets for understanding this method is that it provides a reasonable middle ground
between two extreme positions that are sometimes advocated. They are Vitalism which
claims that life itself is the greatest possible value to be sustained at all cost, and
Subjectivism which allows hosting of treatment and even active killing based totally on
the subject of choice of the individual. Each concept is discussed in turn.

\textbf{Vitalism.}

Absolute Vitalism does not allow withdrawal of efforts to prolong life.
Many hospital professionals have encountered situations where a dying person's relatives
insist that everything be done, perhaps out of guilt or fear of being left alone, or from a
belief that God may perform a miracle. Unfortunately this approach is often misconstrued
as a religious argument. There is no theological support for this view. While fully appreciating the present life is to be treasured, it is not all there is. In the Catholic faith tradition biological life need not be prolonged by the use of extraordinary means.\textsuperscript{22}

The Terri Schiavo case in Florida focused attention on a variety of issues related to the end-of-life; who is the decision-maker, the status of advance directives, the role of family members with respect to married adult children, and issues related to the removal of life support, particularly assisted nutrition and hydration.\textsuperscript{23} Interested parties, who sought to keep Terri Schiavo alive, including Florida’s governor and right to life groups, were seemingly motivated by a Vitalism that, to Kelly's thinking, contradicts traditional Catholic teachings on end-of-life care as well as the American consensus on foregoing morally extraordinary treatments. Ironically, Kelly points out that efforts to keep permanently unconscious persons alive demonstrates a decided lack of faith in life after death.\textsuperscript{24}

The case of Terri Schiavo can be linked with another case that played a critical role in clarifying ethical issues at the end of life. The case of Karen Ann Quinlan raised the issue of removing a ventilator. In her case the physicians were reluctant to do this because they feared legal repercussions. However Quinlan's father asked for extraordinary treatment to be stopped for his daughter and had the support of his parish priest and ultimately the New Jersey Supreme Court. The legal and ethical analysis concurred that such removal was justified because it did indeed constituted extraordinary means of care. On February 25, 1990, Terri Schiavo suffered a heart attack, possibly brought on as a result of chemical imbalances from an eating disorder. She suffered loss of oxygen to her brain and was eventually diagnosed as being in a permanent vegetative
state. A decade later, in February 2000, the husband Michael Schiavo request her feeding tube be removed. The circuit court judge agreed. This set off a lengthy appeal and counter appeal process, including attempted legislative incentives from the state of Florida and the United States Congress and 37 court reviews that were complicated by increasing family acrimony and public commentary from various sources: religious, political, ethical, and legal. After a fifteen-year legal battle, the feeding tube was removed, and Terri Schiavo died on March 31, 2005, at the age of 41.25

Subjectivism.

Subjectivism is the polar opposite to Vitalism and is considered another extreme position. It is a lax position that permits the cessation of treatment, and even active killing, based on the subjective choice of the individual person. Basically, the concept that human life as an intrinsic value is rejected. Life is of value only if the individual gives value to it.

In the Roman Catholic tradition human life, while not of absolute value, is always intrinsically valuable. This is a crucial distinction to understand that life is indeed sacred but need not be prolonged under all circumstances. This does not mean that a person's life loses its worth or ceases to be of intrinsic value. Rather when the benefits of continued living are outweighed by the burdens of the kind of life that is likely to result from life-sustaining treatment and/or by the burdens of treatment itself, the treatment may be stopped. The Roman Catholic tradition has rejected both Vitalism and Subjectivism. It recognizes both the sanctity of life and the ethical import of the quality of life.26
The distinction between ordinary and extraordinary means is applied within the Catholic tradition in a flexible manner. Ordinary means, which are morally obligatory, are those from which the patient can reasonably be expected to receive a significant benefit **AND** avoid a disproportionate burden. Extraordinary means, which are optional, are those that promise little significant human benefit **OR** impose a disproportionate burden. The underlined conjunctions emphasize that a much higher standard must be met for ordinary means to be required. The patient is morally obliged to use ordinary means of preserving life and is not morally obligated to use extraordinary ones. This has implications for hospital policy and for the law. If the patient is not obligated to use every means possible of preserving life, then hospitals and healthcare practitioners may not impose themselves on patients. There needs to be enhanced Sponsorship and Governance oversight to monitor changes in science and health care to ensure the proper application of this crucial principle in the Catholic tradition.

Furthermore, the Catholic tradition recognizes that patients and their proxy decision-makers are the most appropriate decision-makers particularly in end-of-life issues. The US legal system recognizes that not all treatments that prolong biological life have benefit to the patient, and there is a moral difference between killing and being allowed to die. This has been combined with the legal concept of the right to autonomy and privacy in decision-making. One may refuse treatment even against the advice of the patient’s physician. The patient has the right of autonomy to choose and the right of privacy to be left alone. There have been major Supreme Court decisions that have changed the medical landscape on these issues. The Supreme Court's June 1990 Cruzan decision that relied on common-law liberties, established as the law of the land the right
of competent patients to refuse treatment, including the right to withdraw artificial
nutrition and hydration. Similarly, the courts in most cases have decided that patients not
capable of making decisions may also refuse treatment through surrogate decision
makers. Kelly calls the legal authority to refuse treatment “The Ace of triumph” 30

3.a.(ii). Advanced Directives.

The distinction between ordinary and extraordinary means provides crucial guidance for
patients in end of life care, especially when they have advanced directives about the care
they seek and the treatments they might forgo in specific circumstances. Any discussion
of advanced directives needs to highlight the role of informed consent and do-not-
resuscitate orders.

Informed Consent.

A widely acknowledged approach to informed consent is the analysis of the
concept in terms of its basic elements. The information component refers to the
disclosure of information and the comprehension of what is disclosed. The consent
component refers to a voluntary decision and authorization to proceed. Legal, regulatory,
philosophical, medical, and psychological literature often propose the following five
elements as the analytical components of informed consent; competence, disclosure,
understanding, voluntariness, and consent. That is, one gives an informed consent to an
intervention if one is competent to act, receives a thorough disclosure, comprehends the
disclosure, chooses voluntarily and consents to intervention.31
In understanding the notion of informed consent, autonomous choice is central: an informed consent is an individual's autonomous authorization of a medical intervention or of participation in research. The person must do more than indicate agreement or comply with a proposal. The individual must authorize interventions through an act of informed and voluntary consent. An informed consent occurs if a patient or subject, with substantial understanding, and in the absence of significant control by others, intentionally authorizes a professional intervention on the individual.\textsuperscript{32}

The basic idea is that people have the right to give informed consent to medical treatment or to refuse that consent. To do this, they need to have the capacity to choose freely and to understand what is being asked of them.\textsuperscript{33} A good example is cases of acute or chronic pain that can diminish the capacity for consent.\textsuperscript{34} The human person is not an isolated individual, free from all social influences and interactions. Perfectly competent patients are likely to take into account the wishes of their families and others who may be influencing their decisions, and such influence does not mean that the consent is not free.\textsuperscript{35}

In 1914, Schloendorff sued the society of New York Hospitals after a uterine fibroid was surgically removed rather than a manual examination performed under anesthesia. The court convicted the surgeon of assault. What was pivotal in this case was that a conversation had taken place between the patient and the surgeon prior to anesthesia; the patient expressed clear determination that no surgery was to be performed beyond the simple examination. The court's ruling of assault became the first documentation of defending the patient's will over the surgeon's will in a medical treatment, emphasizing that "every human being.... has a right to determine what shall be
done with his own body.” Priority was, for the first time, granted to the will of the patient.\textsuperscript{36}

The term informed consent was coined in case law in 1957 and eventually brought to the full attention of the medical community. However, within short order, informed consent was lifted from a legal context due to the emergence of medical ethics and placed in the center of the debate about decisional authority and the doctor-patient relationship; many would claim that the debate is still underway. The issues raised by civil rights, women's rights, the consumers movement, the rights of prisoners, and of the mentally ill often included healthcare components; reproductive rights, abortion, contraception, the right to healthcare information, access to care, human experimentation, and so forth. These urgent social concerns helped reinforce public acceptance of the notion of rights as applied to healthcare.\textsuperscript{37}

In exploring its history it seems likely that the increase of legal interest in the rights of self-determination, increased philosophical interest in the principle of respect for autonomy and individualism set the grounds for various social movements during the second half of the last century.\textsuperscript{38} These social movements emphasized the value of human life. Human life is of value not simply because it enables autonomous decision-making. Rather, human life is valuable even if persons do not or cannot make decisions.\textsuperscript{39} One of the most controversial areas where respect for human life is manifest is when deciding about resuscitating a patient.

\textbf{Do-not-Resuscitate (DNR).}
Many non-clinicians hold rosy views about the nature and effectiveness of cardiopulmonary resuscitation (CPR). Several studies have underlined their misplaced optimism: in one, the 269 respondents reported a mean expected survival rate for CPR of 65%; in another, 81% of respondents over 70 years old believed the likelihood of leaving the hospital after a cardiac arrest to be at least 50%. The real figure, for all in-hospital cardiac arrests, is roughly 14%, and many survivors will have new functional or neurological impairments.40

The illusion of CPR’s effectiveness can lead patients and relatives to make ill-informed choices about care at the end of life. To emphasize the fallibility of the exercise, many institutions have abandoned the term “do not resuscitate” (DNR) in favor of “do not attempt resuscitation” (DNAR). This is an attempt to bring clarity to patients who are attempting to choose a plan of care. DNR does not mean “do not treat,” much less “do not bother.” With the exception of those in intensive care, many patients with DNR orders survive to discharge. DNR means if the patient has a cardiac arrest, do not attempt cardiopulmonary resuscitation.41

Shortly after the Cruzan decision was released, Congress enacted the patient self-determination act [PSDA] as part of the Omnibus budget reconciliation act of 1990, with an effective starting date of December 1991. It required that health facilities inform patients about their right to refuse medical treatment and their right to formulate advance directives (living wills, etc.). Although all but six states had laws providing for advanced directives, fewer than 10% of Americans actually had executed them. Specifically, PSDA requires hospitals, nursing homes, home health providers, and hospices receiving federal funds (e.g., Medicaid/Medicare) to: [1] provide written information to each individual
concerning his or her rights under state law to make decisions concerning medical care, including the right to refuse medical care and the right to formulate an advance directive such as a living will. [2] document in each individual's medical record whether he or she had executed an advance directive; [3] not condition care or discriminate in care based on whether the patient had executed an advance directive; [4] ensure compliance with requirements of state law respecting advance directives; and [5] provide education for staff and community and issues relating to advance directive. The particular issue around advance directives is based on the principle of autonomy in that it allows our wishes to be known.

The significance of autonomy in end of life care is not only related to ordinary and extraordinary means as well as the debate over advanced directives, but also with the controversial issue of brain death criteria. The connection emphasizes the importance of protecting patient autonomy until death has occurred. Hence, the definition of death constitutes a crucial aspect of respect for patient autonomy. There especially needs to be enhanced Sponsorship and Board oversight in Catholic healthcare because of the developments in science that guide healthcare practice.

3.a.(iii). Brain Death Diagnosis.

The history of the meaning of brain death criteria has by no means yet resolved the meaning of the concept. The life status of the “brain-dead” patient became ambiguous. Such patients possess certain characteristics associated with life: they are warm, they have spontaneous heartbeat and systematic circulation, they produce urine and absorb and metabolize food. Yet they possess characteristics associated with death:
they are totally unresponsive to even the most noxious stimuli, they are apneic, and they make no spontaneous movements.\textsuperscript{44}

Technology has contributed significantly to this debate. For example, electroencephalogram (EEG) measures electrical activity in the brain; also, cranial blood flow scans and tests such as positron emission tomography (PET) or functional magnetic resonance imaging (fMRI) show complete absence of brain blood flow. As a result, knowledge of a brain centered definition of human death has expanded. These raise significant ethical issues that are discussed in the following section on the diagnosis of death and on functional brain imaging.

**Death Diagnosis vs PVS.**

While clinicians are familiar with the concept of death most would agree that to clearly define this concept has proven difficult.\textsuperscript{45} One issues lies in the fact that what the layperson means by death is often different from the criteria by which a physician legally determines when death occurs. Death is not a technical term but a common one which we all use. Part of the issue revolves around how a clear definition of death is defined and by whom. Some of the related issues are: providing the definition is primarily a philosophical task; providing the choice of the criterion is primarily medical one; and the selection of the tests to prove that the criterion is satisfied is a medical matter.\textsuperscript{46}

In 1980 death was defined as the permanent cessation of functioning of the organism as a whole. To clarify this does not mean the whole organism, for example, the sum of its tissue and organ parts; it refers to the highly complex interaction of its organ subsystem. The subsystem functions are those without which the organism as a whole
cannot function. They are in control of respiration and circulation, neuroendocrinology, and homeostatic regulation, and consciousness. Death is defined by the irreversible loss of these functions.

On July 9, 1981 the U.S. President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published their report on the Medical, Legal and Ethical Issues in the Determination of Death. This generated the President’s Commission findings on “Guidelines for the Determination of Death”. This was updated in December 2008 by a different Presidential commission, The President’s Council on Bioethics, Controversies in the Determination of Death. The 1981 report led to the Uniformed Determination of Death Act (UDDA). The act reads as follows: “an individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the stem, is dead. A determination of death must be made with acceptable medical standards. However the UDDA does not define “acceptable medical standards”. In 1995 the American Academy of Neurology (ANN) published practice parameters which emphasized the three clinical findings necessary to confirm irreversible cessation of all functions of the entire brain, including the brainstem: coma, absence of brain stem reflexes, and apnea. Ultimately, and for clarification, death can be measured in two ways, by cardiorespiratory or neurological criteria.

The debate over the diagnosis of death is related to but distinct from the diagnosis of PVS conditions. In 1899 Uber Rosenblat, a German physician reported that 15-year-old tight rope walker who after two weeks in a coma following a fall from a wire, recovered to become “strangely awake” he died eight months later. His life had been
sustained by tube feeding. Then in 1940, a German psychiatrist Kretschmer proposed the term “the apallic syndrome” to describe patients who were awake but unresponsive. By 1956 Dr. Strich reported the pathological findings in five cases of people which she claimed had “severe traumatic dementia”. Since then other terms have been used such as post-traumatic dementia or encephalopathy. In 1972 Jennet and Plum coined the term persistent vegetative state (PVS). The name vegetative state was chosen to refer to the vegetative nervous functioning, recognizing that patients have variable sleep wake cycles, respiration, thermoregulation. The term persistent was added to denote that the condition remained for at least one month after insult.

Over many decades technology advanced considerably to track conditions related to what became known as PVS. This led, for example, to the guidelines from the Royal College of Physicians in the UK to consider a vegetative state to be persistent when it lasts longer than a month and permanent when it lasts longer than six months for non-traumatic brain injuries and one year for traumatic brain injuries. The Royal College of Physicians defined PVS as a clinical condition of unawareness of self and environment in which the patient breathes spontaneously, has a stable circulation, and show cycles of eye closure and openings which may stimulate sleep and waking. Three main clinical features define the vegetative state: a) cycles of eye openings and closings, giving the appearance of sleep-wake cycles; b) complete lack of awareness of the self or the environment; and c) complete or partial preservation of hypothalamic and brainstem automatic functions. Furthermore, the New England Journal of Medicine, on August 5, 1968 published the Harvard Report on brain death: “A Definition of Irreversible Coma: Report of the Ad Hoc Committee at Harvard Medical School to Examine the Definition of Brain Death.”
The Harvard Report described the physical and neurological characters of irreversible coma, chiefly unresponsiveness, no movement or breathing, no reflexes, and flat EEG. This report stated that its primary purpose was to define irreversible coma. Reflecting these developments, human death was determined by neurological criteria, reinforcing that death can be measured in two ways, either by cardiorespiratory or neurological criteria. In turn, new technology emerged yet again to change the ethical debate, functional brain imaging.

Functional Brain Imaging.

The emergence of this new technology reflected a long history of developing concepts and capacities in medicine around the meaning of consciousness. The brain can be explored through methods like a functional magnetic resonance imaging (fMRI) and positron emission tomography (PET). Indeed reconciling discordance between what can be seen on bedside examination and what patients may demonstrate on sophisticated neuroimaging is essential to understanding these conditions. This achievement reflects multiple technological breakthroughs in medicine, from Angelo Mossi in the 19th century onwards. A significant development in the role of functional neuroimaging has been the relative shift of emphasis from PET activation studies to functional MRI (fMRI). Not only is fMRI more widely available than PET, it improves spatial and temporal resolution and does not involve radiation. The advent of fMRI revolutionized neural imaging of the human brain. Beyond enhanced analysis of functional specialization, it enables novel analysis of the casual influences that neural units exert over another. The history leading to fMRI has captured mainstream attention, leading not only to recognition of
the advantage of fMRI over the CT, but to a widespread interest in brain computer interface (BCI).

BCI began in the early 1970s when Dr. J. Vidal started to research a method of creating an alternative output pathway for severely disabled individuals. Recent years have seen an explosion of interest in applying the advances in cognitive neuroscience to developing brain computer interfaces. A BCI is defined as a system that measures and analyzes brain signals and converts them in real time into outputs that do not depend on the normal output pathways of peripheral nerves and muscles. A fully-fledged BCI system involves sensory stimulation and task performance to the measurement and analysis of the resulting brain signal, to outputting of the desired function, and, finally the feeding back of the relevant information to the person undergoing the procedure. The cycle can be repeated until reliable results are achieved.

In an attempt to understand the functioning brain, by utilizing the advancements in neuro-imaging technologies, a closer scrutiny of current research is helpful. Given that the internationally agreed diagnosis criteria for the vegetative state revolve around the concept of evidence of awareness, research continues on this issue. It should be noted that fMRI activation studies have the potential to demonstrate distinct and specific psychological response, changes in regional cerebellum blood flow and controlled external stimulation without the need for any overt behavior by the patient. These functional neural imaging activation studies are indicating a new level of awareness for patients who did not respond to bedside assessments.

An example of the breakthroughs in this fast changing terrain is the work of Adrian Owen from the University of Cambridge. In 2006 a team of neuro-researchers led
by Owen studied a 23-year-old woman who had suffered a traumatic injury to the front of her brain. In mid-2005 the patient was involved in a motor vehicle accident. Upon admission to the hospital she had a Glasgow Coma Scale score of 4. A computer tomographic image revealed excessive damage. Between the time of the crash and the fMRI imaging in early January 2006 the patient was assessed by a multidisciplinary team using repeated standardized assessment. Throughout this period the patient's behavior was consistent with the accepted guidelines defining the vegetative state. She opened her eyes spontaneously, exhibited sleep wake cycles, and had a preserved but inconsistent reflects behavior. There was no evidence of orientation, fixation greater than 5 seconds, or tracking to visual or audio's stimuli. No overt motor responses to commands were observed.

After approximately 5 months the patient's neural responses were tested using fMRI. The patient's auditory responses were checked by the presentation of sentences such as there is milk in the coffee. The results were compared with response to acoustically matched noise sequences. Speech specific activity was observed in an equivalent manner to observation in healthy subjects who listen to the same stimuli. Further testing involved sequences that contained ambiguous words with significant response in the frontal region, similar to that observed for normal volunteers. This response to ambiguous sentences reflected the operation of semantic processes that are critical for speech comprehension.

The investigators then conducted a second fMRI study on the subject and also used the same criteria to test a control group. They were both asked to perform mental imagery tasks. The subject was asked to imagine playing tennis and imagine visiting the
rooms at home. These particular tasks were chosen because imagining “playing tennis” and imagining “moving around the house” enlisted reliable, robust, and statistically distinguishable patterns of activation in specific regions of the brain. When the subject was asked to imagine playing a game of tennis, the fMRI scans showed activity in the supplementary motor area of her brain. This activity was similar to that of the healthy awake control subjects. When she was asked to imagine walking through the rooms at home, the scans showed activation of the network involved in spatial navigation. Again, the response was similar to that in the healthy subjects. The investigators, based on this evidence, concluded that despite the fact that the subject fulfilled all of the clinical criteria for a diagnosis of Vegetative State, the patient retained the ability to understand spoken commands and respond to them through brain activity. This confirmed that the subject was consciously aware of herself and her surroundings. Others are not so sure.

Another example of the remarkable breakthroughs in this field is the research of Martin Monti. He built upon the active language paradigm of Owen to toggle a yes/no response to willful modulation of brain activity. Between November 2005 in January 2009 54 patients with severe brain injury, including 23 in the vegetative state and 31 in a minimally conscious state, underwent fMRI as a means of evaluating their performance on motor and spatial imagery tasks. The motor and spatial imagery tasks are known to be associated with distinct fMRI activity in the supplementary motor area and that parahippocampal gyrus. In the fMRI scanner all patients were asked to perform two imaginary tasks. In the motor imagery task, they were instructed to imagine standing still on the tennis court and then to swing an arm to hit the ball. In the spatial imagery task, participants were instructed to imagine navigating the streets of a familiar city or to
imagine walking from room to room in their home and to visualize what they would see if they were there. After primary localizer scans had been obtained, 16 control subjects and one patient underwent functional MRI to modulate their brain activity. Before each of the imaging sessions participants were asked a yes or no question for example, “do you have any brothers?” They were instructed to respond during the imaging session by using one type of mental imagery either the motor imagery or spatial imagery to answer for “yes,” and the other for “no”. All scans were limited to the brain location within the supplementary motor area and the parahippocampal gyrus.

To determine whether the imagery task produced the expected activations at predefined neuroanatomical locations, two scans were compared for each participant: motor imagery and spatial imagery. Of the 54 patients, five were identified who could willfully modulate their brain activity. In all five of these patients, the fMRI scans associated with motor imagery, as compared with spatial imagery, showed considerable activation in the supplementary motor area. In four of the five patients, the scans associated with spatial imagery, as compared with motor imagery, showed activation in the parahippocampal gyrus. Of the 54 patients, five with traumatic brain injuries were able to modulate their brain activity by generating voluntary, reliable, and repeatable response in predefined neuroanatomical regions when prompted to perform an imaginary tasks. No such response was observed in any of the patients with non-traumatic brain injuries. The fMRI data provided clear evidence that the patients were aware and able to communicate, it is not known whether either was available during earlier evaluations.

These breakthroughs have made a significant contribution to the understanding of consciousness. To understand consciousness it helps to recognize that confusion is often
related to the way we define things. A core problem is that the word “consciousness” is used with different meanings in different contexts, such as in common language, science, and philosophy. In daily life we recognize others as conscious if they can communicate their own experiences verbally or by means of their behavior either spontaneously or in response to external stimuli. Medicine works in a more rigorous way.\textsuperscript{83}

The way consciousness is defined is crucial, as it may govern attitudes towards medical management of disorders of consciousness.\textsuperscript{84} The relationship between mind and brain has philosophical, scientific, and practical implications. Recently two separate but related surveys from the University of Edinburgh and the University of Liege explored beliefs on the relationship between body and mind. The majority of healthcare workers denied a distinction between consciousness and the soma, but more than one third of medical personnel regarded the mind and the brain as separate entities.\textsuperscript{85} Part of the ambiguity revolves around the definition of consciousness. There currently exists no method for acquiring an objective physical measurement of consciousness in either a patient or a healthy volunteer. To assess consciousness in patients requires expert clinical interpretation of voluntary versus reflective behaviors, necessarily relying on ‘motor responsiveness’. Indeed, the only method to demonstrate awareness to others is through some form of motor activity: speech, facial expression, eye tracking, the movement, shrugging shoulders, nodding and shaking hands, etc. Therefore, clinical assessment is limited to the extent to which internal awareness can be established in a patient who lacks the motor function to demonstrate this awareness.\textsuperscript{86}

Although the vegetative state is often referred to as a disorder of consciousness, this term is problematic because it suggests that there is disruption of an underlying, well-
understood and clearly defined system known as consciousness. But there is at present no satisfactory, universally accepted definition of consciousness, though a common understanding considers consciousness as being aware of oneself and the environment.

When referring to patients as those who are in the vegetative state, consciousness is often separated into two basic components: arousal (wakefulness or vigilance) and awareness (i.e. comprising of all subjects perceptions, feelings and thoughts.) Awareness has recently been subdivided into “external or sensory awareness” (i.e., perceptual awareness of the environment) and “internal or self-awareness” (i.e., stimulus-independent thoughts, mental imagery, in speech, daydreaming or mind wondering). Accordingly, vegetative patients are thought to lack awareness of self and environment but have maintained eye arousal such as eye-opening and sleep wake cycles. Distinguishing between various aspects of consciousness in this way is helpful, but it inevitably provokes further questions, such as what constitutes awareness, if indeed it is a sub component of consciousness, and what level of awareness is necessary for a patient to be described as conscious.

Awareness also refers to the collective thoughts and feelings of an individual. Clinically, however, our operational definition is limited to the appraisal of the potential to perceive the external world and to voluntary interact with it, our perceptual awareness. Traditionally this has been carried out at the bedside by careful and repeated examination of the capacity to formulate reproducible, voluntary, purposeful and sustained behavioral response to auditory, tactile, visual, or noxious stimuli. After severe brain damage and the acute setting of a coma, four different clinical entities can be disentangled. A) Patients who "awaken" but remain without reproducible signs of command following. This is
traditionally referred to as the vegetative state, now also called the “unresponsive wakefulness syndrome.” B) Minimally Conscious State, these patients show reproducible, albeit fluctuating, signs of consciousness, but without functional communication. C) There are patients who emerge from Minimally Conscious State, recovering functional communication or objective use. D) Locked In Syndrome – Locked-in patients are fully aware of their surroundings yet completely paralyzed with the exception of small eye movements possibly permitting coded communications.\(^9^2\) 

For the patients involved in Monti’s study diagnosis of the vegetative state was made on the basis of their detailed clinical history, supported by the behavioral observation. They all met the clinical criteria for the diagnosis, i.e., that there must be no evidence of awareness of self or environment, no response to external stimuli of a kind suggesting volition or purpose, and no evidence of language comprehension or expression.\(^9^3\) It is important to recognize that studies of learning during anesthesia and sleep have demonstrated that aspects of human cognition, including speech perception and semantic processing, can go on in the absence of conscious awareness.\(^9^4\)

Despite these insights to the meaning of consciousness and the technological breakthroughs in brain imaging technologies, misdiagnosis is not uncommon. PVS and MCS states are currently distinguished on the basis of exhibited behaviour. The diagnosis process is prone to error. Previous work has suggested that up to 43% of the patients in PVS may be misdiagnosed.\(^9^5\) Researchers generally argue over the exact cause of misdiagnosis but agree that the reasons are multifactorial.\(^9^6\)

Not surprisingly, the controversy around brain imaging and misdiagnosis generates a plethora of ethical issues and dilemmas around consciousness as a reflection
of autonomy in end of life care. These dilemmas include the withdrawal of treatment from PVS patients or chronic minimally conscious state patients. Evidence of consciousness does not preclude withdrawal of life sustaining treatment. It is ethical to withdraw life-sustaining treatment even from patients who are fully conscious, for example when the treatment is futile or when the burdens of treatment outweigh their benefits. Neuroimaging might indicate that a patient who appears to be in a vegetative state is not. Evidence of consciousness in very severely brain-damaged patients may contribute to decisions to discontinue life-sustaining treatment.

The possibility of establishing a direct communication and control channel between the human brain and computers has been a topic of scientific speculation and even scientific fiction for many years and has grown into one of the fastest growth areas of scientific research. As mentioned earlier, brain computer interface (BCI) now allows users to control external devices using brain signals rather than the brain's normal output pathway of peripheral nerves and muscles. A BCI is an artificial intelligence system that can recognize a set of patterns in brain signals following consecutive stages: signal acquisition, processing, feature extraction, classification, and control interface.

Functional neuroimaging provides the ability to measure the brain's activity and correlate this with consciousness. The two main strategies seem promising for reducing the consistently high misdiagnosis rate in disorders of consciousness. Firstly, behavioral assessment needs to be conducted more thoroughly and by trained staff, i.e., a neurologist or another healthcare professional that has been trained to use sound assessment methods. Secondly, the inclusion of fMRI will increase the detection of awareness in the
circumstances susceptible to misdiagnosis. It may even allow the patient to interact with their environment and to some extent let their voices be heard.\textsuperscript{103}

In other words, brain imaging technology offers a new technology to diagnose complex conditions of consciousness, such as PVS or the minimally conscious state.\textsuperscript{104} Possibly some communication capacity may enable PVS patients to indicate a preference to withdraw life-sustaining measures, thereby respecting their dignity and providing some control of their destiny.\textsuperscript{105} This suggests an opportunity for a neuroethical construct to develop our understanding of consciousness and refine the concept of consciousness if we are to adequately evaluate its ethical significance.\textsuperscript{106} These breakthroughs hold significant scientific and practical uses for patients who suffer from disorders consciousness to once again have a “voice” and be heard.\textsuperscript{107}

In sum, these technologies raise pivotal ethical issues regarding respect for autonomy in end of life care that require enhanced oversight of Sponsorship and Governance in Catholic healthcare. In turn, these technologies also contribute to the ongoing debate about futile treatment at the end of life. Just as Sponsorship and Governance oversight needs to be attentive to emerging science that guides practice in end of life care (the first section of this chapter), Sponsorship and Governance oversight also must be attentive to evolving Church teaching on issues about care at the end of life (the second section of this chapter). This second section of the chapter focuses on the ethical issues on patient care around withdrawal of treatment to examine the meaning of suffering in the dying process and to explain evolving Church teaching that justifies withdrawing futile treatment while robustly opposing assisted suicide and euthanasia.
3.b. **Withdrawal of Futile Treatment.**

Modern medicine increasingly forces us to make choices, to be responsible for medical care.\(^{108}\) Death may be tamed, divested of the blind violence of natural forces, and ritualized, but it is a natural phenomenon,\(^{109}\) one with a very long history of interpretation.\(^{110}\) To grapple with the ethical debate over the withdrawal of futile treatment in Catholic health care requires an understanding of several related topics: the relation between suffering and dying, the teaching of the Catholic Church on withdrawing treatment, and the secular trend towards assisted suicide or euthanasia.

3.b.(i). **Suffering and Dying.**

Suffering is one of the most profound and disturbing human experiences. The very word suffering has a resonance that relates to life's meaning and threat suffering poses to happiness. Suffering does not just refer to maladies, pains and difficulties. It also involves crises and threats that constitute degradation or alienation of our being.\(^{111}\) Cassell defines suffering as the state of severe distress associated with events that threaten the intactness of the person. Although suffering occurs for many reasons, it commonly arises when a person resists feelings such as uncertainty, lack of control, fear, despair, or grief this then threatens the wholeness of the person, who is unable to accept life simply as it is.\(^{112}\) The relation between suffering and dying reflects a failure in medicine as well as a danger of dualism in health care. Each point is considered in turn.

**The Failure of Medicine.**
The failure of medicine to effectively address suffering reflects a failure to deal adequately with patients. This failure also reflects personal and social experiences in modern society. The meaning of suffering is problematic in the context different cultures. Suffering has been referred to as a spiritual phenomenon, an event that strikes at the fate we have in life. For many grappling with suffering is entwined with the deity, such as by violating the supernatural order. The obligation of physicians to relieve human suffering stretches back into antiquity. However, in today's technologically advanced medical arena it is not uncommon for suffering to occur not only during the course of the disease but as a result of the treatment.

To frame the notion of modern suffering, Cassell recounts the story of a 35-year-old sculptor with metastatic cancer originating in the breast. The tumor invaded the nerves near her shoulder, she lost the ability to sculpt, and became profoundly depressed. The nausea and vomiting from the chemotherapy were distressing, but the suffering included the way she was treated. Common responses of physicians in such settings include "a sense of failure and frustration when the patient's illness progresses, feelings of powerlessness against illness and its associated losses, grief, and fear of becoming ill oneself, and a desire to separate from and avoid patients to escape these feelings." The patient desired to live by the end of each remission. When a new manifestation of the cancer would appear she was torn between her desire to live and the fear that the hope which would emerge again would merely expose her to misery if the treatment failed. She was constantly tortured by fears of what tomorrow would bring. She was sure she was going to die. She suffered from the side effects of the disease and its treatments on her appearance and her abilities. She also suffered from her perception of the future. She
suffered from threats that were social and others that were personal and private. Her severe pain, physical symptoms and her internalization of this conflict can enlighten the meaning of suffering.\textsuperscript{121}

Western medicine tends to treat suffering as a tragic event, rather than something present within the fabric of life. The fear of death and dying are a source of suffering for many people, and health-care providers often suffer while working with suffering patients.\textsuperscript{122} The relief of suffering, it would appear, is considered one of the primary aims of medicine by patients and the general public, but not by the medical profession. In the care of the dying, patients and their families and friends do not divide up suffering into its physical and nonphysical sources the way the doctors do. Physicians appear to be primarily concerned with the physical pain. In understanding the word suffering most physicians coupled it with pain.\textsuperscript{123} This problematic approach to suffering reflects a dangerous dualism in the western approach to medicine.

\textbf{Dualism.}

The understanding of the place of a person in human illness requires a rejection of the historical dualism of mind and body. Suffering occurs when an impending destruction of the human person is perceived; suffering can be defined as the state of severe distress associated with events that threaten the intactness of the person. Suffering can occur in relation to any aspect of the human person.\textsuperscript{124} Focusing on the person helps to understand the relation between compassion, suffering and the goals of medicine.\textsuperscript{125}

The intensity of family ties cannot be overestimated. Just as a person’s past experience gives meaning to the present, so does the past experience of the person’s
family. If the majority of patients consult with their family before minor or routine procedures, end of life decisions should not be different, especially regarding suffering. One’s culture also contributes to belief and values. This plays a crucial part in the effects of disease and the life of the person who can be very isolated when sick.\textsuperscript{126} As Broyard stated, “I’d like my doctor to scan me, to grope for my spirit as well as my prostate. Without some such recognition, I am nothing but my illness.”\textsuperscript{127}

A large-scale government-funded empirical study on Dutch euthanasia from 1990 to 2001 shows that unbearable suffering is most frequently mentioned by the surveyed physicians as reason for committing euthanasia. Other reasons are de-humanizing conditions, loss of dignity, and pain. Considerably more surprising is a cluster of reasons that concern the individual patient's ability to cope with the situation: the lack of meaning in suffering, being dependent, and being tired of life. These reflect the expansion of suffering as a justification for euthanasia.\textsuperscript{128} In this regard Catholic teaching makes a robust distinction between legitimately withdrawing futile treatment when patients have unbearable suffering and enacting assisted suicide or euthanasia to relieve their suffering.

3.b.(ii). Pope John Paul II & the Ethical and Religious Directives #58.

The Catechism’s emphasis upon the relationship between human dignity and the sanctity of life provides a solid foundation for the \textit{Directives for Catholic Health Care Services} from the Bishops of the United States. The Directives explain that we must deal with the whole person whose innate dignity and sacredness reflects the divine presence among us: “Christ's redemption and saving grace embrace the whole person, especially in his or her illness, suffering, and earth” (part five, introduction). Moreover, the sanctity of
life relates our human dignity with our eternal destiny. The directives explained: “the dignity of human life flows from being created in the image of God (Gen 1:26) from redemption by Jesus Christ, and from our common destiny to share a life of God beyond all corruption” (part two, introduction). The pivotal passage in the ERDs regarding legitimately withdrawing life-sustaining treatment is ERD number 58. This passage in the ERDs was crafted by the U.S. Bishops to engage an important teaching on the matter by Pope John Paul II just before he died.

Pope John Paul II's Letter.

On March 20, 2004 Pope John Paul II addressed participants in an international Congress at the Vatican on “life sustaining treatments and vegetative states: scientific advances and the ethical dilemmas.” The Pope's speech “care for patients in that permanent vegetative state,” set off a vigorous debate, especially in the United States, regarding its authority as well as how the speech should be interpreted. This focused on the debate about the moral justifiability of foregoing or withdrawing artificial nutrition and hydration for patients in PVS. The Pope delivered his address to 400 participants in an international Congress promoted by the World Federation of Catholic Medical Associations and by the Pontifical Academy for Life. In his allocution, the Pope stated that hydration and nutrition are morally ordinary treatments for PVS patients and that foregoing this treatment is “euthanasia by omission.” David F. Kelly maintains that this statement is inconsistent with the received tradition of Catholic medical ethics.
Kelly explains that Catholic teaching distinguishes internal and external authority. Internal authority comes from the integrity of the arguments and their consistency with the rest of Catholic tradition on this and similar issues. The point of Pope John Paul II is not consistent with the rest of Catholic teaching on foregoing treatment. External authority comes from the authority of the author of the document as well as from the way in which it was proclaimed. There is a hierarchical order of importance. Papal documents are more authoritative than documents ordered by individual bishops. Formal encyclical letters are more authoritative than more simple papal statements. Decrees from an ecumenical Council, such as Vatican II, are generally seen as more authoritative than encyclicals, and so on. Thus the external authority of this talk is not very high. This is simply a talk Pope John Paul was asked to give to a meeting in Rome. Nonetheless it was a papal address and the U.S. Bishops revised their ERDs in light of this important teaching, specifically ERD number 58.

ERD Directive 58.

On November 17, 2009, at its meeting in Baltimore, the United States conference of Catholic Bishops voted 264 to 4 to approve the revision of Directive 58 of the Ethical and Religious Directives for Catholic Health Care Services, which deals with medically assisted nutrition and hydration, reflecting the statement of Pope John Paul II. This revision in 2009 was the fifth revision of the ERD’s. In the previous 2001 edition of the ERDs the Vatican had not resolved the dilemma about providing medically assisted nutrition and hydration to patients in a persistent vegetative state.
The 2001 introduction to part five stated that there were necessary distinctions between questions already resolved by the magisterium and those requiring further reflection as, for example, the morality of withdrawing medically assisted hydration and nutrition from a person in a persistent vegetative state. After Pope John Paul II addressed this issue in 2004, in August 2007 the Congregation for the Doctrine of the Faith issued a clarifying document. The introduction to part five and Directive 58 have been revised in light of these statements. The revised edition retains the legitimacy of withdrawing life-sustaining measures in some cases at the end of life, for example: “Medically assisted nutrition and hydration become morally optional when they cannot reasonably be expected to prolong life or when they would be excessively burdensome for the patient or would cause significant physical discomfort” (ERD, 58). However, the justification by the U.S. Bishops in ERD #58 of the withdrawal of futile treatment is distinguished emphatically from the wrongfulness of both assisted suicide and euthanasia.

3.b.(iii). Assisted Suicide and Euthanasia.

The debate on these controversial topics draws a strict distinction between mercy killing and the sanctity of life. Each is discussed below,

Mercy Killing.

During the 1960s and 1970s the notion of death increasingly became prominent in public discussion. There was a rising tide of complaints about the way people died, often alone in ICU's wrapped in a harsh cocoon of tubes and wires with their families their families denied admittance. By the end of the 1980’s it is estimated that 80% of people in
the United States were dying in hospitals or nursing homes. Coupled with such statistics were the personal stories of medical indignities, poor palliative care, inefficient pain relief, and a chilling indifference to the anxious friends and relatives.\textsuperscript{135}

The ethical debate over assisted killing and euthanasia has a long history from Greek mythology onwards.\textsuperscript{136} The concept of a terminally ill patient seeking a physician to assist in suicide was not seriously proposed until the 18th century, with the discovery of analgesics and anesthetics which had the potential to relieve suffering for dying patients. As medicine learned to control acute infectious diseases, life expectancy gradually increased from a norm of 40 in 1852 to almost double that figure today, and degenerative and late onset diseases, especially cancer, made the discussion of end-of-life care more urgent.\textsuperscript{137}

Today the official Belgium Law on Euthanasia permits euthanasia only if “the patient is in a medically futile condition of constant and unbearable physical or mental suffering that cannot be alleviated, resulting from a serious and incurable disorder caused by illness or accident.”\textsuperscript{138} Similarly, the Dutch definition of euthanasia is: “The intentional termination of the life of a person by someone other than that person, at the latter's request”\textsuperscript{139}

In Dutch society only physicians have such legally sanctioned power.\textsuperscript{140} Approximately 130,000 people die in the Netherlands each year. In 49,000 of these incidences it was physicians who assisted in the patient’s death, deciding who should continue life support, from whom treatment should be withdrawn, and to increase the dose of morphine to provide adequate pain relief even at a potentially lethal level.\textsuperscript{141}
An empirical study in the mid-1980s about the Dutch practice of euthanasia and physician assisted suicide suggested that the request for euthanasia were about three times more common. While acknowledging the legal distinction between euthanasia and assisted suicide, the Royal Dutch Medical Association claims that there is no significant moral difference between the two. The same report expressed a preference that patients assume more responsibility for their own death by taking the lethal medication themselves rather than expecting physicians to administer them. This is exactly what distinguishes assistance in suicide from euthanasia – the patient is the victim who is being killed while the physician is empowered in an increasingly technological environment.142

This calls for a re-examination of the doctor-patient relationship that seeks to balance patient autonomy and physician’s duty of benevolence and non-maleficence, primum non nocere, first do no harm.143 The doctor has an obligation to act in the patient’s best interests, but in assisted suicide and euthanasia they appear to be exempted from their duty to protect life and health.144 Often assisted suicide and euthanasia are translated as forms of ‘mercy killing’. However, it is important to remember that ‘mercy’ may be the motive but death remains the outcome. The physician who is drawn into and moved by the patient’s suffering to enact assisted suicide or euthanasia seems to intend the patient’s death.145

Also, in the Netherlands euthanasia has turned out to be a preferable intervention despite palliative and hospice options. Respect for patient autonomy is used as a dubious justification for the practice of assisted suicide or euthanasia.146 The Dutch debate continues elsewhere in the world with similar paradoxes. One paradox results from the dialectic relationship between the moral principle of respect for individual autonomy and
the moral principle of benevolence. The relief of suffering acts the second paradox. Contrary to these disconcerting trends that undermine the core meaning of the patient-physician relationship, the Catholic tradition upholds a robust respect for life. Even though life-sustaining measures can be withdrawn in some circumstances as discussed previously, assisted suicide and euthanasia are forbidden as being contrary to a basic respect for life.

**Respect for Life.**

Chapter two explained the close connection between human dignity and sanctity as a relational connection that requires respect for individual human life. This respect for life contrasts robustly with trends to support assisted suicide or euthanasia. This concept of human dignity emphasizes relationality. Human dignity must be relational an order to respect the social nature of humanity. It does not claim that human dignity is dependent upon one's capacity for relationships. Rather, human dignity as relational simply indicates the interpersonal nature of human dignity, including that of the individual who lacks rational rationality or autonomy.

Relational human dignity is important in a healthcare setting precisely because the entire premise of healthcare intervention rests on the moral demands to have respect for individual human life. This relational view of respect for life does not diminish the importance of autonomy; rather it emphasizes that inherent human dignity is indispensably relational. The reason one respects another's autonomy, particularly in the end-of-life setting, is because autonomy is a relational construct that focuses upon respect for human life. In a theological vein, the value of human activity can be understood in
a relational way as a distinct moral response to God's invitation to relationship, as discussed in the Vatican II document, Gaudium et Spes. The ethical import of the Imago Dei (discussed in chapter two) derived primarily from a fundamental respect for individual human life. All humans are created in the image and likeness of God. The notion that humanity is invited to participate fully in respecting the gift of God's creation provide the foundation for respect for human life. Respect for individual human life is absolutely opposed to assisted suicide or euthanasia as a means to address patient suffering at the end of life. Euthanasia has been unequivocally and absolutely condemned as an object of wrong, such as by John Paul II in Evangelium Vitae #65 and the Congregation of the Doctrine of the Faith.

3.b. Conclusion.

The previous chapter explained the meaning of sponsorship and governance oversight within the context of the Catholic social tradition in a manner that adopts the lens of organizational ethics to integrate patient care and the public good. The next chapter will focus on the public good. This chapter has focused upon current issues in patient care to highlight the need for enhanced Sponsorship and Governance oversight in Catholic healthcare. The need for enhanced oversight refers to giving more attention than typically occurs in routine board matters to dilemmas in Catholic healthcare that are changing significantly, either because of advances in science and healthcare or because of evolving Church teaching. The first part of the chapter discussed changes in science that impact patient care at the end of life, and the second part of the chapter reviewed evolving Church teaching that determines when withdrawal of futile treatment can be
justified. In each, the need for enhanced oversight was emphasized. The next chapter shifts from a patient care focus to address pivotal dilemmas in public health that also require enhanced Sponsorship and Governance oversight in Catholic healthcare.
Notes


21 Kelly, Contemporary, 129.

22 Kelly, Contemporary, 129.


27 Kelly, Contemporary, 133. See, ERD 57.

28 Kelly, Contemporary, 133.

29 Kelly, End of Life, 21.


34 Beauchamp, *The Ethics of Consent*, 14


36 Jones, *Surgeons Silence*, 57


39 ten Have, *Death and Medical Power*, 14


41 Sokol, DNR, 1724.


70 Bruno Et Al, "Assessment Of Consciousness With Electrophysiology And Neurological Imaging Techniques," he *Current Opinion In Critical Care* (2011, January 01), retrieved from pubmed.


84 Demertzi, "Ethics In Disorders," (2011,): 675.


92 Thibaut, "Metabolic Activity In External," (2012,).


110 Aries, Attitudes, 4-10, 44, 63-65; Aries, Hour, 457-459, 606, 611, 614, 643; Callahan, Dream, 26-27.


113 Connelly, Suffering, ix.


115 Aries, Hour, 604
116 Van Hooft, Suffering, 2.


118 Cassell, Suffering, 30-31.

119 Connelly, Suffering, 7.

120 Cassell, Suffering, 31.

121 Cassell, Suffering, 31.

122 Connelly, Suffering, 20

123 Cassell, Suffering, 32.

124 Cassell, Suffering, 33.


127 Harvey Max Chochinov, "Dignity and the Essence Of Medicine," *BMJ* 335, (July 2007)


130 Ronald P. Hamel and James J. Walter, eds., *Artificial* 203.

131 Kelly, *End of Life*,104.


137 Foley, The Case against Assisted Suicide, 6.


139 ten Have, *Death and Medical Power*, 14

140 ten Have, *Death and Medical Power*, 1-2.


143 ten Have, *Death and Medical Power*, 75-76.


145 ten Have, Death and Medical Power, 148.

146 ten Have, Death and Medical Power, 15.

147 ten Have, Death and Medical Power, 6-8.


Chapter 4. Enhanced Oversight of the Public Good: Illustrative Issues.

Introduction.

Chapter 2 explained that the need for enhanced Sponsorship and Governance oversight in current healthcare practice extends from patient care to the public good. Just as chapter 3 discussed enhanced oversight of patient care, this chapter discusses enhanced oversight of the public good. This oversight of the public good is more complex than for patient care insofar as Sponsorship and Governance have a less direct control than of hospital care of patients. Nonetheless, in the Catholic social tradition oversight of the public good is indispensable and Catholic healthcare organizations must engage in advocacy to influence public policy.

The chapter discusses controversial topics related to the public good to provide leadership in Catholic healthcare for sound public policy. Over recent years many several issues about the public good have become increasingly controversial from the perspective of social policy and regulation. Insofar as Catholic healthcare organizations advocate for public policies, Sponsorship and Governance oversight of these efforts is becoming increasingly important. Several issues can illustrate the need for enhanced Sponsorship and Governance oversight to influence changes in current public policy, including: the role of rationing in healthcare, the protection of minorities in research, the place for mandatory vaccinations in public health, and the dangers of antibiotics from a global perspective. A more expansive summary of each category follows.
Distribution of limited healthcare resources involves the subject of rationing.\textsuperscript{1} While some forms of rationing are understood as morally justifiable others are not.\textsuperscript{2} Rationing is defined as the allocation of goods under conditions of scarcity.\textsuperscript{3} The Catholic Health Association guides this debate through its document, With Justice for All: the Ethics of Healthcare Rationing.\textsuperscript{4} Catholic healthcare has been proactive in setting out criteria as a guideline for evaluating healthcare rationing.\textsuperscript{5} Similarly, enhanced Sponsorship and Governance oversight in Catholic healthcare organizations is needed to guide the debate on rationing, especially addressing the CHA document on rationing in the context of the recent Affordable Care Act.

Medical research involves collecting data about human beings.\textsuperscript{6} Based on the Catholic social justice tradition, attention is needed to protect minority populations. There are many vulnerable research subject categories including children, prisoners, pregnant women, handicapped persons, mentally disabled, economically disadvantaged, and educationally disadvantaged. In the U.S., federal regulations provide guidance about dealing with vulnerable populations such as minorities. These ethical guidelines constitute what is known as the Common Rule – this pertains to biomedical and behavioral research that involves human subjects.\textsuperscript{7}

The need to care for vulnerable populations in research is also acknowledged internationally. For example, The UNESCO Universal Declaration on Bioethics and Human Rights (2005) lists as a core ethical principle “Respect for human vulnerability and personal integrity.”\textsuperscript{8} Also, the CIOMS International Ethical Guidelines for Biomedical Research define “vulnerable persons” as “those who are relatively, or absolutely, incapable of protecting their own interests.”\textsuperscript{9} Because Catholic healthcare
organizations undertake considerable medical research, there needs to be enhanced
Sponsorship and Governance oversight in accordance with regulatory developments,
especially to ensure respect for and appropriate participation by minority populations.

There is clear evidence that vaccination programs can be highly effective.
Vaccines are medicines that contain weakened or dead bacteria or viruses that weaken or
destroy disease-causing organisms.\textsuperscript{10} For example, due to effective vaccination programs,
the last case of smallpox reported in the United States was in 1949, and the last case of
smallpox in the world was in Ethiopia in 1976.\textsuperscript{11} Because of the ongoing threat to
healthcare workers with regard to infectious and contagious diseases, there has been
increased debate over the mandatory vaccination of healthcare workers. Catholic
healthcare organizations can provide leadership in this debate both nationally and
internationally. For example, the U. S. Center for Disease Control (CDC) estimates that
the N1H1 virus resulted in an estimated 42 to 86 million cases of infection and caused
between 8,522 to 17,620 deaths. The influenza vaccine is approximately 80\% effective in
healthy adults, with the effectiveness being even higher when there is a close match
between the vaccine and circulating strain of the virus.\textsuperscript{12} These data contribute
significantly to the ethical debate of mandatory vaccination of healthcare workers as a
matter of public health to more effectively deal with infections, especially when they
effectively deal with infections as routine and serious as influenza.\textsuperscript{13} In this context, there
is need for enhanced Sponsorship and Governance oversight in Catholic healthcare
organizations to guide public health policy about the vaccination of healthcare workers.

Similarly, enhanced oversight is needed with regard to the use of antibiotics,
especially to decrease unnecessary use and to maximize effectiveness. Because of the
ability of bacteria to develop resistance, antibiotics can decrease or lose their
effectiveness. For antibiotics to be used appropriately there needs to be restrictions of
unnecessary use, and new more potent antibiotics need to be developed. As a result,
there is cause for a widespread change of practice regarding the prescription and use of
antibiotics. In this regard, enhanced Sponsorship and Governance oversight of
antibiotics in Catholic healthcare organizations can provide significant leadership for
hospital policy and for public policy regarding this growing concern.

Briefly, the need for enhanced Sponsorship and Governance oversight in current
practice extends from patient care to the public good. Enhanced Sponsorship and
Governance oversight of the public good in Catholic healthcare can provide leadership
regarding a variety of issues dealing with hospital policy and public policy where
modifications in social trends can significantly impact the health status of communities
and populations.


It is very difficult to balance quality, suitability, and price in healthcare. For
these crucial aspects of healthcare to be kept in balance typically requires some form of
rationing. In the United States there are significant distributive justice issues in the
allocation of resources. In other countries that have a socially determined healthcare
budget, such as the United Kingdom, cuts in one area can be justified on the grounds that
the money will be spent on other, higher priority services. This closed system of funding
provides a moral underpinning for resource allocation across a range of potentially
unlimited demands. However, in the United States, there is no structure to affect a trade-
off between savings in one area and benefits in another. Therefore it's difficult to refuse additional resources for patients, because there is no certainty that the funds will be put to better use elsewhere.\textsuperscript{18} Many recognize the need to limit the use of some healthcare, but on the other hand they resist those limits when they apply to themselves or others about whom they care deeply.\textsuperscript{19}

To contribute to this difficult debate, the Catholic social justice tradition can be enlightening. The Catholic understanding of distributive justice refers to the obligation of society to provide all of its citizens with a means to ensure that all can have access to a sufficient level of basic human goods.\textsuperscript{20} However, the contribution of Catholic social justice tradition to the debate on rationing in healthcare needs to be understood within the context of the Catholic tradition perceiving healthcare as a right.


An example of the right to healthcare in the United States is Medicare legislation that confers a legal right to healthcare for the elderly.\textsuperscript{21} Until the passing of the Affordable Healthcare Act 2010, health was seen as a failure in the political arena. As early as 1912, President Theodore Roosevelt made healthcare a plank in his presidential platform.\textsuperscript{22} Healthcare was considered in early versions of the Social Security Act, but was eliminated in part to ensure that the retirement benefits portion would pass. Then in 1944, President Franklin D. Roosevelt called for a "Second Bill of Rights," including "the right to adequate medical care and the opportunity to achieve and enjoy good health." President Harry Truman made a stirring healthcare address calling for universal coverage in November 1945. Notably, his plan called not for a healthcare benefit for the needy but
a plan to include all classes of Americans. The program faced immediate resistance from doctors' groups and fell prey to Cold War hysteria including a fear of "socialized medicine." Once the Republicans took control of Congress in 1946, abortive attempts at statutory reform continued in the post war period.

Then in 1956, President Eisenhower praised market-based healthcare reform as a way to achieve universal access. In the 1960s President Kennedy pushed for healthcare coverage and his efforts partially paid off, posthumously, with the passage of Medicare and Medicaid in 1965. In 1970, there was a strong push in Congress for the Kennedy-Griffiths Bill, a single payer plan. In 1974, President Nixon proposed a plan for universal coverage via group purchasing that was soundly rejected by those on the left, with some accusing him of attempting to use the plan to divert attention from the Watergate scandal. By 1979, President Carter made only feeble efforts to pass his campaign proposal of a national health plan. The 1990 Pepper Commission suggested a "play-or-pay" solution not dissimilar to the program put forward by President Nixon some sixteen years earlier.

President George H.W. Bush pushed for healthcare reform in his final state of the union address. President Clinton's Health Security Act, considered in 1993 and 1994, proved to be a policy and political failure. In this ambivalent history in the U.S. healthcare is construed to be part of the nation's covenant with its future.

This sense of reciprocal obligation can be construed in the language of rights. For example, the World Health Organization in 1976 affirmed the enjoyment of the highest attainable standard of health to be one of the fundamental rights of every human being. Also, this stance is reflected in Catholic social teaching. Pope John XXIII stated in Pacem in Terris paragraph 11, that “a human being has the right to security in cases of sickness.”
Even more pointedly, in their 1981 pastoral letter “Health and Health Care,” the U.S. Catholic bishops acknowledged that “healthcare is so important for full human dignity and so necessary for the proper development of life that it is a fundamental right of every human being” – this is a dramatic claim even though the Catholic tradition adopts a language that is somewhat different from the U.S. legal tradition. Nonetheless, a right to healthcare may be defined generally as the right to a basic minimum of healthcare necessary to function in society, making the right to healthcare a welfare right. The right to healthcare provides the general context for engaging the debate on rationing in healthcare.

4.a.(ii) **Catholic Principles for Rationing Healthcare.**

The Catholic tradition offers a challenging perspective on healthcare rationing insofar as not all care expected to be beneficial is provided to all patients. Rationing is deemed to be necessary to affect cost containment and introduce discipline into rising public expectation about the availability of healthcare. This approach offers a “painful prescription” for society. In this context rationing means withholding truly beneficial treatment, raising the core question of which approaches to rationing are justifiable. Of course, debates on rationing vary considerably from country to country depending largely on the funding of healthcare, such as a single payer system in the United Kingdom versus private insurance in the U.S. However, there is general agreement that we no longer have the luxury of debating whether to ration healthcare; the only question is how this should be done.

The secular debate on rationing in healthcare is robust. For example, Norman
Daniels emphasizes the role which justice should play in healthcare policy. His work is embedded in political philosophy, in particular related to the social contract tradition of John Rawls. A central tenet of Rawls' theory of justice is that we must adopt fair procedures to resolve disagreements over issues of distributive justice. In the absence of agreement on substantive principles of justice that would guide our allocation decisions, we must establish fair procedures in order to secure legitimacy for the results that will be viewed by many as less than optimally just. In this context, Daniels recognizes that we must adopt systems of rationing that set limits fairly.33

Similarly, the Catholic social tradition sheds significant light on responsible Christian living today in general,34 and on specific principles to guide healthcare rationing.35 The Catholic tradition sheds light on just procedures to guide rationing. In the secular arena, there is agreement that for procedures to be just, they must satisfy four conditions: they must be openly made, or at least the rationale for a decision must be publicly accessible; the rationale must be reasonable; appeal of a decision must be possible; and there must be some enforcement of these conditions.36

In the arena of the Catholic social tradition a more complex set of criteria are presented to guide healthcare rationing. The Catholic Health Association has identified the following criteria. First, the need for healthcare rationing must be demonstrable. Because the contract and the life or health those people healthcare rationing has to be ethically justified. Second, healthcare rationing must be orientated to the common good. Public policy should reflect the idea that healthcare is a social good belonging to all people. Third, the basic level of healthcare must be available to all. Justice demands that any government rationing initiative should ensure at least a basic level of healthcare for
everyone as a fundamental right. Fourth, rationing should apply to all. A rationing system that allows some people access to whatever they wish when establishing limits on services for the economically less secure would be less than equitable. Fifth, rationing must result from an open, participatory process. Because rationing would affect everyone, everyone should have a way to participate in the process that creates and distributes the burdens it entails. Sixth, the healthcare of disadvantaged persons has an ethical priority. Given the life-threatening conditions in which disadvantaged persons typically live, healthcare policy should reflect the biased towards improving their health status first. Seventh, rationing must be free from wrongful discrimination. Neither the process of rationing nor its outcome should embody any wrongful discrimination based on age, gender, race, religion, national origin, education, place of residence, sexual orientation, ability to pay, or presumed social worth. Finally, the social and economic effects of healthcare rationing must be monitored. The likelihood that harmful outcomes will result from rationing, despite the best intentions, call for legislative and regulatory safeguards and for a willingness on the part of the public officials to revise disproportionate harmful rationing programs.  

Basically, these criteria focus upon the usefulness of treatment, and respect for the common good. This typically means that healthcare is provided via rationing that preserves a right to basic healthcare. Justice demands that any rationing initiative should ensure at least a basic level of healthcare for everyone as a fundamental right. This basic right can be consistent with levels and tiers of access are necessary. Unless the basic package covers all beneficial health services, the principle of distributive
justice, that all people equally receive a reasonable level of medical services without regard to ability to pay, would be compromised.\textsuperscript{43}

This respect for the common good reflects the basic principle of solidarity in the Catholic tradition.\textsuperscript{44} There is a need for enhanced Sponsorship and Governance oversight of how the Catholic social tradition is applied to the increasingly important policy debate on healthcare rationing in the U.S. While this oversight cannot directly form secular policy and regulation there is a significant influence that Catholic healthcare can have through advocacy by its hospitals and professional organizations.

Another controversial topic that requires enhanced Sponsorship and Governance oversight in Catholic healthcare is medical research, especially to protect vulnerable populations like minorities that are so important to the Catholic tradition.

4.b. Minorities in Research.

Since World War II the U.S. has developed many codes to provide an ethical framework for biomedical research, often in reaction to scandals and controversies over research involving human subjects. After the Nuremberg tribunals condemned the Nazi research as a crime against humanity, important international declarations were developed to guide research, including: the Universal Declaration of Human Rights (1948); the Declaration of Helsinki (1964); the International Covenant on Civil and Political Rights (1966); and the Belmont Report (1979). Reacting to a variety of scandals about research on human subjects, the federal government instituted regulations to govern the conduct of research involving human subjects.\textsuperscript{45}
4.b. (i). **Federal Regulations.**

In 1964 the World Medical Association presented the Declaration of Helsinki and it became an important backdrop for the development of U.S. Federal Regulations. This declaration was amended in 2000. Two further clarifications were also issued in 2002 and 2004. This is probably the most influential document governing research worldwide. The declaration was promulgated specifically to address biomedical research with human subjects. Its purpose was to regulate medical researchers who were enrolling patients as participants. The declaration addresses combining clinical research with medical care, framed in terms of the duties of the physician to promote and safeguard health.\(^{46}\)

In 1963, considerable media attention focused on experiments with vulnerable populations in America. Investigators at the Jewish chronic disease hospital in Brooklyn, New York had injected live cancer cells into elderly patients without obtaining consent, and without their knowledge.\(^{47}\) Then in 1966 Henry K. Beecher’s published an article in the New England Journal of Medicine entitled “Ethics and Clinical Research.” Beecher chronicled 22 human subject experiments that involved ethically unacceptable are questionable procedures, including the failure to obtain informed consent. One particular case involved the deliberate injection of viral hepatitis into developmentally disabled children at the Willowbrook State School in New York. Beecher's report claimed that parents were coerced into enrolling their children in the research. There was a long waiting list for children to enter the school. Families were contacted and informed that their child could enter the schools if they agreed to allow their children to participate in what they believed was routine research. These parents were purposely misled. The
extent or the consequences of the research was not disclosed and the parents were coerced into agreeing assuming that they were providing the best care for the children.\textsuperscript{48}

Following Beecher’s report several startling examples of ethical research and other abuses came to light. In 1971 the discovery of the syphilis observation experiment at the Tuskegee Institute in Alabama was uncovered. The extent of, the magnitude, and the deception of this research undermined the public trust of its governments’ ability to protect its people. Although the experiments began in the early 1930s, it continued into the 1970s, at least 20 years after penicillin became the accepted treatment for syphilis.\textsuperscript{49}

The American public was shocked to find, that in the poorest of poor conditions in the southern United States 400 African American males were coerced into participating in the longitudinal observational study while they were led to believe that they were receiving treatment. Researchers used various offers to stimulate and sustain the subject’s interest and their continued participation. Socioeconomic deprivation certainly made them vulnerable to these overt and unjustified forms of manipulation.\textsuperscript{50} Removing the participant’s names from the selective service roster prevented them from joining the military service where they would have received antibiotics for their syphilis.\textsuperscript{51}

In 1973 Sen. Edward Kennedy of Massachusetts held hearings on the Tuskegee study and other human experiments. The following year the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. Perhaps the most important contribution of the national commission for the protection of human subjects of biomedical and behavioral research was the report entitled Ethical Principles and Guidelines for the Protection of Human Subjects. This report was
commonly referred to as the Belmont Report, named after the conference in Maryland where it was conceived. The Belmont Report identified and applied three overarching principles of research ethics in; respect for the person, beneficence, and justice.52

A crucial component of these federal regulations to oversee research is informed consent of research subjects. Consent must be informed, voluntary, and given by a competent person. Voluntary consent entails that participants can withdraw at any time without loss of benefits to which they are otherwise entitled. There should also be information on who should one contact for answer any questions. While regulations such as these specify the kinds of information, they do not regulate how much detail should be imparted to the participants.53 The federal regulations are designed generally to protect vulnerable populations. The following section looks more closely into this aspect of research with minorities, considering a specific case to highlight the relevant issues.


Similarly to the African-American community’s reaction to the Tuskegee study, the American Indian/Alaska native (AI/AN) have been keenly aware of their minority status and their vulnerability in research. Their Tribal Government argues that the Belmont Report does not go far enough in protecting its people. Its main criticism is that the Belmont Report focuses too much on the rights of an individual and does not include much discussion of the rights of groups or the need for protection for specific groups in research.

In light of the AI/AN criticism on the Belmont Report it was proposed that “respect for communities “should be included into a fourth principle for clinical research
ethics. The AI/AN argue that both individuals and the tribal community as a whole need protection. Despite Federal Regulations to protect human subjects of research, which were established in 1974 and adapted and codified in 1981, the AI/AN have felt victimized and vulnerable. The regulations were revised in 1991 as the U.S-Code of Federal Regulations for the Protection of Human Subjects also known as the Common Rule. However, unlike other ethical guidelines it does not define vulnerability. Instead, it provides special protections for “particularly vulnerable populations.” It is interestingly to see whom they list, mainly, pregnant women, human fetuses and neonates, prisoners, and children. A particular study brought this problem prominence and public scrutiny, highlighting the vulnerability of minorities in research – the study of the Havasupai Indians in Supai, in the Grand Canyon.

In 1989 Rex Tiliousi a representative of the Havasupai Indians, an isolated indigenous community that lives in the bottom of the Grand Canyon, asked a friend, anthropologist John Martin from Arizona State University (ASU) if he could help stop the spread of type II diabetes among the tribe. Dr. Martin was a longtime anthropology professor and one of the few outsiders who gained the Havasupai tribe’s trust. This controversial case of research with a minority and vulnerable population is all the more disconcerting insofar as researchers widely recognize the need to foster public trust for the projects to succeed. He had spent more than a year in Supai in the early 1960s and had published his doctoral dissertation on the tribe at the University of Chicago. In the study that ensued the Tribe became utterly dismayed by Dr. Martin. Court documents reveal the hurt expressed by the tribe as many hold Martin responsible for a breach of personal and research integrity.
Dr. Martin contacted Teresa Markow, a geneticist at his University to see if there was a genetic foundation for the disease process in the tribe. Both professors received money from the University to study diabetes in the tribe. However, Dr. Markow was also interested in schizophrenia research. In the summer of 1990, with a grant from the national alliance for research on schizophrenia and depression, she and her doctoral assistant began collecting blood samples in Supai (likely around 41 members of the tribe participated). She claims to have used a “Broad Consent” form for study permission.

The tribal concern was that the ASU researcher duped them into giving blood under a pretext that the tribes perceived diabetic epidemic was their sole concern. Instead Dr. Markow and her doctoral assistant used the blood to study tribal schizophrenia inbreeding and migration patterns without getting proper, or perhaps any, permission to do so. (This enterprise recalls a native Alaskan saying which states researchers are like mosquitoes, they'll suck your blood and leave). For example, the Havasupai DNA linked the tribe’s ancestry to Asia, migrating via the Bering Straits – thereby clashing with tribal religious belief that the Grand Canyon was its origin, from which their claim as guardians of the Canyon developed.

Also, some of the tribal members provided handprints and fingerprints. Without their consent these were used in testing for inbreeding. By the 1990s the Havasupai had received no information to indicate a genetic link or predisposition to diabetes. They believed the study was over after a freezer failure at ASU that damaged the blood samples. However unbeknownst to the Havasupai, cell lines damaged from the freezer failure were salvaged and vials of blood were sent to other laboratories and shared with other researchers. Thus, genetic research on the tribe continued beyond its understanding.
of the scope and duration of the study. As a result the tribe was deprived of making an informed decision on whether or not to participate. In addition, none of the other researchers shared their research findings.\textsuperscript{62}

In 2003 it was confirmed that some of the blood was used for a multitude of tests including schizophrenia, metabolic disorders, alcoholism and inbreeding. There were 23 papers published from the Havasupai’s blood samples. Several vials of blood were sent to other universities for research. Although only some members of the Havasupai gave their blood for genetic studies, the entire tribe was harmed by the research, especially suggesting that the tribe as a whole was “inbred”.\textsuperscript{63}

The Havasupai tribal body is a sovereign government. This community has the legal authority and the imperative to regulate research that is conducted on its land. Federal law public law 93-638, the Indian Self-determination and Education Assistance Act of 1975, as well as the federal doctrine of self-governance, provides Native American communities with the legal basis for taking over the administration of health and social services provided to its members. Broadly defined these services would include research related to health and social issues. This includes all research done with their people.\textsuperscript{64}

Hence, the tribe undertook a lawsuit that alleged among other things fraud, breach of fiduciary duty, negligence, and trespass.\textsuperscript{65} Much of the court arguments rested on the adequacy of the informed consent process. The wording of the consent form seems to be in violation of the guidelines published by the National Commission for the Protection of Human Subjects that state: approved research protocols in which the research intends to collect and store human specimens or data must include a written description of the intended use of the samples; how they will be stored; how to be tracked; what will
happen to the samples/specimen/data at the completion of the protocol, and what circumstances would prompt the principle investigator to report the loss or destruction of samples. Consent forms should, but in this case did not, remind participants that they can withdraw from the research at any time without penalty and asked that their samples be destroyed. Nor was it clear whether the consent process addressed the downstream use of the samples; the consent form could have stated that the participant’s specimens would not be used for further research without additional consent. Most importantly an informed consent process that separates individuals from their community may fail to convey the significance of the study and thereby compromise the integrity of the informed consent process.

The tribe won the lawsuit to have the research stopped and to have the remaining 150 vials of blood returned. On April 20, 2010 the University, whose legal bills totaled $1.7 million to defend the suit, finally settled for $700,000. The University also issued an apology to the Havasupai people. The court documents indicate that Dr. Markow’s first research protocol which was submitted to the IRB was entitled “Schizophrenia in the Havasupai.” Dr. Markow insisted that she did everything correctly. She testified that the study participants were informed that the research had a wider purpose. Yet there was nothing to show whether the Havasupai people understood this information. The majority of the tribe has English as a second language with only a second grade education.

Moreover, it is widely recognized that research must not only be free from controlling influences but also that determining capacity is crucial for research. There is no indication that concerns about capacity were addressed in the Havasupai study. As a result of this sort of compromise of vulnerable minorities in research, a framework for
evaluating protocols has been proposed with seven guidelines that focus on the value of the study: its scientific validity, subject selection, the risk-benefit ratio, independent protocol review, informed consent, and respect for the participating subjects.\textsuperscript{72}

As mentioned earlier, the Common Rule is highly attuned to the protection of vulnerable populations (45 CFR 46. Subpart A§46.107[a]).\textsuperscript{73} It is used by the U.S. Department of Health and Human Services in its Office Human Research Protection (OHRP) to protect children, prisoners, pregnant women, handicapped, mentally disabled, economically disadvantaged, or educationally disadvantaged persons.\textsuperscript{74} Naturally, this list of vulnerable populations can be easily expanded.\textsuperscript{75} A disputed concern about the Common Rule is its primary focus on an individual for consent with regard to vulnerability. A broader approach seems to be needed. In other words, vulnerability needs to include groups of people, such as the Havasupai Indians in the study discussed above.\textsuperscript{76} Certainly, court documents indicate that in the Havasupai study, the letter requesting consent to obtain blood was presented to the Havasupai Governing Council.\textsuperscript{77} The dilemma is how much the Council understood to sufficiently represent the vulnerable population as a whole.

Although there is uncertainty about defining vulnerability,\textsuperscript{78} there is general agreement that consent must be elicited from vulnerable groups, especially minorities.\textsuperscript{79} That is why scrutiny of the decision by the Havasupai Governing Council is an important feature of determining the sufficiency of the consent for the tribe as a whole. In this regard the CIOMS International Ethical Guidelines for Biomedical Research are enlightening. These guidelines define “vulnerable persons” as “those who are relatively, or absolutely, incapable of protecting their own interests. More formally, they may have
insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.\(^{80}\) For vulnerable populations like indigenous communities the worldview of the population is crucial, such as with the American Indian worldview of collectivism, collaboration, and compassion.\(^{81}\)

As a result of the Havasupai study, governing boards of the Native American populations developed recommendations to guide future research. The South West American Indian collaborative network suggests that researchers are introduced to the appropriate tribal leaders by members. They need to explain plans to the tribal Council and geographic district leadership stressing that is crucial to show what benefit can be achieved. However the challenge is to design a sound informed consent process for diverse population, especially for long-term studies. One recommendation is a tiered consent process where researchers give participants the choice of consenting to the use of DNA for a particular study or disease, for other research, or for storing the DNA for further use. Especially, researchers could ask subjects if they want to consent for future use of DNA.\(^{82}\) Also, informed consent from Native Americans needs to address the colonial background of this process as threatening to indigenous tribes. This need has arisen out of research practices of the past having served the agenda of the colonization process in suppressing indigenous knowledge and the objectification of indigenous populations.

The challenge is to enter into reciprocal partnerships where indigenous and nonindigenous researchers can work jointly towards a shared goal, focusing upon trust, self-determination, mutuality of interests, full participation, reciprocity, collective benefit, and long-term commitment.\(^{83}\) Most important of all, researchers must be
respectful of the cultural, religious, and ideological beliefs of their research subjects if the research relationship is to be sound. For example, for the Havasupai tribe the cultural symbol of tobacco is a gift of the earth that is used in funerals, weddings, praying, and sharing stories. Researcher must respect this cultural view, even though they may have a very different view of tobacco. In other words, researchers must develop culturally sensitive means of building reciprocity to establish effective research partnerships with vulnerable populations, especially minorities.84

There is a need for enhanced Sponsorship and Governance oversight of research in Catholic healthcare to protect minorities in research. The oversight needs to be enhanced from what might typically occur insofar as federal regulations are increasingly complex and the obligation to protect vulnerable populations is a crucial component of Catholic social teaching. Another controversial topic that requires enhanced Sponsorship and Governance oversight in Catholic healthcare is the controversial concern over mandatory vaccinations for healthcare workers.

4.c. Mandatory Vaccinations.

The debate on mandatory vaccinations for preventable diseases is widespread and controversial, extending from the population in general to healthcare workers in particular. This section focuses on the latter insofar as Sponsorship and Governance oversight in Catholic healthcare can address policies for vaccination of their personnel. The analysis first discusses the competing ethical principles that pertain to this debate and then examines a specific case to highlight the importance of vaccinations for healthcare workers.
4.c. (i). Ethical Principles Related to Vaccinations.

Vaccines are medicines that contain weakened or dead bacteria or viruses. When a person takes a vaccine, his or her immune system responds by producing antibodies. The process of building up immunity by taking a vaccine is called immunization. There are two general types of vaccines: live attenuated vaccines and inactive vaccines. The latter tend to be less immunogenic, requiring more doses.

There is a long history in the development of vaccines. For example, in early China (AD 590) immunization against smallpox involved using the dried crusts from smallpox pustules that were either sniffed into the nose or placed on an open scratch, using cotton that had been stored with the dried crusts. This process is called variolation, and was precursor of modern smallpox vaccination. In 1798 Edward Jenner’s scientific approach to vaccination used cowpox exposure to prevent smallpox. The United Kingdom not only embraced Jenner’s concept but also passed the Vaccination Act of 1840 providing free vaccinations for the poor. The Vaccination Act of 1853 made vaccination compulsory for all infants in the first three months of life and made parents who refused liable to fine or imprisonment. Resistance to these laws began immediately and in 1898 a new Vaccination Act removed penalties and introduced a conscience clause, allowing parents to obtain a certificate of exemption. This act introduced the concept of the “conscientious objector” into English law regarding vaccines.

Previously, in the 18th century London smallpox caused 20% of all deaths. Now, because of the worldwide vaccination effort against smallpox, the last case of smallpox reported that the United States was in 1949. The last case of smallpox in the world was in Ethiopia in 1976.
However, the widespread infection of smallpox has been replaced by another virulent infection, influenza that continues to cause enormous numbers of deaths globally. For example, an estimate of the death toll of the 1918 pandemic was that the virus may have killed 8 to 10% of all young adults worldwide.\textsuperscript{91} As a result, in the U.S. an immunization campaign resulted in the vaccination of 45 million persons.\textsuperscript{92} Each year in the United States there are on average more than 36,000 deaths and 200,000 hospitalizations associated with the influenza virus, which makes influenza outbreaks a major public health concern and vaccination the most effective preventive measure.\textsuperscript{93} Influenza immunization rates for healthcare professionals in surveyed healthcare institutions have been reported to range between 15\% to 40\%. Despite recommendations by the Center for Disease Control (CDC) that healthcare professionals receive influenza vaccinations annually.\textsuperscript{94}

The ethical debate on mandatory vaccinations for healthcare workers revolves around competing principles of bioethics. The principles of benevolence and non-maleficence are used to give healthcare workers greater immunity, provide less risk to patients, and increase their capacity to provide care during outbreaks of influenza. However, these distinctions however do not provide the rationale for distinguishing obligatory from non-obligatory precautions,\textsuperscript{95} though there is a clear duty for a health professional not to infect patients.\textsuperscript{96} Similarly, the principles of autonomy and justice also shed light on the debate from the perspective of human dignity.\textsuperscript{97} This argument is sensitive not only to the perceived risk of vaccines,\textsuperscript{98} but also to the relation between personal and professional lives of healthcare workers.\textsuperscript{99} The argument also addresses the need to treat people equally as a matter of justice.\textsuperscript{100}
In addition to these standard principles, the concept of trust also plays a crucial role in the clinician-patient relationship; without trust patients may not seek to access services at all, let alone disclose all medically relevant information. For example, the majority of Americans believe nurses are the most honest and ethical professionals in the country, according to results of an annual Gallup poll. A total of 83% of respondents viewed nurses as having either “high” or “very high” ethical standards. Two other medical professionals, pharmacists and physicians, took the number two and three spots. Nurses have topped the list for nine of the 10 years in which the survey has been running. Not surprisingly, trust can erode because of the ongoing struggle against the anti-vaccination movement.

In 1998 an article (later retracted) in the prominent medical journal the Lancet created a worldwide controversy over the measles-mumps-rubella (MMR) vaccine by claiming that it could have a causative role in autism. The claim led to decreased use of MMR vaccine in Britain, Ireland, the United States and other countries. Ireland, in particular, experienced measles outbreaks in which there were more than 300 cases, 100 hospitalizations and three deaths. The author of this report has since been disbarred. The debate has once again flared in the United States in 2015. Connected with professional trust is professional integrity that is relevant not only for healthcare workers but also healthcare institutions.

Different countries adopt a variety of strategies to increase vaccination levels, not only among health professionals but also across the population, including financial incentives. Vaccinations are undoubtedly a matter of personal and public health as well as of patient and professional welfare. The above ethical principles undergird debates on
these the health and welfare concerns. A specific example can help to clarify both the tension between the ethical principles.


Virginia Mason Medical Center is a 336-bed acute care facility in Seattle, Washington. It employs between 600 and 700 registered nurses, represented by the Washington State Nurses Association (WSNA). Because the elderly and immune-compromised patient population that Virginia Mason serves is at high risk for contracting the flu and for suffering severe and even fatal consequences if infected, the hospital has long recommended that its employees, including nurses, be vaccinated for influenza to reduce the chance of transmitting the virus from staff to patients. Studies have shown that staff-to-patient flu transmittal is prevalent in hospitals and other health care facilities because about half of those infected with influenza are asymptomatic and because as many as 70% of health care workers continue to go to work even when experiencing flu symptoms.\(^\text{109}\) The Public Employee Federation, which has about 5000 members covered by the regulations, said it encouraged its members to be vaccinated against the flu but opposed making the vaccine a condition of employment.\(^\text{110}\)

Virginia Mason implemented a voluntary flu immunization program in 1998 under which flu vaccines were given free of charge to hospital staff. Although this voluntary program had some success, after six years it had achieved a staff immunization rate of only 55%. As a result, the hospital decided in September of 2004 to make its flu immunization program mandatory. Virginia Mason then circulated a memo to all staff stating that, except in cases of a religious objection or documented vaccine allergy, proof
of flu vaccination was going to become a “fitness for duty requirement” and that anyone who could not show proof of vaccination by January 1, 2005, would “face termination” unless he or she agreed to take flu prophylaxis medication at his or her own expense.¹¹¹ The hospital deferred implementation of the new mandatory policy to the 2005-06 flu season because of a vaccine shortage, but in the meantime the WSNA filed a grievance about the proposed policy, stating that, although “receiving influenza vaccine is a good choice for most nurses, it is just that-a choice” and that “receipt of any medical treatment is up to the individual.” The grievance was submitted to an arbitrator who held a hearing on June 1, 2005.

Although the policy had not yet been enforced because the 2005-06 flu season had not begun, both parties authorized the arbitrator to determine prospectively whether the hospital had the right to impose such a policy unilaterally without bargaining over it with representatives of the union.¹¹² It was claimed that the program involved in impermissible alteration of employment rules without collective bargaining rather than being seen from the perspective of patient safety and infection control measures.¹¹³ The arbitrator found in their favor. The hospital countered by arguing that out of a total of 515 of the 599 unionized inpatient nurses (89.9%) elected to be vaccinated during this time and by the following season that portion had increased to (95.8%). In other words, while the nurses refused mandatory vaccination in principle, the majority of them adopted the hospitals vaccination program.¹¹⁴

An ethical analysis of this controversy can shed light on mandatory vaccinations for healthcare workers (HCWs).¹¹⁵ Mandatory influenza immunization for HCWs should be construed as a matter of patient safety and infection control. The risk of transmitting is
genuine insofar as HCWs can be on duty when they are mildly symptomatic which puts their coworkers and patients at risk. A survey conducted in four ICUs in the United Kingdom revealed that 23% HCWs had serologic evidence of influenza virus infection during a single influenza season; the majority reported mild illness or subclinical infection.\textsuperscript{116} That is, HCWs can transmit influenza virus to patients and coworkers before the onset of symptoms or during symptomatic illness.

The results of two studies highlight the effect that HCWs infected with influenza can have on their patients. In one case, in a NICU, 19 of 54 (34%) infants were infected with influenza A as a result of transmission from HCWs: six became ill, and one died. Only 15\% of the staff in NICU had received influenza vaccine. Employees reported taking time off work because of illness, which suggests that the symptomatic personnel may have had some role in transmission.\textsuperscript{117} In another case, during an outbreak of influenza in a bone marrow transplant unit, there were seven cases of HCW influenza: six patients develop pneumonia, and two patients died. Five staff members developed influenza like illness during the outbreak. The surveys revealed that the vaccination rate of 12\% among the staff. The hospital took measures the following influenza season to implement a multifaceted voluntary education program aimed at improving immunization rates. However, even with these measures, 42\% of the staff in the bone marrow transplant unit remained unimmunized in the following year.\textsuperscript{118}

In light of these rates, it is no surprise that infection was a concern at Virginia Mason to the extent that some of the nurses expressed anti-vaccination ideas and were not immunized.\textsuperscript{119} This is especially worrying insofar as the CDC estimates that the N1H1 influenza virus resulted in an estimated 42 to 86 million cases and between 8,522 to
17,620 deaths. Not surprisingly, the CDC has recommended vaccination of healthcare workers against influenza since 1981.\textsuperscript{120} Influenza vaccination programs for healthcare workers are cost effective in both direct medical costs and indirect costs of absenteeism. Vaccinating employees and reducing absenteeism can save employers $2.58 for every dollar invested in influenza vaccination program. The influenza vaccine is approximately 80% effective in healthy adults, with the effectiveness being even higher when there is a close match between the vaccine and circulating strain of the virus.\textsuperscript{121} The very nature of HCW duties implies they will be taking care of the sick and the marginalized. Persons most vulnerable to the disease do not respond optimally to vaccination themselves and therefore would be much better protected if everyone they came in contact were vaccinated.\textsuperscript{122}

There is a legal precedent for mandating vaccination and public health crisis with high morbidity and mortality rates. In Jacobson versus Massachusetts (1905) during a smallpox epidemic in Cambridge, Massachusetts, the court ruled that the police power of state included reasonable regulations established by legislators to protect public health and safety, specifying that the state could require vaccination as the Board of Health deemed it necessary for public health or safety. This case has subsequently been upheld on numerous occasions.\textsuperscript{123}

In 2010 the world celebrated the 30th anniversary of the eradication of smallpox by vaccination. There was a call that vaccinologists across the world unite in a common statement that influenza vaccine should be required of every HCW with patient contact, that influenza vaccination should be considered an ethical responsibility as a patient safety issue. Hence, vaccination should be seen as a personal issue, a professional
responsibility, and an institutional duty. Two randomized controlled studies evaluating the effects of healthcare workers vaccination and nursing home residents found that healthcare workers vaccination was associated with a 44% decrease in the resident mortality rate. Also, an algorithm evaluating the effect of HCWs’ influenza vaccination and patient outcomes predicted that if all healthcare workers in the facility were vaccinated, then approximately 60% of patient influenza infections could be prevented.

In sum, a persuasive ethical argument can be made for mandatory HCW vaccination programs. The programs assist healthcare workers to carry out their professional duties to provide care for all patients without the threat of undue harm caused by influenza transmission. It can also foster public trust in healthcare organizations. The public has the right to expect that healthcare workers and the institutions in which they work will hold necessary and reasonable precautions to keep them safe and minimally harmed. This lays the burden on the healthcare organizations and the government to ensure that healthcare workers fulfill their obligations. There is a serious professional duty to protect the public against influenza. Hence, efforts should focus on education and persuasion of HCWs to fulfill their duty, especially when vaccination rates among the public do not approach levels to achieve herd immunity.

At Virginia Mason Medical Center, the mandatory vaccination program has gone forward. The controversy has led to several publications for their work and the hospital has repaired relations with the unions by implementing the influenza vaccination as part of a culture of safety.

There is a need for enhanced Sponsorship and Governance oversight of the controversial issue about mandatory vaccinations of healthcare workers in Catholic
facilities. The secular debate refers to traditional moral principles to address this issue. However, there is need for more than routine oversight in Catholic healthcare insofar as the Catholic social tradition emphasizes the importance of solidarity. This focus upon solidarity as a matter of social justice requires enhanced Sponsorship and Governance oversight to protect patients in Catholic facilities from potential infections from HCWs. Another controversial topic that requires enhanced Sponsorship and Governance oversight in Catholic healthcare is the controversy over the over-use of antibiotics that leads to global antibiotic resistance.


In 2005 the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights. Article 16, calls the world to awareness on the impact of life sciences to protect future generations. A specific component of this general problem is the over-use of antibiotics. Over recent decades the global community has recognized the dangers of overusing antibiotics, generating a worldwide epidemic of antibiotic resistance. Coupled with this epidemic is the concern that progress is very slow in developing new antibiotics. Antibiotic resistant bacteria are increasingly seen to be just as virulent as their sensitive counterparts, and their genetic adaptability gives bacteria a huge advantage.

While working with staphylococcus bacteria, Scottish scientist Alexander Fleming noticed that a type of mold growing by accident on a laboratory plate was protected from, and even repelled by the bacteria. The active substance, which Fleming called penicillin, was an antibiotic that killed living organisms. Medical professionals
and patients around the globe observed the drug’s miraculous ability to cure infection while leaving its host unharmed. An air of awe and enthusiasm surrounded Fleming’s finding.\textsuperscript{132} A so-called miracle drug had been created.\textsuperscript{133} The success of antimicrobials against disease-causing microbes is among modern medicine's greatest achievements.\textsuperscript{134}

But, Fleming had a major worry. In a 1945 interview with The New York Times, he cautioned that the misuse of penicillin could lead to the rise of mutant bacteria with a developed resistance to the drug. In the years that Fleming had been studying the behavior of the world’s first antimicrobial, he discovered that when he used amounts of penicillin too small to destroy targeted bacteria, the pathogens evolved and mutated so that their cell walls were less susceptible to a second dose.\textsuperscript{135}

What Fleming was quick to understand, the rest of the world has tended to ignore. Today, resistant bacteria pose significant public health risks. Routine infections once treated with penicillin pills now require hospitalizations and intravenous drip antibiotics. Infections from such strains of bacteria are believed to cause thousands of deaths a year. This understanding recognizes the fact that the single biggest problem in infectious disease today is the rapid growth of resistance to antibiotics arising from the widespread misuse of antibiotics.\textsuperscript{136} In fact, more people now die of MRSA (methicillin-resistant staphylococcus aureus) infection in US hospitals that of HIV/AIDS and Tuberculosis combined.\textsuperscript{137}

Unlike several chemicals that are lethal to bacteria, such as arsenic or cyanide, antibiotics provide selective toxicity, meaning that they destroy bacteria without significantly harming their host.\textsuperscript{138} Humans do not develop a tolerance for antibiotics. Antibiotics work by inhibiting or killing the bacteria living inside of us. The reason they
no longer work is that the bacteria are no longer inhibited or killed by the drug, they are resistant to the effects of the antibiotic. There are several ways that bacteria resist the effects of antibiotics. Some resistant bacteria inactivate the antibiotic by destroying or modifying the drug itself so that it is no longer toxic. Some resistant bacteria pump the drug out of the bacterial cell so that the concentration of the drug is too low to be effective. Still, other resistant species have an altered form of the target site of the drug, where the drug binds, so the antibiotic cannot “find” its target.\textsuperscript{139} This widespread development of antibiotic resistance across the globe threatens the food chain and healthcare.

4.d. (i) \textbf{Food Chain.}

Despite the availability of antibiotics, infectious disease remains the second-leading cause of death worldwide and the third-leading cause of death in the United States.\textsuperscript{140} Yet antibiotics are very widely used in humans, animals, and plants. A report from the Union of Concerned Scientists estimated that approximately 50 million courses of treatment, or 3 million pounds of antibiotics, are administered to humans annually, while 1.5 million pounds are used in topical creams, soaps, and disinfectants. The same report estimated that 27.5 million pounds of antimicrobials are used for disease prevention (prophylaxis) and growth promotion in animals intended for human consumption.\textsuperscript{141} Every year, 100 to 150 million domestic pets receive antibiotics, 147 pounds of antibiotics are used per square acre of farmed salmon, and 40,000 to 50,000 pounds of antibiotics are sprayed on fruit trees. As their presence is everywhere, antibiotics have become an engrained part of the modern living.\textsuperscript{142}
The high and often inappropriate use of antibiotics has accelerated the development of antibiotic resistance, creating a major challenge for the sustainable treatment of infections world-wide. Bacterial communities often respond to antibiotic selection pressure by acquiring resistance genes, that is, mobile genetic elements that can be shared horizontally between species. Microbes can migrate to other species and eventually become human pathogens. For example, Swedish researches measured chemicals in a river near Patancheru, India. Levels of the potent antibiotic ciprofloxacin were discovered at amounts greater than those found in the blood of humans taking the drug. The team discovered that a major source of these drugs was from treated wastewater from pharmaceutical manufacturing plants that was discharged into the river and surrounding environs. This finding now links the drugs with downstream development of microbes which possess genetic resistance to multiple antibiotics typically used to treat human illness. Hence, people in the region are continually exposed to resistant microbes as they use the river water for agriculture and everyday life.

The amount of antibiotics freely used on domestically grown fruit is staggering. In 1999, the US Department of Agriculture reported that 30% of the pear acreage received a total of 6000 pounds of streptomycin and another 40% of all the acreage received a total of 12,000 pounds of oxytetracycline. These are two powerful antibiotics. Apples received 15,000 pounds of streptomycin on 20% of the acreage, or 3000 pounds of oxytetracycline on 5% of the acreage. As early as 1997, 39,800 pounds of streptomycin and 26,800 pounds of oxytetracycline were used, mostly on pears and apples. Streptomycin use has decreased over the decades, but oxytetracycline use has increased. One reason for the increased use of oxytetracycline is the increasing
prevalence of streptomycin resistance in the target bacterium. Yet the EPA waived environmental data requirements on these antibiotics.\textsuperscript{145}

In 2006 the EPA granted Michigan apple growers an exemption to spread their crops with gentamicin which is an antibiotic used to treat dangerous gastrointestinal and urinary tract infections. EPA officials have noted that using gentamicin in agriculture could reduce its value in treating human infections.\textsuperscript{146} The irony of this situation is that the EPA will have already restricted fruit imports from Latin America due to its abundant use of gentamicin. From a global sense the use of gentamicin for plant agriculture in Latin America is extremely troubling. The extent and quantity of antimicrobial use in this region are not known or recorded, and the degree of human exposure is unclear. The American Society for Microbiology and others persuaded the EPA that fruits and vegetables treated with gentamicin should not be imported, and gentamicin in food should not be permitted because of the importance of gentamicin in human medicine. The concern was that any unnecessary residues on food could compromise use of this antimicrobial, which is the last economically feasible drug for some human bacterial infections. No data is available on gentamicin use in agriculture in Latin America or on the occurrence of antimicrobial resistance of bacteria on fruits and vegetables from Latin America. Data needs to be collected from spraying crops.\textsuperscript{147}

In December 2003 a workshop on the Scientific Assessment of Non-Human Antimicrobial Usage and Antimicrobial Resistance was sponsored by the United Nations Food and Agriculture Organization, WHO, and the World Animal Health Organization. The workshop recognized clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials. The panel warned
that these consequences include infections that would not have otherwise occurred. They pointed to increased frequency of treatment failures (in some cases death) and increased severity of infections, as documented for instance by fluoroquinolone resistant human Salmonella infections. The evidence which was presented shows that the amount and pattern of non-human usage of antimicrobials has a serious impact on the occurrence of resistant bacteria in animals and on food commodities resulting in unnecessary human exposure to these resistant bacteria. Much of the antibiotic abuse is as a result of modern farming techniques.148

Modern animal production for food is characterized by densely concentrated animals and routine antibiotic use, which may have facilitated the emergence of novel antibiotic-resistant pathogens. For example, the jump of Strep from humans to livestock was accompanied by the acquisition of tetracycline and methicillin resistance.149 MRSA has been found in a variety of animals, including horses, cattle, and swine. It is reported that the prevalence of MRSA among Dutch pig farmers was 760 times higher than that among patients admitted to Dutch hospitals.150 In the Netherlands Strep now accounts for 20% of all MRSA detected in that country, documenting the importance of considering livestock and other animals when examining the epidemiology of MRSA.151 (Similarly, but not surprisingly, approximately 1.5% of the United States populations, about 4.1 million people are colonized with MRSA; deaths from MRSA infections have eclipsed those from many other infectious diseases, including HIV/AIDS, with MRSA causing 94,000 infections and over 18,000 deaths in the U.S.).152

On January 1, 2006, the EU banned the feeding of all antibiotics and related drugs livestock for growth promotion purposes. The US has not implemented similar control
policies for antibiotics use in animal farming. However, a recent issued FDA guideline to industry called for the use of antibiotics in food producing animals only when they needed to ensure animal health with veterinarian oversight and consultation. This is attracting growing support within Congress for new legislation.\textsuperscript{153}

The problem extends from farming to the natural environment in general.\textsuperscript{154} Birds and migratory waterfowl in particular are carriers. For example, gulls and geese nesting near waste or agricultural water harbor more antibiotic resistant E. coli than do birds associated with unpolluted water.\textsuperscript{155} And animals that live with humans, including pets such as cats and dogs, are reservoirs of antibiotic-resistant bacteria as a result of both antibiotic treatment for disease and the transfer of resistant bacteria from humans.\textsuperscript{156}

The problem carries over to drinking water. The presence of trace levels of antibiotics, antibiotic-resistant bacteria (ARB), and antibiotic resistance genes (ARGs) in source water is an emerging issue for the general public and the drinking water industry. We now have to face the reality that water distribution systems may serve as an important reservoir for the spread of antibiotic resistance to opportunistic pathogens.\textsuperscript{157}


At the turn of the 20\textsuperscript{th} century, the three leading causes of death in the United States were pneumonia, tuberculosis, and enteritis, infectious diseases with few effective therapies. Many of the patients were young, and most infected patients died of the disease or its complications.\textsuperscript{158} Because of the impact of antibiotics, these diseases became manageable and a century later heart disease, cancer, and stroke became the leading causes of death. This shift in leading causes of death from infectious to chronic diseases
is partly credited with raising average life expectancy by over 30 years.\textsuperscript{159} However, the introduction of antimicrobial agents in the mid-1930s caused the transformation.\textsuperscript{160} Antimicrobial drug development became one of the most transformative moments in human history.

The CDC has described antibiotic resistance as one of the world’s most pressing health problems, and the World Health Organization has identified antibiotic resistance as one of the three greatest threats to human health. As a result, costs due to antibiotic resistance, both in the numbers of lives lost and in economic terms, are exceedingly high.\textsuperscript{161} For example, a deadly infection, untreatable by nearly every antibiotic, spread through the National Institutes of Health’s Clinical Center. The staff built a wall to isolate patients, gassed rooms with vaporized disinfectant and even ripped out plumbing. They also used rectal swabs to test every patient in the 234-bed hospital. Still, for six months, as physicians fought to save the infected, the bacteria spread, reaching 17 gravely ill patients. Eleven died, six from bloodstream superbug infections. The bacteria, Klebsiella pneumoniae, was the proverbial superbug that everyone had feared. The CDC detected this type of antibiotic-resistant bacteria in 2000. Since then it has been recorded in 41 of the 50 States.\textsuperscript{162}

Yet, despite these high risks, physicians continue to prescribe dangerously.\textsuperscript{163} And as pharmaceutical companies invest in high-profit drugs, there is little incentive to develop new antibiotics because of their low return on investment.\textsuperscript{164} Most antimicrobials introduced since the early 1970s have been chemical modifications of previously discovered classes of drugs.\textsuperscript{165} The rate of development by the pharmaceutical industry of
new antibiotics has declined in the past few decades, while antibiotic resistance has been increasing massively.\textsuperscript{166}

The impact of antibiotics resistance, from humans to animals to plants to water, highlights the common heritage of the natural environment.\textsuperscript{167} As emphasized by the 2005 General Conference of UNESCO that was mentioned earlier, there is an obligation for future generations.\textsuperscript{168} Addressing antibiotic resistance must be a crucial component of this agenda. Hence, for example, self-medication, which drives antibiotic overuse in developing countries where antibiotics can be bought over the counter, needs to be curtailed.\textsuperscript{169} Also, proper hand-hygiene in healthcare facilities can significantly reduce infection and the need for antibiotics.\textsuperscript{170} Above all, it must be recognized that antibiotics promote the common good as they enable life itself to exist. In addition to their extremely high level of effectiveness and the value they provide to society, over time antibiotics lose their ability to treat the diseases for which they were developed—due to the ability of bacteria to develop resistance to the antibiotic. Therefore, in an effort to prolong antibiotics’ effectiveness for as long as possible, infectious diseases physicians and professional societies urge that antibiotics be used appropriately and sparingly and seek ways to limit unnecessary use of these drugs.\textsuperscript{171}

In response to the global crisis of antibiotic resistance, Europe has implemented a comprehensive and well-validated surveillance network for antibiotic consumption and resistance. In 2011, the World Health Organization dedicated the world health day to the topic of anti-microbial resistance with the aim to highlight it as a global threat and to call for consolidated efforts to avoid regressing to the pre-antibiotic era. This is a pivotal time for a tangible and sustained effort by WHO through a worldwide campaign.\textsuperscript{172} Also, the
European medical agency has urged pharmaceutical companies to accelerate the search for new antibiotics.\textsuperscript{173}

Another response to the global crisis of antibiotic resistance occurred in France in June 2011 with international expert’s formulating “The Pensieres Antibiotic Resistance Call to Action.” The experts examined data and results of country specific intervention programs that targeted the control of antimicrobial resistance and associated infections. They especially focused on infection prevention and control and antibiotic stewardship strategies.\textsuperscript{174} As a result a coordinated program recommended on six lines of action as follows. 1] A worldwide upgrade in infection control practice to limit resistance bacteria cross transmission. 2] A worldwide antibiotic stewardship strategy to decrease antibiotic pressure on bacteria. 3] The improved use of diagnostic techniques. 4] An acceleration in the discovery and development of new antibiotics. 5] The acceleration of a vaccine development program. 6] A strong educational program for healthcare practitioners, consumers and children. It was generally agreed that effective infection control programs must be implemented worldwide for lasting results.\textsuperscript{175}

Vigorous and coordinated measures must be taken worldwide to save and protect the erosion of existing antibiotics and facilitate the appearance of new and potent antibiotics.\textsuperscript{176} Education programs targeting both healthcare professionals and consumers, including children, are urgently needed. Cooperation between healthcare providers, researchers and consumers is the key to future success.\textsuperscript{177}

There is a need for enhanced Sponsorship and Governance oversight of the controversy about over-use of antibiotics that leads to the global crisis about antibiotic resistance. There is need for more than routine oversight in Catholic healthcare insofar
the risk of abuse or over-use impacts not only individual patients in Catholic facilities but also the global community. The scientific and medical urgency of this crucial concern about global antibiotic resistance requires enhanced Sponsorship and Governance oversight in Catholic facilities to take the necessary steps to contribute both national and worldwide endeavors to resolve this looming catastrophe.

4.e. Conclusion.

So far, the dissertation argues for enhanced Sponsorship and Governance oversight in current healthcare practice, extending from patient care to the public good. The previous chapter discussed enhanced oversight of patient care. This chapter has discussed enhanced oversight of the public good. It is important to note that oversight of the public good is much more complicated than for patient care – that is because Sponsorship and Governance have less direct control over healthcare issues about the public good, regionally, nationally, and globally. However, the emphasis in the Catholic social tradition upon justice and solidarity require continuing oversight of the public good as an indispensable feature of sound Sponsorship and Governance in Catholic healthcare.

The topics discussed in this chapter indicate that more than routine Sponsorship and Governance oversight is needed for them from a variety of perspectives. In general, enhanced oversight on these topics needs to advocate for effective public policy. More specifically, each topic highlights a particular problem that enhanced oversight can address in different ways. First, the debate over rationing in healthcare requires Catholic healthcare to provide enhanced oversight to ensure that the right to healthcare for all citizens is protected while also addressing the difficult issues of allocating limited
resources at a national level. This oversight pertains as much for Catholic healthcare facilities as for national policy. Second, the importance of protecting minorities in research requires Sponsorship and Governance oversight to be enhanced from what might typically occur insofar as federal regulations are increasingly complex and the obligation to protect vulnerable populations is a crucial component of Catholic social teaching.

Third, the continuing controversy over mandatory vaccinations for healthcare workers requires enhanced oversight, rather than typical oversight, insofar as the Catholic social tradition emphasizes the importance of solidarity. This focus upon solidarity as a matter of social justice requires enhanced Sponsorship and Governance oversight to protect patients in Catholic facilities from potential infections from its healthcare workers.

Finally, the over-use of antibiotics than is causing a global crisis in antibiotic resistance elicits the need for enhanced Sponsorship and Governance oversight so that Catholic healthcare can provide best practices than can help to shape national and global policies to curtail this crisis.

The next three chapters shift from a focus on enhanced Sponsorship and Governance oversight to address the need for intense oversight on issues that are crucial for both patient care and the public good. The chapters deal with pivotal issues that will determine the continuing existence of Catholic healthcare, thereby highlighting the need for intense Sponsorship and Governance oversight: patient care quality and safety, community benefit programs, and conflicted organizational partnerships.
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Chapter 5. Intensive Oversight of Patient Care: Quality & Safety.

Introduction.

This chapter discusses the need for intensive Sponsorship and Governance oversight of patient care focusing on quality & safety. Just as enhanced oversight of patient care and the public good is needed to deal with issues that have changed based on revised Church teaching or changing secular trends (as discussed in chapters 3 and 4), there also needs to be much more intensive oversight of patient care and the public good to address emerging trends that are pivotal for healthcare (discussed in chapters 5, 6, 7). The first of these pivotal trends that deals with patient care is the issue of patient care quality and safety.

Healthcare must be of high quality and be safe for patients. Iatrogenic harm is avoidable harm caused by the delivery of healthcare rather than by an underlying injury or disease. This problem of medical error has been recognized as one of the top four public health problems in the developed world. For example, 10% of admissions to acute care facilities are associated with an adverse patient safety event. According to The Joint Commission, leadership failure in healthcare organizations is one of the most frequent causes of sentinel events, thereby requiring much more effective organizational oversight to protect and foster patient safety. In light of the widespread awareness of patient safety endeavors to prevent medical error as an emerging pivotal trend, there needs to be intensive Sponsorship and Governance oversight in Catholic healthcare to foster a culture of safety across the organization.¹
There are two main types of errors: errors of execution and errors of planning. A slip or lapse constitutes an error of execution that occurs when the action is not what was originally intended. A mistake constitutes an error of planning where the action happens as planned but does not accomplish its intended outcomes because the original intended action was mistaken or wrong. Active errors transpire with the frontline staff and their effects are felt more or less immediately. Latent errors are typically removed from the operator’s control, such as occurs with poor system design. These errors pose the greatest threat to patient safety as they are linked to the failure of the system itself.²

Traditionally, organizational oversight delegated quality and safety to medical staff. There is now widespread recognition of the need for patient care quality and safety across the organization.³ Given the systemic nature of the problem, there is need for intensive Sponsorship and Governance oversight of this issue in Catholic healthcare. Prevention of harm and sustainable transformation to greater reliability can be related in a direct manner with oversight engagement and accompanying executive management. Intensive oversight is needed to engage the issue and to ensure that senior administrative leadership implements appropriate measures for evidence-based safety practices, including monitoring staff and caregivers.⁴

There are two general approaches to understanding and addressing injuries which reflect very different cultures and philosophies about mistakes and improvements.⁵ The professional sanctions model places practitioners in charge, being held personally responsible for patient injuries. This approach blames and punishes individuals but does little to improve the delivery system.⁶ In contrast, the patient safety model recognizes that individuals make mistakes, but they do so typically not because they are insufficiently
trained or sanctioned but because systems work against them. The patient safety model addresses medical error by seeking changes in the systems and processes that lead to or cause individuals to make medical mistakes. There is a crucial shift from fixing blame upon individual professionals to fixing problems and implementing system-related change.

In the past few decades, the root cause analysis (RCA) process has become the main tool used by hospitals to investigate adverse events and to prevent medical error. Root cause analysis is a process to identify the causal factors that underlie unexpected occurrences involving death or serious injury, focusing primarily on systems and processes rather than upon personal performance. It does not assign blame, but enables an understanding of the cause or potential cause of medical error, and promotes system-related change. The RCA approach, asks answer three questions: (a) what happened, (b) why did it happen, and (c) what should be done to prevent it from happening again. The product of the root cause analysis is a system-related action plan for corrective action.

To foster patient care quality requires an organizational approach that seeks to avoid medical errors in healthcare by fostering a culture of patient safety. According to the Institute of Medicine, the biggest challenge to patient care quality and safety is changing the organizational culture from blaming individuals for medical errors to one in which medical errors are treated not as personal failures, but as opportunities to improve the system to prevent recurrence and future harm. Professional and organizational cultures in healthcare must undergo a transformation in the interests of promoting systems for safer patient care. Healthcare must come to see itself as a high hazard
industry that is inherently risky. A culture of patient safety must be developed across each organization. \(^\text{13}\)

5.a. **Oversight Responsibility.**

To foster a culture of patient safety requires intense oversight responsibility that focuses upon systems across the organization. To shed light on the significance of systems a paradigm can be helpful. The automated teller machine (ATM) that dispenses cash and other banking transactions have become abundant in today’s society. Machines follow one of two sequences to complete a transaction. Some dispense the money first and then return the card. Others reverse these two steps. \(^\text{14}\) Since the aim of the transaction is to obtain the money, common sense and research in human factors predict that the person using the machine is more likely to forget the card if it is returned after the money is dispensed. \(^\text{15}\) The order is designed into the system and produces a predictable risk of error.

The magnitude of errors, their effect on institutional and patient safety, and the overall medical impact are well covered in current medical literature. Unfortunately the results are a challenging concern for society. Similar to the card forgotten at the automated teller machine, the majority of the adverse events result from an error made by an individual who is capable of executing the task safely. While it is true that we cannot change the aspects of human cognition that cause us to err, healthcare has the oversight responsibility to design systems that have the potentially to reduce error and make them safer for patients. \(^\text{16}\) Focus on systems improvements have been emphasized by both the Institute of Medicine and the National Scorecard on U.S. Health System Performance.
5.a.(i). **Institute of Medicine.**

The Institute of Medicine Report (IOM) in 2001 emphasized that patient safety is an imperative for healthcare. The delivery must be ethical and reflect a strong interdependence between both concepts. Ethical principles are the foundation of an intuitions healthcare’s mission and compliance with such principles ensures quality care and is a function of patient safety.\(^{17}\) According to the IOM, “the biggest challenge to moving towards a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm.”\(^{18}\)

Today’s health care market is paying special attention to medical errors. Medical research indicates an alarming high prevalence of adverse events, the majority of which are preventable. While the range of severity in errors is large, they all cause harm either individually or collectively. There are many factors that cause error. These include system inadequacies and human interactions. Continued attention on the action of individuals rather than closer scrutiny of the system has led to an environment which remains counterproductive for improving overall patient safety.\(^{19}\)

Ethical quality in healthcare is the overarching umbrella under which patient safety resides. The Institute of Medicine also considers patient safety as indistinguishable from the delivery of quality health care. The understanding is that a new delivery system is necessity to achieve and maintain substantial improvements in patient safety. This innovative system must have dual capability. Chiefly, it must be able to preventing errors from occurring in the first place, while at the same time incorporating real-time lessons from errors that occur. To achieve such a system will require a culture of safety and the
active participation of, not only all health care professionals, but organizations, and indeed the patients themselves. There is much work to do in this oversight responsibility in healthcare.


The National Scorecard on U.S. Health System Performance in 2011 updated a series of comprehensive assessments of U.S. population health and health care quality, access, efficiency, and equity. Health system performance continues to fall far short of what is attainable, especially given the enormity of public and private resources devoted nationally to health. Across 42 performance indicators, the U.S. achieves a total score of 64 out of a possible 100, when comparing national rates with domestic and international benchmarks. Overall, the U.S. failed to improve relative to these benchmarks. Costs were up sharply, access to care deteriorated, health system efficiency remained low, disparities persisted, and health outcomes failed to keep pace with benchmarks. As observed in previous scorecards, the U.S. is not achieving the health outcomes or quality that should be possible with the resources the nation invests. More intense oversight responsibility is needed.

Today fiscal and political climate bring many changes to health care systems in the name of health care reform. The federally funded Medicare payment model has abolished payments for several conditions including hospital-acquired conditions. These initiatives, coupled with the 2010 Affordable Care Act, have established new financial incentives for quality care. Also there are financial deterrents for preventable medical errors. These and other factors have created a significant increase in the financial burden
associated with medical errors in hospitals. Coupled with the negative repercussions from adverse patient care, medical errors directly impact the hospital’s bottom line. This comes at a time when government funded programs such as Medicare and all commercial health insurance plans are reducing reimbursement to hospitals. Medical errors are preventable. Oversight responsibility in cannot overlook the financial burden associated with failure to analyze causes of medical errors and improve patient safety. Because patient safety is a function of quality patient care it requires intense Sponsorship and Governance oversight responsibility in Catholic healthcare. In exploring the relationship of quality and ethics to provide safe, high quality care in an ethical manner, it is important to understand the different types of medical errors.

5.b. Medical Error.

Medical Error is an adverse event (AE) regarding patient care. Adverse events are undesirable outcomes attributable to medical care rather than to the underlying disease process. On an individual basis AE costs and impacts on health are very large. A recent Canadian study showed that the risk of AE for a Canadian adult who is admitted to an acute care hospital for a medical or surgical diagnosis is 10%. Therefore, for a typical acute care hospital that will admit 20,000 patients annually, 2000 patients will experience an AE. This will translate to up to$20 million in direct incremental charges, 1600 additional days in hospital and 300 deaths. Furthermore, by extrapolating the number of hospital admissions nationally, it has been estimated that up 24,000 Canadians die annually owing to AEs. The strong imperative for action requires an understanding of iatrogenic harm and a theory of error to categorize and explain these harms.
5.b.(i). Iatrogenic Harm.

Iatrogenic harm is avoidable harm caused by the process of healthcare rather than by an underlying injury or disease. Iatrogenic harm has been recognized as one of the top four public health problems in the developed world. In 1990 the United States Institute of Medicine (IOM) published its report, To Err Is Human: Building a Safer Healthcare System. Exploiting data from Harvard’s Medical practice study the report estimated that as many as 100,000 Americans die each year from medical errors. The report maintains that such a death toll would be equivalent to a jumbo jet crashing each and every day in United States. The IOM report identified an extensive array of problems including, medication errors, communication problems in intensive care units, gaps in the discharge process, and retained sponges in the operation room. In short, everywhere the report looked, evidence was found of major problems in patient safety.

This annual toll exceeds the combined number of deaths and injuries from motor and air crashes, suicides, falls, poisonings, and drowning’s. In fact with as many as 10% of admissions to acute care hospitals associated with an adverse patient safety event, traveling in an airplane is far safer than being a patient in hospital. Most errors are made by good but fallible people working in dysfunctional systems. However, to categorize and understand these harms, the IOM Report on medical error turned to the theory of James Reason.


The theory of error or harm proposed by James Reason highlights two types of errors: errors of execution and errors of planning. The IOM report adapted James
Reason’s theory to clarify difference between mistakes and slips/lapses. A slip or laps constitutes an error of execution which occurs when the action is not what was originally intended. A mistake, constitutes an error of planning, the action happens as planned but does not accomplish its intended outcomes because the original intended action was mistaken or wrong. Reason’s theory also distinguished between active and latent error. In essence, active errors transpire with the frontline staff and their effects are felt more or less immediately. These errors, perhaps unfortunately, receive the greatest responses and they focus on the individuals responsible. There is little supporting evidence to suggest that this method creates systematic change. These sorts of medical errors should not be blamed on individual healthcare professionals. Rather, emphasis should be focused on deficient or inappropriate systems that need to be improved. Latent errors are typically removed from the operator’s control, such as poor organization design. These errors pose the greatest threat to patient safety as they are linked to the failure of the system itself.\

A key challenge has been agreeing on a yardstick for measuring the safety of care in hospitals. Some studies have relied on the rate of AE’s based on voluntarily reported sentinel events (any unanticipated event in a health care setting resulting in serious injury or death, not related to a natural course of the patient’s illness) at the national or state level. Many health care organizations have also used their own internally reported sentinel events to measure the safety of their system. Some studies have suggested that these automated measures of patient safety are neither sensitive nor specific enough to correctly identify AE. This concern has prompted the search for more direct approaches to measuring AE. Such approaches generally rely on more exhaustive physician or nurse reviews of a patient’s complete medical record or chart. This is extremely labor-intensive,
which limits its use. Reports indicate that two methods commonly used by most care delivery organizations and supported by policy makers to measure the safety of care (enhanced voluntary reporting systems and the use of the Agency for Healthcare Research and Quality’s Patient Safety Indicators) fail to detect more than 90 percent of the adverse events that occur among hospitalized patients.\textsuperscript{32}

As more has been learned about the factors that contribute to the occurrence of errors, the focus of patient safety must move upstream from detecting and analyzing errors to redesigning the care delivery environment to prevent errors. Indeed, patient safety \textit{is} the prevention of errors.\textsuperscript{33} Some recent studies show how much work we have to do as a nation. In 2008 nearly one-third (32\%) of U.S. patients noted that, in the last two years, a medical mistake or a medication or laboratory test error was made during their care, with the majority of respondents reporting that the mistakes occurred outside the hospital. The likelihood of reporting an error was twice as great among those patients who see four or more physicians. To attain the 16 percent error-reporting rate, as found in the Netherlands, the U.S. rate would need to be 50\% less.\textsuperscript{34}

There are also ethical issues of vulnerability. For example, patient injuries from medications may be caused by drug side effects, by human error, or by system-level failures in prescribing and monitoring medication use. Elderly patients are at particular risk for experiencing adverse drug events because of their greater medication use and physiological vulnerability. In 2007, 25 percent of elderly Medicare beneficiaries received at least one drug from a list of 13 classes of high-risk prescription drugs that experts say the elderly should avoid.\textsuperscript{35}
To improve patient safety, a systems approach is required to address the conditions that contribute to errors. Two competing worldviews seek to define the problem and channel policy responses: the Professional Sanctions Model and the Patient Safety Model. They reflect two very different cultures and philosophies in their approach to medical mistakes and system improvements.\textsuperscript{36}


Effective safety improvements require exploring a systems approach rather than focusing on individuals. The debate on emphasizing individuals versus systems is connected to the debate on the Professional Sanctions Model that focuses upon individual professionals versus the Patient Safety Model that focuses upon organizational systems to reduce medical error.\textsuperscript{37}

5.c.(i). Focus on Individuals.

The focus on individuals in the debate on medical error reflects a traditional view that practitioners are in charge, need to be held personally responsible, and should take the blame for injuries. This is referred to as “professional sanctions.” This approach blames injuries on practitioner errors due to inattention, carelessness, or incompetence. Interestingly, physicians and attorneys tend to share this perspective which emphasizes penalties for transgressions, although doctors and lawyers hold very different views about the sanctions to be applied – medical peer review versus professional liability lawsuits.\textsuperscript{38} In reality punishing measures do little to bring healing or improvement in the system. The medical peer review can be devastating for the physicians and the liability lawsuit can
sever patients from the provider. The medical institution and the patient often become adversaries, and patients and attorneys frequently seek punitive as well as loss-based damages. Studies found that of 127 families who sued their healthcare providers after perinatal injuries, 43% were motivated by the suspicion of a cover-up or by the desire for revenge. Medical lawsuits are expensive where high legal assessments are seen as substitutes for punitive awards.\textsuperscript{39}

The majority of healthcare professionals choose their profession because they wish to improve the lives of others. When a patient is accidentally harmed in the care process, this can be a traumatic experience not only for the patient but also for the staff involved.\textsuperscript{40} The professional sanction approach does little if anything to support the practitioner or patient. A recent Swedish study showed that in a single year preventable AEs may have contribution to 3000 patient fatalities and to permanent disability for 10,000 patients.\textsuperscript{41} These numbers indicate that numerous healthcare professionals are likely to be involved in an AE at some point in their professional careers.

In the year 2000, the term “second victim” was introduced to describe how healthcare professionals may be traumatized by AE’s in a similar fashion as the patient “first victim.” Commonly reported reactions among professionals, after an AE, are fear, guilt, shame, self-doubt, anger and disappointment.\textsuperscript{42} A recent survey of American and Canadian physicians resulted in similar findings. Of the of 3171 physicians interviewed the majority reported increased anxiety about future errors, diminished self-confidence, trouble sleeping, and overall loss of job fulfillment following medical errors. This was coupled with a fear of disciplinary action ultimately leading to a loss of professional reputation.\textsuperscript{43}
Such findings correspond to what James Reason calls the Person Approach. The person approach remains the dominant tradition in medicine, as elsewhere. From some perspectives it has much to commend it blaming individuals is emotionally more satisfying than targeting systems. If something goes wrong, it seems obvious that an individual (or group of individuals) must have been responsible. Nevertheless, the person approach has serious shortcomings and is not suited to the medical domain. Indeed, continued adherence to this approach is likely to thwart the development of safer healthcare as it isolates unsafe acts from their system context.44

The long term effects on the individual healthcare practitioner can be devastating. It is been suggested that the emotional toll may be similar to those found in victims suffering from post-traumatic stress disorder. Recent studies report healthcare professionals considered radically changing careers as a direct consequence of AE. Similar study reported a decrease in the quality of life and an elevated risk of burnout, ultimately resulting in an increase in the use substance abuse, suicidal ideology, and even suicide.45 One of the most important reasons limiting error detection is the way errors make clinicians feel. Any time a patient experiences a bad outcome, a physician will feel it to be their personal failing. If the treating physician perceives that he or she made an error, then these feelings are greatly inflated even if the perception of error is invalid.46 Emotions make it difficult to examine the outcome objectively and critically. Combined with the adversarial nature of the court system handling malpractice, it is no shock when physicians report feeling threatened once they are mandated to participate in any systematic methods of error detection.47 Also, despite hefty penalties and personal shame, the extent of medical errors has not abated. In fact, the professional sanction model, so
evident in malpractice claims, does not appear to have any impact in reducing medical errors.\textsuperscript{48}

It is obvious that radical change is needed. Such an undertaking begins by understand the medical structures and its methods as the perilous foundation in the majority of errors, not direct practitioners. To do so entail’s a departure from the existing culture of fear embodied with admitting error and blame. Such restructuring requires participation of both leadership and individuals. While radically innovative to healthcare, other industries have successfully made this move. In doing so their traditional ethic of personal responsibility has remain intact and has actually matured. Now individuals assume personal accountability for reporting error and become part of a culture which promotes improvements. This is the direction healthcare needs to follow. To promote such a move takes strong leadership and conviction.\textsuperscript{49} This understanding is developed in the area of the patient safety model.

5.c.(i). \textbf{Focus on Systems}.

In sharp contrast, the patient safety model focuses on organizational systems. The model accepts that people make mistakes not because they are insufficiently trained or sanctioned but because they are human.\textsuperscript{50} The patient safety model addresses medical error by seeking changes in the system and processes of care that support the practices causing individuals to make medical mistakes.\textsuperscript{51} So there is a shift from fixing blame upon individual professionals to fixing problems via root cause analysis of what happened in order to implement systematic safeguards that can prevent reoccurrence.\textsuperscript{52} This approach borrows from the management philosophy of continuous quality
improvement and holds that errors occur more often in systems with imperfect processes. Individuals cannot be expected to perform perfectly, but over time systems can be brought ever nearer perfection.

Such observation highlights the sharp difference between the culture of patient safety and the culture of professional discipline and liability. The latter is negative, seeking to sanction behavior found substandard. The former sees patient safety as a positive thing, to be continuously improved, evolving to prevent bad outcomes. This approach has been adapted in several different industries. For example the aviation approach is to deal with errors non-punitively and proactively, and this approach defines behavioral strategies taught in crew resource management training. This did not happen overnight.

In the 1950s’ the volume of aviation accidents dropped significantly. This was primarily due to the introduction of the much safer jet engine system. As a result of fewer accidents focus was now directed to the cause of non-mechanical failure events. As statistics accrued, it became apparent that most accidents were as a result of failures in crew coordination, communication, and decision making. This began the transformation of an industry towards a more transparent culture one which promoted questioning and understands human limitations. Such a transition was a gradual but firm development. This led investigations into public accidents and confidential reporting of near misses, and their analysis. They have been rigorously pursued by the aviation industry in their successful effort to improve air safety. After three decades, over 500,000 confidential near miss reports, currently over 30,000 yearly reports, have been logged by the aviation safety reporting system. Information gathered on near misses have been successfully
used to redesign aircraft, improve air traffic control systems, airports, and pilot training, and to reduce human error. The decades long aviation efforts to improve safety through system monitoring and feedback holds many important lessons and opportunities for healthcare.  

In their respective occupations both pilots and physicians function in complex settings where teams interact with technology. The similarities are striking. Fluctuation in risk varies with dangers coming from a variety of sources. Safety is vital for both professions, but several factors including cost, can influence the commitment of valuable resources. Aircraft accidents are uncommon. However, they are highly visible and potently involve massive loss of life. Such events normally trigger exhaustive investigation into causal factors, public reports, and remedial action. Research by NASA has discovered that 70% involved human error. Work has begun to see how such information can be meaningfully transferred to healthcare. Today hospital departments such as emergency and intensive care units have been challenged, due to their need to maintain flexibility to cope with developing situations, to consider not civil but military aviation’s methods of adapting. Civil aviation has zero tolerance for risk and will cease operating if conditions are too dangerous, as when a volcanic ash cloud covered Europe in April 2010.

However, military aviation enjoys no such reprieve. Parallels scenarios have been explored between aviation crews and OR/ED staff. Both military and OR/ED personnel operate in a high stakes environment where crews with limited resources deal routinely with complex and time critical operations. In many areas of healthcare, personnel can be under continual pressure, in unpredictable situations with external constraints.
Innovation, improvisation, and timely information for personal are critical to success.

Similarly, aviation is one of the many complex dynamic worlds, in which specific medical fields such as anesthesiology have been compared to frequently. Both Military aircrews, and clinicians, endure extended periods of downtime, followed by immediate immersion in situations that require full concentration often for prolonged periods.

Military pilots continually work within prescribed boundaries and with little margin for error. Their physical and cognitive impact is often magnified by fatigue. Clinicians face comparable challenges in their performance. Similarities between operating physicians and pilots, or between anesthesics and aviation, include operating in dynamic environments with rapid and unpredictable changes in workplace pace, and solving poorly structured problems while under pressure with limited information.

The potential to support healthcare’s patient safety model by understanding similarities in both industries is strong. The aviation industry is not alone in taking initiatives to prevent disasters. In the politically charged, fiscally regulated, and legalistic atmosphere of the nuclear power, there are no penalties for reporting any non-consequential event. They are the industries “close calls.” Such events are pivotal in tweaking the human performance enhancement system. These improvements come as a result of the Three Mile Island disaster. This event promulgated new norms throughout the industry. When the reporting system for near misses was being created, any objection was dwarfed, by the unimaginable fear of even a singular nuclear event.

The petroleum industry has also taken advantage of an AE to bring about substantial change. After the inquiry into the 1988 Piper Alpha disaster in the North Sea, the industry complied with recommendations and implemented risk reduction strategies.
This included the formation of a governance body to regulate the industry and to oversee all offshore petrochemical safety. Specific examples included relocation of pipeline emergency shutdown valves, establishment of disaster refuges for oil workers, rehearsed evacuation procedures, and the implementation of emergency safety training for all personnel. Accountability changes insisted the oil companies demonstrate that hazards had been minimized and were as low as could reasonably be expected.63

There is little doubt that a patient safety model needs to focus its further development by closely examining analogous industries. Healthcare by its very structure is complex. The nature, control and arrival adverse events are difficult to predict.64 An ethical driver behind healthcare failures demands that institutions develop mechanisms to learn from mistakes and as incorporate such finding in the clinical setting so as to do no harm. One widely accepted process is Root Cause Analysis.

5.d. Root Cause Analysis.

In today’s legalistic environment human error is considered the source of adversity in processes, complex surgery, and generally in the overall health care system. However, the desire for snap judgments and designations of blame can mask a deeper and often more complex truth. To identify inaccuracy from standard protocol is simply the beginning of an inquiry. While the obvious error or omission may be the immediate cause, explorations of incidents often reveal systematic discrepancies, each one interrelated and interdependent on the immediate environment. This understanding is gaining acceptance in health care.65 Preventable mistakes are common. In the last decade,
the root cause analysis (RCA) process has become the main tool used by hospitals to investigate adverse events and to prevent their recurrence.  

5.d.(i). Adverse Events.

From a hospital organizational perspective, successful disclosure systems require a willingness to put the interests of patients and families first, and to maintain transparency, honesty, and trust. Patient safety systems only work when there is an atmosphere that permits and supports open exchange of information, whether it is through reporting systems or investigation of the root causes of AE. The focus must be upon reporting, analyzing, and understanding adverse events.

There are a number of methods of investigation and analysis available in healthcare, but they tend to be underdeveloped in comparison with the methods discussed from different industry. The RCA process was originally developed in psychology and systems engineering to identify the basic and causal factor(s) that underlie variation in performance that leads to errors. For this, it is very effective. The RCA provides structure to the retrospective analysis of errors, and it has been used successfully for decades to uncover latent errors in high-reliability organizations such as aviation and nuclear power. Mandated now by the Joint Commission it is an intensive process which finds it origins in “total quality management” methods of health care improvement. The Joint Commission published manuals in 2003, 2006 and in March of 2013 in which they revised their root-cause analysis and action plan framework template. By highlighting the prevention of system failures JACHO attempts to assist healthcare organizations in the reduction of medical errors and the enhancement of patient safety.
RCA focuses primarily on processes rather than upon personal performance, does not assign blame, but enables an understanding of the cause or potential cause of medical error. Such a platform indicates the changes needed to prevent a reoccurrence. The RCA approach, attempts to answer three questions about errors that result in patient harm: (a) what happened, (b) why did it happen, and (c) what should be done to prevent it from happening again? It functions by exploring the causes of sentinel events after they have occurred. It is normally undertaken by experienced personnel who follow appropriate protocol. When preformed correctly an RCA also has the potential to forecast the possibility of a reoccurrence of an AE. Reviews of RCA’s have been remarkable. Their success has been directly linked with reduced mortality from hip surgery, increased patient and graft survival in liver transplant, and reduced rates of adverse drug events.


To ensure RCA’s are maximally productive clear procedures are indispensable elements. Firstly, an interdisciplinary team approach consisting of representatives of all relevant disciplines, at minimum, physicians, nurses, pharmacists and administrators should be present. Secondly, strong administrative leadership and facilitation is necessary to prevent the assigning of blame and to steer the conversation towards key system defects. Thirdly, individuals who participated in the case should be invited to “tell their stories.” Again, strong administrative leadership is required to prevent finger-pointing. Finally, RCA’s should invite involved front-line workers, nurses and physicians, to help educate them in the process and demystify the ritual.
Procedurally, RCAs involve the appointment of a working party called the RCA team by the hospital’s quality manager or someone in a comparable role. They invite “appropriate” clinical and administrative staff to participate in the investigation. Ideally these are people who are willing and available but not involved with the incident, and not so far removed from the specialty in question that they need to do vast groundwork to be able to contextualize the incident. The team usually meets three times. The first meeting focuses on establishing the facts behind the case and devises a series of interview and research questions. At the second meeting, team members pool interview data they collected from the clinicians who were involved in the adverse event and any additional targeted research into the clinical domain in question to understand the dynamics of the relevant disease and treatment and the organizational aspects of care. During the third meeting they use the information gathered to develop statements about causal relationships conjectured to underlie the incident. This leads to preparation of a report that puts forward the main “systems” causes behind the adverse event, as well as a set of practice change recommendations to prevent future failures.73

Without attempting to oversimplify the RCA process, the method it uses to understand what occurred has been applied to different industries. For example the “5 whys” is one adaptation. Here the process of the case of an associate who worked in a factory and had damage his thumb follows: Why did the associate damage his thumb? Because, the associates thumb got caught in the conveyor. Why did his thumb get caught in the conveyor? Because he was chasing his lunch bag. Why did he chase his bag? Because he had placed his bag on the conveyor, which had then started unexpectedly. Why was his bag on the conveyor? Because he was using the conveyor as a table. And
so, the root cause of the associate’s damaged thumb is that he simply needed a table. A table was not present in his work environment so he used the conveyor as a table. To eliminate further safety incidences, the company installed tables at the appropriate work stations and update safety training. It also reviewed its preventative maintenance standard of works to ensure that the machinery doesn’t self-start.

The product of the RCA is an action plan that identifies the strategies that the critical access hospital intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

The RCA is considered to be the golden rule when it comes to incident investigation, but it also has its drawbacks. In investigating the clinical errors of work colleagues, RCA team members operate between the complexity of set practice and the abstractness of formal rules. They perform the task not as clinical practitioners applying formal knowledge to in-situational specifics. Rather, RCA puts them in a position of having to deduce organizational managerial generalizations from the specifics of practice. This normally is a function reserved for managers and not inscribed into practitioners’ roles. Concurrently studies indicate that some RCA team members have difficulty with two issues. Firstly, they report having trouble understanding capacity and function limits of particular clinician’s scope of practice, and if/when these boundaries are violated. Secondly, there is concern on providing articulate rule based advice and which method of communication works best for clinicians.
However, by participating in an RCA healthcare organizations are more likely to adopt a proactive system/process approach. This promotes a culture of safety. Safe healthcare facilities would be of little value unless they provided quality, effective and ethical treatment to those who needed them. Developing a culture of patient safety that diminishes medical error is an indispensable characteristic of patient care quality.

5.e. Culture of Patient Safety.

A culture of safety means how patient safety is understood, applied, and, executed within an organization. This requires a climate or culture of safety across the healthcare organization. And a culture of safety is inextricably connected with improving outcomes in the quality of patient care.

5.e.(i) Patient Care Quality.

Patient care quality is crucial for the development of a culture of patient safety. Research on quality in health care has over the last 30 years resulted in a substantial increase in knowledge of the measurement of quality, on variations in health care delivery, on the implementation of clinical ethical practice guidelines based on best-evidence, on assessing patient satisfaction and experience and, more recently, on estimating the incidence of AE which led to focusing on patient safety. Quality of care cannot be looked at in isolation but in conjunction with safety. In describing quality of health care, the (IOM) defines quality as “the degree to which health services for individuals or populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”
There have been several landmark events that laid the foundation of quality in patient care. As early as the Crimean war, 1850s, Florence Nightingale studied mortality rates in military hospitals. In 1912, Ernest Codman developed a method to measure the outcomes of surgical interventions. By 1918, the American College of Surgery had defined the minimum standard that hospitals needed to fulfill to obtain accreditation. In 1950, the medical audit method was developed. The following year the Joint Commission on Accreditation of Hospitals (JCAH) was created to accredit hospitals utilizing applied standard quality measures. In 1970, J. Williamson, began patient chart review and patient questionnaires, and introduced a new method for assessing what is achievable but not achieved by the standard of care. And in 1992, Avedis Donabedian applied the industrial model of structure, process, and outcome measures to the healthcare process. Dr. H. Palmer is credited with defining the different dimensions of quality.82

The IOM report To Err Is Human emphasized the importance of quality by developing a culture of safety. An organization’s care processes must focus on improving safety of patients. The Agency for Healthcare Care Research and Quality (AHRQ) characterizes organizations with a positive safety culture as having a foundation of mutual trust, a common view that patient safety is important, and a belief that preventative measures are effective. However, efforts to make patients safer through focusing on culture have met with mixed success.83 Results from studies of AHRQ Patient Safety Indicators, for example patient safety outcomes, have been unpredictable. It appears that rather than a one-way causal relationship with culture influencing behaviors and clinical outcomes there is be a circular relationship with changes in behaviors and outcomes also improving safety culture.84
According to the IOM, the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which error are treated not as personal failures, but as opportunities to improve the system and prevent harm. Professional and organizational cultures in health care must undergo a transformation in the interests of promoting safer patient care. Health care must see itself as a high hazard industry that is inherently risky. It must abandon the philosophy of requiring perfect, error free performance from individuals and focus, instead, on designing systems for safety.

The IOM emphasized the need for system and processes changes to promote a culture of safety in healthcare. To guide these changes, they identified a set of principles that should be applied to large healthcare systems, individual hospitals, and small practices. They are as follows: to provide leadership; to respect human limits in the design process; to promote effective team function; to anticipate the unexpected, and, to create a learning environment.

One of the most reasons obstructing the adoption of error detection systems are the “invisible” nature of errors. Adverse consequences are often thought to be attributed to the natural course of illness; it is not uncommon for patients, families and physicians to assign them to illness rather than treatment. Only through careful peer review can the cause of an outcome be determined. Take for example a patient with diabetes. Diabetic patients often experience renal failure. Hence, a patient might consider diabetes, rather than an angiotensin converting enzyme inhibitor that was recently prescribed, to be the cause of renal failure. The ability to uncover contributing causes is best served by an expert reviewer.
The National Scorecard on U.S. Health System Performance 2011 indicators were not promising over previous years. The overall score for U.S. health system performance failed to improve over the five years since the first National Scorecard in 2006. The quality of health care did not consistently get better, as there was improvement in only half of the 22 National Scorecard indicators that are followed. These include the extent to which patients receive care that is effective, safe, well-coordinated, timely, and most importantly patient-centered. Among those indicators for which baseline data were available, 52 percent substantially improved by 5 percent or more, 14 percent substantially worsened, and 34 percent showed little change. Even though quality was the highest score among the five dimensions of performance, it still fell 25 percent below its desired benchmark level. Quality suffered greatly in the following: adult preventive care, care coordination indicators such as follow-up after mental health hospitalizations and hospital admissions or readmissions of nursing home residents, safety indicators such as medical errors and appropriate antibiotic prescribing, and finally in patient-centered care indicators which measure the ability to get timely appointments and after-hours care. The belief is growing that an institution’s ability to avoid harm will be realized only when it is able to create this culture of safety. This is vital to ensure that systems and innovations introduced to improve patient safety actually reach their potential.

Simultaneously, the Joint Commission published a manual on Patient Safety which presents their guidelines to foster a culture of safety. Firstly, the Joint Commission requires accredited healthcare organization to integrate patient safety standards into their existing processes and structures. Secondly, it expects organizations to enforce its sentinel policy in a clear and defined manner. Thirdly, a culture of safety must require a
shift towards an environment that can identify both actual and potential risk. Finally, the work an institution undertakes in promoting a culture of safety must be developed in a written plan for a patient safety program. In essence, when healthcare organizations implement proactive risk assessment they can prevent errors as well as near misses and protect their patients from harm.\textsuperscript{90} The set of principles from the IOM and the practical guidance by the Joint Commission provide substantive leadership to foster a culture of patient safety in US healthcare. That leadership increasingly focuses upon the participation of patients in contributing to their own safety.\textsuperscript{91}

5.e.(ii). \textbf{Patient Participation.}

Since the publication of the IOM’s report To Err Is Human much has been done to build a culture of safety. The voice of the patient has been largely missing. The emphasis now is very much upon patient participation to create a culture of safety. The term medical error suggests that something has happened to a patient. Increasingly, patient’s participation is being emphasized to ensure that their personal care is safe and suitable.\textsuperscript{92} However, this is not without obstacles. To begin with, the actual concept of patient participation remains poorly defined. No single definition exists. There are numerous terms such as patient collaboration, patient involvement partnership, patient empowerment, and patient-centered care which are used interchangeably. Also, patient participation can relate to aspects of health care as diverse as decision making, self-medication, self-monitoring, patient education, goal setting, or taking part in physical care.\textsuperscript{93}

The US National Library of Medicine defines patient participation as "the
involvement of the patient in the decision-making process regarding health issues.” However, this focus on the decision-making process does not include the many and varied aspects of health care in which the patient could participate. There is a clear distinction between participation in decision making and participation in other aspects of care. Today the roles of health care provider and patient have developed beyond the traditional physician paternalistic approach to a more active joint collaborative understanding based on the ethical principles of autonomy and justice. While actively engaging patients in managing their conditions continues to show improved clinical outcomes, there remain opportunities for further physician/patient partnering. Such a venture can be understood as one in which they both join to collaboratively chart the patient journey towards increased healing and overall wellness. As advances in medicine continue, an increasing array of options will become available to combat many of today’s conditions. Overall healing will best be served by an informed and active patient who works in tandem with their healthcare provider to maximize healing.

In 2000, the Joint Commission began focusing on patient safety. They launched new campaigns with the objective of engaging patients and their families in the hospital and other care settings. The campaigns began in 2002 with the Speak Up initiative, in collaboration with the Centers for Medicare and Medicaid Services. This program urges patients to take an active role in preventing health care errors by becoming involved and informed participants on their health care team. By January 2010, the Joint Commission made available 13 Speak Up publications for various health services. By 2008, 80% of 1,900 hospitals surveyed were utilizing Speak Up materials. The Agency for Healthcare Research and Quality (AHRQ) has also made several patient publications available.
most widely known is its 20 Tips to Help Prevent Medical Errors. Similarly, the National Patient Safety Foundation includes patient publications on its Web site, and several of the AHRQ documents are posted there. The focus of the patient materials encourages patients to be observant, to ask questions, and encourages conversation with their care providers if they believe anything is wrong with their care.96

Other countries are also beginning to foster a culture of patient safety. The UK Healthcare Commission released its annual report on the State of Healthcare in 2005 for the British Isle. The report was based on three questions, asked from the patients’ perspective: Firstly, do people receive effective health care? Do they have enough control over the care they receive, and do some people get a better deal from health care than others? The report’s findings showed that substantial development is still needed in all three areas. There still lacks a level of patient involvement in decisions about their own health care. The findings challenge providers to improve services and to center them on patients' needs, rather than their own. Ideally a healthcare system would function optimally with greater collaboration between providers and patients. Nowhere is this acknowledged in the Healthcare Commission report.97

At the center of patient participation resides a redefinition of the patient role. Historically, in many cultures, the relationship between the patient and the health care worker follows a paternalist model, and the patient has been traditionally a passive spectator in his or her own healing process. However, in today's definition of health care, the patient must be seen as a key player.98 In truth involving patients in efforts to improve an overall culture of safety makes sense. Understanding today’s often fragmented care and the large numbers of clinical providers with whom patients interact, patients are
usually the only participants who are involved in the entire process of care. Actually, the
patient holds a unique position in that they are only ones who are both, the center of the
treatment process and, the observer of almost the entire process. Patients who are
educated about the course of their treatment and medications in the context of a trusting
relationship will participate in the culture of safety by being effective in identifying and
preventing errors. Patients should be empowered to ask questions and to speak up when
they are unsure of a particular circumstances or procedure. Such an understanding can
only come to fruition when both patients and medical personnel see themselves as
partners in healing.

This vision calls for a radical change in the method by which care is delivered.
Work is being spearheaded by European countries which have a history of advocating for
stronger patients participation. Recently the United Kingdom’s National Health Service
revised its constitution. Many of the reforms focused on promoting a culture of patient
safety. In this effort, a program to promote patient awareness entitled “Nothing About Me
Without Me,” has become a defining mantra. Other international communities are equally
committed. In December 2010 the Salzburg statement on shared decision making was
published. This paper was circulated by a group of 58 international healthcare leaders and
researchers. Its focus is centered on a stronger commitment of collaboration between
providers and patients for a greater “co-production of health.”

There is strong clinical evidence to support such action. Recent mega-systematic
reviews of 86 studies, involving 20,209 participants, in randomized controlled trials
conducted over the past 25 years, trended in support of shared decision making
particularly with initiatives aimed at changing behavior. Such results indicate that
patients who are involved in shared decision making are better informed than those who are not and are more determined about the best course of action at the end of a consultation. Interestingly, they are more likely than their doctors to defer or decline surgical intervention. The studies have revealed that such decisions have had no measurable adverse impact on patient’s health outcomes or satisfaction. Also, these actions have the potential to significantly reduce medical expenditures. The results have also shown that involved patients are more compliant with medical treatment regimens and less likely to initiate litigation against their providers. 103

There is growing interest in the role patient participation can play in enhancing the culture of patient safety. Researchers maintain that perceptual measures of patient safety and quality can help to identify areas in which there are higher risks of preventable AE. 104 This is largely due to the fact that patients interpret lapses in service quality such as delays in care, lack of coordination or poor hygiene as risks to their safety. 105 Patients may be more perceptive about safety problems than they have been given credit for. For example, results showed that poor coordination of care, poor interpersonal skills and unprofessional behavior were associated with the occurrence of AE, close calls and low-risk errors. Two possible explanations for these findings were offered. Firstly that patients’ experience of harm may increase their vigilance and critical assessment of service quality. Secondly, general attributes of the organization, such as the quality of inter-professional and patient–clinician communication, may lead to service quality problems as well as AE and errors. 106

In reality patients must play numerous important roles in their own safety. To begin, patients must be involved in monitoring and reporting adverse events. Recent
reports verify that AE are chronically underreported by staff. Therefore, patient reporting could provide another lens with which to view care delivery systems.\textsuperscript{107} Patients who are educated about their medications and potential side effects report being empowered to verify medication administering, timing and amount. Patients must be aware of expectations around surgeries and enabled to report any deviations or adverse events immediately. Further evidence proposes that informed patients can reduce hospital acquired infections by being vigilant in observing staff hand-washing. Finally by keeping aware of their medical histories, allergies, and current medications patients can ensure that they are being properly identified. With Electronic Medical Records becoming the new norm patients must ensure that their information is current and accessible to providers.\textsuperscript{108} Some of the preliminary effects of patient involvement are interesting.

In one of the experiments concerning hand washing, it turned out that the increase in soap usage by staff had already occurred. Staff had anticipated the need to increase hand washing before patients were encouraged to ask about hand hygiene. This indicates that patient safety improvements cannot be considered in isolation rather, developed in a pattern in which the context of implementation remains a factor. In this situation a possible threat of embarrassment, which can result from a disclosure of unsafe behavior, is actually an encouragement to increased hand washing.\textsuperscript{109} This resembles a phenomenon that has also been demonstrated for public reporting of performance data. Public disclosure of substandard performance triggers professionals and managers to improve the quality of care.\textsuperscript{110} This is related to the fact that safety performance is an important attribute that determines patients’ choice of a hospital especially for elective procedures.
There are obviously many other requirements to modify culture. For example, effective leadership is foundational to building trust within healthcare. Deliberate attention needs to be directly focused on patient safety issues. Physician leadership is crucial to such change. Physician leaders need to lead meaningful progress to achieve a patient safety culture. Such an embracing of physician leadership will be liberating and empowering for all clinicians, as it can securely direct mechanisms of blame away for the individual.\textsuperscript{111} In particular, in Catholic healthcare effective leadership requires intense Sponsorship and Governance of patient care quality and safety.

5.f. Conclusion.

To securely establish patient safety requires direct governance oversight of patient quality of care. Enhanced Sponsorship and Governance oversight is crucial to establish a robust culture and practice of patient care quality and safety.\textsuperscript{112} A survey of more than 1,000 governance board chairman revealed that 58 percent of those from hospitals in the bottom decile of quality believed that they were above average, and no respondent reported that their performance was worse than that of the typical U.S. hospital.\textsuperscript{113} The Institute for Healthcare Improvement had recommended 12 interventions that have the potential to reduce 5 million incidents of harm occurring in Hospitals. The only non-clinical intervention was to fully engage the governance leadership in quality and safety. They suggest that, at a minimum, each board meeting should allocate 25% of their time to quality and safety issues. They suggest that the board meet with at least one patient or a family member of one, who had sustained serious injury at their organization during the previous year.\textsuperscript{114}
Until recently, discussions about organizational leadership in quality and safety tended to focus on the commitment and focus of the CEO and physician leaders. But in many healthcare organizations, the role of the board can be decisive in agenda setting and resource allocation. Traditionally, hospital boards delegated quality and safety to medical staff, focusing instead on their fiduciary responsibility. This move was a result of the lay board’s make-up that was primarily community businesspeople who felt clinically inadequate and therefore allowed medical personnel to supervision of quality and safety. However, emerging evidence indicates that boards have become reengaged in the issues of quality and safety and as a result metrics have changed.\textsuperscript{115} Some of this is driven by market share and some by the education of boards on their mission and responsibilities. But the key driver remains the utilization of money. Recent studies show that care in the U.S. in accordance with 439 indicators dealing with basic healthcare was being delivered only 55\% of the time. The figures range from as low as 10\% to as high as 80.\textsuperscript{116} The financial impact is profound. The IOM report estimated that the overall national costs for preventable AE’s even in the late 1990s was between $17 billion and $29 billion.\textsuperscript{117} Healthcare governance can no longer remain complacent. Hence, patient care quality and safety requires intense Sponsorship and Governance oversight in Catholic healthcare.

Governance scholars agree that a well-organized committee structure, comprised of educated and engaged members, is one of the major keys to effective governance. Determining specific allocation of oversight accountability for vital governance functions is a key benchmark of good governance standards. The board has several options in oversight. There are circumstances when a board may choose to handle oversight directly as a committee of the whole. In reality, today’s health care economy places demands on
board members’ time. This coupled with the broadness and complexity of issues that boards must address often result in the direct oversight responsibility for governance functions being assigned to board committees. The parameters of such committees are firmly established by the board and consistent with current legal and fiduciary responsibilities. This has a direct correlation with patient care quality and safety.

A survey of hospital and system leaders found that 80 percent of the 562 responding CEOs disclosed that their governance boards establish strategic goals for patient quality improvement or use quality dashboards to track performance and follow up on corrective actions related to AE. While this was a good beginning, only 61 percent stated that their governance boards have a quality committee. Such findings are grounds for concern as studies of organizations from all industry sectors reveal that failure in reliability and systems performance stems from inconsistent execution more than from failure of strategy. Strongly indicating that quality, cost, and trust are intrinsically interdependent and tightly joined.

Obviously, assigning oversight responsibility to a standing committee is only a single step in meeting this standard. However, research indicates that the existence of a board-level committee on patient quality of care is positively associated with adoption of other quality oversight practices. Having a governance board quality committee was associated with lower mortality rates for six common medical conditions measured by the Agency for Healthcare Research and Quality (AHRQ) Inpatient Quality Indicators and State Inpatient Data-bases.

Also, since 2008 Medicare and commercial health plans no longer reimburse hospitals for preventable medical errors. Further financial disincentives have been created
to decrease rates of hospital-acquired infections and preventable readmissions while incentivizing hospitals on the basis of the quality of care in the Accountable Care Act.¹²² For hospitals to remain open, an important step should be a rigorous analysis of medical errors and comprehensive preventative programs to reduce their occurrence.

In sum, quality patient care is inextricably related with patient safety, hence this chapter has discussed patient care quality and safety. This trend in patient care is pivotal for healthcare across the U.S. and requires intensive Sponsorship and Governance oversight in Catholic healthcare. Developing a culture of patient safety is very complex and requires astute and robust leadership. Catholic healthcare is especially well positioned to provide leadership nationally with regard to this emerging trend insofar as the focus upon patient care quality and safety reflects the integration of organizational ethics with the Catholic social tradition. To ensure that this system-wide organizational change occurs, intensive Sponsorship and Governance oversight is needed for the foreseeable future.
Notes


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Chapter 6. Intensive Oversight of Public Good: Community Benefit Programs.

**Introduction.**

Chapter 6 discusses intensive oversight of the public good focusing on community benefit programs. As discussed previously, there are emerging trends that are pivotal for healthcare and require intensive Sponsorship and Governance oversight. The previous chapter examined a pivotal trend from the perspective of patient care. This chapter examines another pivotal trend that deals with the public good, the issue of community benefit programs. This requires intensive Sponsorship and Governance oversight because Catholic healthcare could lose its nonprofit status if this characteristic of tax-exemption is not honored.

Nonprofit healthcare organizations need to be increasingly attentive to institutional integrity.¹ The founders of mission-driven health care organizations were called by their values and civic duty to meet pressing health needs in their communities. Government recognized the benefits that these charitable organizations provided and granted them exemption from taxes so that those resources can be used to benefit the public. In return for this tax exemption, hospitals are expected to provide specific community benefits along with other legal requirements.²

Hence, community benefit programs can be seen as a litmus test of organizational integrity. This litmus test pertains not merely from the perspective of compliance with tax code for nonprofit status, but especially from the perspective of an organization’s nonprofit mission. When a nonprofit organization foregoes its duty to society by not
providing community benefit, it fails to fulfill its legal obligation with the tax code, and it undermines the organization's integrity. This challenge relates directly to the mission of the nonprofit organization. It is the connection between board oversight and healthcare mission that allows boards to successfully respond to community benefit as an organizational ethical imperative.³

This responsibility fits well with the social tradition that requires Catholic healthcare institutions to have a prophetic role in service to the needy.⁴ Catholic healthcare emphasizes that within the marketplace where healthcare functions there are indispensable social responsibilities.⁵ Catholic healthcare commits itself to defend human dignity, care for poor and vulnerable people, promote the common good, provide sound management of resources, all being components of community benefit programs.

An extensive list of specific issues in the Catholic tradition combine together to reinforce the importance of community benefit from a theological perspective: having a healing mission; expressing social justice, equality, and compassion; respecting human dignity; fostering a holistic vision of health care that cares for the physiological, psychological, social, and spiritual aspects of persons; ensuring high quality health care; demonstrating a preferential option for the poor by providing charity care and acting as advocates in political forums; forming a community of employers and employees devoted to social justice; fostering the common good; observing the Ethical and Religious Directives for Catholic Health Care Services; being a nonprofit organizations; and being approved by the hierarchy of the Church or as a public juridic person within the Catholic Church.⁶
Given the importance of this emerging trend that focuses on community benefit programs, and given its fit with the Catholic social tradition, there is an urgent need for intensive Sponsorship and Governance oversight in Catholic healthcare to provide leadership for community benefit programs – without which Catholic healthcare as nonprofit could be in jeopardy. This oversight means that the Catholic organization’s mission is carried out in a manner that extends from patient care in the hospital to addressing the public good through its community benefit programs. Hence, developing plans and priorities as well as monitoring progress of community benefit programs not only represents a basic indicator of effective Sponsorship and Governance oversight, but also constitute basic hallmarks of organizational integrity. Developing effective community benefit programs is organizationally complex and requires robust leadership. Catholic healthcare is especially well positioned to provide leadership nationally insofar as the focus upon community benefit programs reflects the integration of organizational ethics with the Catholic social tradition.

This chapter discusses the responsibility of nonprofit healthcare organizations to have community benefit programs by first considering the Community Benefit Standard and then exploring how Catholic healthcare provides oversight of community benefit in its organizations.


The Community Benefit Standard was developed over several decades as a requirement of the tax code for tax-exempt or nonprofit status of hospitals or healthcare facilities. In 1946 the Commission on Hospital Care after World War II enacted the
Hospital Survey and Construction Act, commonly known as the Hill Burton Act. This act was subsequently amended by Congress in 1975, and became Title VI of the public health service act. This introduced the expectation that nonprofit, tax-exempt healthcare should serve defined community needs. In 1956, the Internal Revenue Service issued revenue ruling 56–185 to include charity care as a requirement for tax-exempt status.

However, in 1969, after Medicaid and Medicare programs were established to expand coverage for the poor and the elderly patients, the Internal Revenue Service significantly loosened the criteria affording tax-exempt status to nonprofit hospitals. This ruling meant that hospitals qualify if they engage in serving the needs of the community. This provided the context for establishing the community benefit standard still in use today.10 Within this context board oversight of community benefit is a profound responsibility. The duty to fulfill this obligation transcends compliance requirements for a nonprofit healthcare organization to be consistent with its basic sense of purpose or mission.11

Community benefit programs require organizational integrity insofar as boards of tax-exempt hospitals and systems must assign community-based resources for the benefit of the community – they must budget for community benefit.12 There are best practice guidelines for nonprofit boards in planning, implementing, accessing and reporting and the community benefit. Examples of these standards include the following. Boards should conduct regular reviews and ensures the dissemination of community benefit data both internally and externally; there should be a board statement that includes the definition of community benefit and describes the organization’s commitment to community benefit program; there should be an integration of community benefit with other aspects of
operations as an essential component of its mission and incorporated as an essential
dimension of performance; community benefit packages and services should be described
in plans and budgets; boards should have dedicated meetings which are primarily devoted
to community benefit goals, progress, and results; boards should ensure that
compensation for CEOs (as well as other executives, managers, and staff) is linked in part
to community benefit performance.¹³

The Internal Revenue Service regards the community benefit standard as an
imprecise standard to ascertain whether a not-for-profit hospital should be exempt from
federal income. Under section 501(c)(3) organizations must serve the public rather not
private interest. Not surprisingly, non-profit healthcare organizations and their governing
boards are being scrutinized more closely than ever before. That is, although these
programs have existed for a considerable time, there is renewed scrutiny that focuses
upon community benefit as a nonprofit requirement to substantively engage communities
that typically find themselves at the margins of society.

6.a.(i). Scrutiny of the Community Benefit Requirement.

The American Hospital Association recommends that oversight of system-wide
involvement in community health needs and benefits is a core governance responsibility
in nonprofit healthcare to be undertaken in cooperation with other community agencies.¹⁴
The Internal Revenue Service, the Government General Accountability Office, the Senate
Finance Committee, and a growing number of state legislatures and attorneys general, as
well as bond rating agencies are closely scrutinizing the governance of nonprofit
hospitals and health systems. Governance oversight of charity care and other forms of
community benefit, compliance issues, conflicts of interest, and executive compensation are among the areas receiving attention. In effect, the expectations for boards of nonprofit healthcare organizations are becoming more stringent.\textsuperscript{15}

In 2006, the Internal Revenue Service initiated a major study of the tax-exempt status of over 500 non-profit hospitals across the nation looking at many areas of compliance with the community benefit requirement. The report was startling, but not surprising. Approximately 47\% of those responding did not meet the 5\% of total revenue expended. As a result, greater emphasis was placed upon the need for consistent definition and reporting standards.\textsuperscript{16} This problem is compounded by the growing distrust among the public of all charities, arising out of egregious fundraising practices of some organizations combined with news that a relatively small percentage of funds collected for charity purposes were used for that purpose. Part of this dismay could be caused by a mistaken belief that tax exemption is based upon the provision of amounts of charity care at least equal to the face value of the tax exemption.\textsuperscript{17}

Also, in a 2007 national survey, CEOs of community health systems were asked if their system board had adopted a formal written policy that defines overall guidelines for the system’s community benefit programs. Nearly all (90\%) of the CEOs of high-performing systems answered affirmatively. Considerably smaller proportions of the CEOs of mid-range systems (60\%) and low-performing systems (27\%) said their boards had adopted a formal written policy on community benefit. This reveals that a large proportion of the U.S. nonprofit community health systems currently are operating with limited or no formal board direction and guidance for their community benefit programs and services.\textsuperscript{18} This is disconcerting from a governance perspective.
The growing distrust of among the public of healthcare organizations reflects a widespread skepticism of governance in the corporate world. The recent jolt to the financial system and revelations of large-scale corporate greed unveiled a troubling view of governance and the corporate world. Not surprisingly, healthcare felt the impact of this governance compromise and accompanying public dismay. Much needs to be done to regain trust and confidence in nonprofit healthcare.\textsuperscript{19} A crucial role for governance is to regain the lost trust and to recover the confidence of communities, whether referring to the business community or the healthcare community. Corporate America and organizations in healthcare need to win back the respect of skeptical customers, disheartened patients, and distrusting communities. This task can be accomplished properly when organizations and their business practices have a renewed commitment to ethics.\textsuperscript{20}

To address this standoff requires much ethical and effective leadership. The Joint Commission emphasizes the needs for much improved leadership standards in healthcare.\textsuperscript{21} For ethical and effective leadership, organizational integrity requires that an organization’s nonprofit mission provides the context for fiscal responsibility that connects operations with the community. This entails a two-way commitment of loyalty.\textsuperscript{22} To qualify as being tax-exempt, a nonprofit hospital must be both organized and operated as a public charity and as a community benefit organization. The first part is the “organizational test” whereby the hospital is incorporated as a non-for profit corporation under the relevant state law. The second part is the “operational test” that is satisfied only if the hospital is actually run as a charitable and a community benefit institution. Because nonexempt hospitals may also pursue a mission of simply providing
hospital service, a tax-exempt hospital must do something more than its hospital service. That is why community benefit is so important, not least to meet the operational component in the law. This is where an organization’s nonprofit status requires robust board oversight.\textsuperscript{23}

In this complex context of competitive and financial pressures in healthcare, community benefit constitutes an ethical imperative for board oversight. This ethical imperative requires that community benefit programs be managed with due diligence and effective leadership.\textsuperscript{24} Naturally, it is the responsibility of organizations to ensure that their boards have the resources they need to bring their mission to fulfillment. However, a glaring lack in the resources required is an ethical framework that governance can use to integrate their organizational mission with their community benefit responsibilities.\textsuperscript{25} The next section seeks to fill that gap.


There is a helpful paradigm in organizational ethics that can help leaders in nonprofit healthcare deal with their community benefit responsibilities. The ethical paradigm connects mission with decision-making and conduct. This paradigm combines analytical and evidence-based approaches to identify emerging benchmarks that are crucial for effective governance. The paradigm combines three related components (the organizational mission, its deliberative process, and its practical conduct) as necessary for reliably identifying and resolving different dilemmas in healthcare.

First, an organization’s mission sheds light on the organization’s basic values and the ethical principles that guide it. These mission-related ethical principles constitute the
foundational component of an ethics paradigm. Secondly, the deliberative process in an organization illuminates how ethical decisions are made. This decision-making focus constitutes the process component of the ethical paradigm. Thirdly, the standard that determines practical conduct influences the ethical caliber of the organization. These three components account in a substantive manner for the reciprocity between the following: who we are, based on the ethical principles that reflect the organization’s mission; how we function, focusing on decision-making processes adopted by the board; what we do, highlighting the ethical conduct that applies the principles and decision-making process.²⁶

The levels of quality that arises from this sort of ethical paradigm in healthcare organizations can be illustrated by the approach to organizational ethics adopted by the Veterans Health Administration (VA). The VA uses the image of an iceberg to illustrate organizational ethics as connecting three inter-related but distinct levels. First, decisions and actions (level I): there are observable decisions and actions, and the events that flow from them in the everyday practices of an organization and its staff. Second, systems and processes (level II): these drive the steps of decision-making. Third, environment and culture (level III): these distinctively shape an organization’s ethical practices and they include a variety of features such as values, assumptions, habits, etc.²⁷

The approach to organizational ethics in the VA’s healthcare system is similar to the organizational ethics paradigm: the paradigm’s foundational mission component is akin to level III of the VA approach; the paradigm’s deliberative process is akin to level II of the VA approach; and the paradigm’s ethical conduct component is similar to level I of the VA approach. In other words, the VA approach confirms the robust nature of the
organizational ethics paradigm discussed above. More specifically the organizational ethics paradigm suggests how board oversight of community benefit can contribute to making organizations ethical by enabling the development of benchmarks that relates the organization mission to its deliberative process and practical conduct, as is apparent in the following explanation.

The first component of the organizational ethics paradigm is the foundational component. This involves the mission related ethical principle of organizational integrity. This ethical principle is crucial to upholding the mission of a healthcare organization that focuses on healing and trust and therefore speaks to who we are in healthcare. One of the greatest dangers we face in healthcare today, especially as we struggle to survive is to focus so much the fiscal demands that we compromise basic mission of healing. Organizational integrity provides the foundation for organizational ethics in healthcare and can more readily foster our hospital and organizations as ethical organizations. In turn, good ethical conduct will reinforce those decision-making processes and principles thereby further developing an ethical organization. Community benefit is an ethical endeavor that reveals the core commitment of the board to the organizations fundamental mission as a tax-exempt organization that is committed to the population it serves. This is especially important when the ethical principle of organizational integrity is aligned with the mission of the healthcare organization. It inspires evidence-based emerging benchmark for board oversight of community benefit.

The second component of the organizational ethics paradigm is the decision-making process. Here an organization aligns the principle of organizational integrity with ethical conduct by engaging in appropriate decision making processes. These processes
contribute to the development of an ethical organization. That is, decision-making processes indicate how we function in an organization. This reflects and fosters the ethical character not only of a healthcare organization but also of the board as an effective governance body.\textsuperscript{33} This decision-making process can be described in the following manner. First, the process identifies the problem using three steps: there is the recognition of the problems relevant aspects; there is the designation of the root problem; and there is the assessment of the cause and effect relations. Second, the process of ethical resolution involves another three steps: the clarification of realistic options available; the determination of the best solution to fix the problem; and the implementation of the decision.\textsuperscript{34} This process component of decision-making in the organizational paradigm inspires evidence-based emerging benchmark for board oversight of the community benefit through deliberate communications.\textsuperscript{35}

The third component of the paradigm is the practical component that deals with the ethical conduct. Here the ethical conduct across an organization emanates from the combination of ethical principles (the first component of the paradigm) and decision-making (the second component of the paradigm). The ethical conduct deals with what we do. Ultimately, the evaluative bar for an ethical organization is its conduct enacted across the spectrum of its responsibilities.

This paradigm can enlighten governance oversight responsibility for community benefit in nonprofit healthcare organizations. In other words, this oversight of community benefit constitutes a threshold responsibility that reveals the ethical caliber of the organization in general and that of the board in particular. That is because community benefit is not just one item among a litany of other competing demands in health
organizations. Rather, community benefit responsibilities are at the core of the mission of nonprofit organizations in healthcare. They are required not only by state statutes and the Internal Revenue Service regulations, but also they are ethically obligatory from the perspective of social responsibility.36

This paradigm of organizational ethics can have a direct impact on governance of community benefit responsibilities. That is, boards need to invest in decision-making processes of deliberate communication to focus on community needs assessments in order to plan appropriate resource allocation and development of community benefit programs. Such practices will in turn increase board accountability by enforcing the obligations of nonprofit organizations to respond to the government requirements for community benefit. These processes of deliberate communication constitute an emerging benchmark for addressing the ethical imperative of board oversight of community benefit. In other words, the board must foster decision-making processes that meaningfully connect an organization’s mission with its practical conduct.37 This means developing a strategy that combines deliberative processes and policy with practical plans for action accompanied by performance reports. This undertaking aligns community benefit programs with measurable objectives of effective reporting for quality improvement. As a result, the organization’s objectives are delineated in measurable terms to ensure that reporting and accountability mechanisms are in place to track progress and to conduct performance reviews on a regular basis.38

The relevance of this paradigm in organizational ethics for governance of community benefit responsibilities is reinforced by recommendations for board oversight by the American Hospital Association. The AHA has provided specific recommendations
to the nation’s nonprofit hospitals that board oversight requires an objective assessment regarding community health needs. This should be undertaken preferably in cooperation with other community agencies to establish priorities. In other words, having a robust community benefit program is an emerging benchmark of good governance for nonprofit hospitals and health systems.\textsuperscript{39}

This focus emphasizes that for nonprofit organizations, healthcare is not a commodity even though fiscal responsibility is necessary. Community benefit requires managing two goals together, the fiscal health of the organization and the health of individuals and community alike. Nonprofit healthcare understands that although marketplace pressures have to be dealt with, social responsibility is of paramount importance.\textsuperscript{40} It is here that the principle of organizational integrity safeguards an organization’s mission by ensuring its independence and strategic success. This approach necessarily includes the proper management of limited resources that address the community needs to support community benefit programs. The boards of nonprofit healthcare organizations are responsible for ensuring that the organization’s mission is being carried out, that its tax-exemption requirements are being met and that the organization’s resources are being used wisely.

The organizational ethics paradigm discussed above provides a practical framework to undertake the crucial oversight of community benefit. The integration of the three components of the paradigm (mission, decision-making, and action) can guide boards to have intensive oversight so that the pivotal requirements for community benefit do not threaten an organization’s continued existence as a nonprofit organization. This is especially the case in Catholic healthcare where the need for intensive Sponsorship and
Governance oversight allows Catholic healthcare to live out its Mission. To understand this oversight responsibility for Sponsorship and Governance in Catholic healthcare, the following section explores the recommendations and requirements of the Catholic Health Association.

6.b. **Oversight Responsibility: the Catholic Health Association Approach.**

The Catholic Healthcare Association provides guidelines for healthcare to honor its Community benefit responsibilities. Boards of nonprofit healthcare organizations are responsible for ensuring that the organization’s mission is being carried out, that its tax-exemption requirements are being met and that the organization’s resources are being used wisely. Reporting community benefit helps fulfill each of these board responsibilities and truly allows Catholic healthcare to live out its mission.

6.b.(i). **Healthcare Mission, Community Needs and Environment.**

The significance of Community Benefit in Catholic healthcare reflects the original mission that led to it being founded in the United States. Catholic healthcare began as mission in responding to a community need. In 1727, 12 Catholic sisters arrived in New Orleans to minister to persons who were ill or living in poverty. This faith-based response to the health needs of those vulnerable persons started the healthcare mission to serve the poor and others at the margins of society. This ministry has been flourishing ever since. There was a significant community need that required a response.

Today, mission-driven healthcare organizations continue to provide community benefit. In the spirit of the original congregations, Catholic health care remains
committed to, human dignity, promoting and defending it vigorously. This mission is accomplished in how Catholic healthcare promotes the common good. As a mission-driven organization, Catholic healthcare does not provide community benefit because of external tax-exempt pressures. Rather, it is done because it affirms the mission and meaning of Catholic identity – community benefit is indispensable for its ministry.\textsuperscript{43}

The mission of Catholic healthcare is guided by the original intent of its founding congregations. These ideals have been developed into foundational believes which are a core component of Community Benefit programs in Catholic healthcare. Chiefly, particular attention should be given to those who are poor and marginalized. The health of the local community is addressed by focusing on the social determinants of health through health promotion and prevention. The focus of work within the community should be done in collaboration with the local community. This should not be haphazard but strategically planned and funded. Community benefit programs need the active support of senior management and governing Boards to ensure their success. That close affiliation enables Catholic organizations to ensure that resources are being utilized wisely – it is crucial that community benefit endeavors demonstrate how human and financial resources have been utilized to address the local community needs.\textsuperscript{44}

The endeavors of Community Benefit should reflect the organization’s mission and core values, emphasizing service to the community and addressing the needs of the most vulnerable persons. It is imperative that the community sees the organization as worthy of its exempt status.\textsuperscript{45} It is crucial that Catholic healthcare organizations communicate their community benefit programs effectively.\textsuperscript{46} The Affordable Care Act specifically requires that the community health needs assessment “is made widely
available to the public.” For example, organizations should never be afraid of sharing human-interest stories in recalling the impact a plan had on a community. A story can put a face on a statistic or illuminate a program’s cost. To maximize the overall good which community benefit encompasses, organizations should develop a robust media and public information strategy. These programs would include buy-in from board members, local elected officials, community members whose life have been effected, and policy makers who can make constructive change permanent. The organization should also promote the benefit through social media and on their home web-page.

The Catholic Health Association created the document Beyond Charity Care to address two critical questions about Community Benefit responsibilities. Chiefly, how do nonprofit hospitals distinguish themselves as charitable institutions and should non-profit health care organizations continue to be tax exempt? To address this question CHA revisited the 1987 United Hospital Fund document, Mission Matters: A Report on the Future of Voluntary Health Care Institutions. The document identified distinguishing characteristics of values, governance and accountability, long-term commitment, physician-hospital relationship, and institutional voluntarism as essential.

The guidance of the Catholic Health Association focuses the needs of special populations, particularly the poor, the underserved and vulnerable populations within our community. Facilities must go beyond the walls of the hospital to identify unmet community or public health needs, assuming a responsibility to address them. Catholic health understands that values are reflected in mission. Appreciating that health care is both a marketplace phenomenon and social good remains counter cultural, yet an
imperative in today’s fiscally driven health care market. Actions should be seen to reflect values and decisions directed by robust governance.\textsuperscript{51}

Impressive strides have been made by Catholic healthcare to better define community benefit, account for it, and report it so public policy makers may understand how and why our organizations serve the public good.\textsuperscript{52} Governance, accountability, long-term commitment, physician-hospital relationship, and institutional voluntarism are at the heart of mission, driving Catholic healthcare organizations in service to community benefit programs.\textsuperscript{53}

To integrate the hospital’s mission with community benefit there needs to be a community needs assessment. The mission of Catholic healthcare has always been centered on responding to the health needs of communities, especially to the most vulnerable. To carry out this mission the Catholic Health Association has developed a deliberate approach to addressing community health needs. The Patient Protection and Affordable Care Act enacted in 2010 has emphasized the importance of developing an accountability matrix to communities served. Its implementation mandates further requirements for tax-exempt hospitals –they must conduct community health needs assessments and adopt implementation strategies around the identified needs.\textsuperscript{54}

To honor the mission in Catholic healthcare and in keeping with the federal guidelines, the Catholic Health Association has defined a protocol called Community Health Needs Assessment. It is a systematic process involving the community to identify and analyze community health needs and assets in order to prioritize these needs, to plan, and act upon significant unmet community health needs. Furthermore such a process defines an implementation strategy to be integrated into hospital strategic plans for
addressing community health needs, including significant health needs as identified in the community health needs assessment. The implementation strategy is more commonly referred to as the hospital’s overall community benefit plan.55

The Community Health Needs Assessment plan begins with the Governing board. This sends a clear message that the process is identified as a priority and will allow the process creditability, help establish appropriate practices, and promote compliance with federal requirements. The hospital leadership should determine who should participate in the needs assessment process. The process should guide who needs to be engaged within the community, such as local agencies, to make the process successful. Once the relevant community participants are clearly identified, work needs to be focused on developing a community health needs assessment. The recommended approach involves a multiple organization partnership in which the hospital will be one of several community organizations collaborating to develop the needs assessment.56

The community health needs assessment will examine health issues for its geographic area and priority populations, as well as the social and economic issues, which impact that communities overall health. Careful consideration should take place when looking at specific populations. Factors that need to be considered are participant’s age, race/ethnicity, geography location, and income. Such details identify the fact that in some communities, the overall population has good outcomes for important health measures, but specific subpopulations have poorer outcomes for the same measures.57 This approach helps to focus the overall plan.

Because each community is different a broad set of health and quality-of-life indicators should be included in the community health needs assessment.58 Once an area
has been identified a timeline which would allow for planning and conducting a needs assessment is suggested. \(^{59}\) Surveys, community forums and meetings can be used to collect information from community members, stakeholders, providers, and public health experts for the purpose of understanding community perception of needs. This information enables hospitals to benchmark their community needs and identify relevant disparities. \(^{60}\)

Once the analyzing indicator data is completed, comparisons, trends, and benchmarks will help identify and summarize the most severe and important needs facing the community. The needs are then documented in a data summary. \(^{61}\) Once the assessment is completed federal law states that assessments must be made widely available to the public. Most health care organizations have a communications department that coordinates all of the organization’s communications efforts. This often includes publishing, listing on facility web sites, and holding public presentations to discussing the needs assessment report. \(^{62}\)

To undertake a satisfactory community needs assessment requires keen awareness of and attention to the environment of the communities being served. Mission leads Catholic health care organizations to expand their focus of healing beyond their facilities and into the overall health of their communities. This orientation calls for a concentration on social and environmental determinants of health while being mindful of working with health departments and other community partners to identify health problems and to assist in designing a partnership solution. Such focus should focus on the physical environment, including the quality of air, water, food, public energy and chemical
policies. This requires a collaborative approach to improve community health through environmental improvements.63

Environmental factors can play a critical role in the health and well being of communities.64 The Center for Disease Control reports that seven out of ten deaths in the United States are caused by preventable conditions such as stroke, heart disease, and cancer. The biggest cost-factor of these chronic diseases is socioeconomic and physical determinants of health, such as a lack of physical activity and poor nutrition. The cost to the country’s health systems are amazing with the Institute of Medicine reporting that preventable conditions cost as much as three-fourths of national health care budget.65

It is obvious that a community benefit strategy fits with the mission of Catholic healthcare organizations. The nonprofit mission of Catholic organizations and their tax-exemption legal requirements mandate fostering partnerships in the community. These partnerships draw upon the knowledge and experience of community members who are passionate about where they live and aware of the environmental and social factors which pose the greatest health risks.66

A cross-section of leaders should be willing to share their expertise to the community, including executives who can provide knowledge of environmental issues and coordinate efforts to integrate communities with the mission that drives organizations. Also, management staff could be included, especially those who understand infrastructure improvements, waste management, and pest control. Also, clinicians must be included, especially those with community relationships, sub-specialties and public health degrees. In addition, participants from the community might include members of the Public Health Departments, other nonprofits such as the United
Way and Head Start programs, and community representatives. Furthermore, local and state organizations with interests in environmental health, environmental justice, and the elimination of poverty, with sustainable economic development personnel can be excellent partners.67

Research has indicated that after community needs around environmental issues have been identified there is no requirement to reinvent the wheel, so to speak. One of the key opportunities for Catholic healthcare is to partner with existing resources. Existing programs, such as advocating for mass transit or educating lawmakers on green initiatives, can benefit greatly from the collaboration of knowledge and resources that Catholic healthcare can provide to help community programs become more effective. Communities should apply for awards from agencies like Practice Greenhealth, the Environmental Protection Agency, and the Department of Energy, etc. These partnerships present an excellent opportunity to utilize community platforms to emphasize the importance of environmental health as a mission driven directive and as part of healthcare’s continuing commitment to the community.68

There are many examples of how environmental improvement can constitute a community benefit by building activities to reinforce and encourage existing goodwill. An example can be establishing community vegetable gardens to combat nutrition deprivation that leads to obesity, diabetes, and other health problems. This sort of approach creates awareness of the need for proper nutrition as a part of overall health.69

With health care reform establishing a new standard of practice within the United States, more recognition is given to the fact that our current acute care model does not produce results in accordance with the vast amount of money invested. In particular, the
current acute care model of medicine does not address the social and environmental conditions which create the epidemic of chronic disease in America. The imperative, from both a fiscal and mission perspective in healthcare, is to conduct community needs assessments and align community benefit programs with community partners. There are many opportunities to address those needs and to create an opportunity to improve the overall health of communities. To ensure compliance with these nonprofit requirements regarding Community benefit, the Internal Revenue Service has updated its requirements.

6.b.(ii). Compliance with the Internal Revenue Service Form 990.

From the perspective of the Internal Revenue Service, included in the broad classification of nonprofit organizations are museums, libraries, colleges and universities. However none of these organizations address vulnerable populations or those living in poverty, as occurs in healthcare. The Internal Revenue Service understands this significance and since 1956 has been grappling with the “free care standard” as charity care became to be known. The Internal Revenue Service, in its Revenue Ruling 69-545, after struggling to define community benefit, declared that a hospital satisfied the community benefit standard if these conditions are met: a health system maintains an emergency department for people whether or not they can pay, has a Governance board of community leaders, retains an open medical staff, participates in Governmental programs such as Medicare and Medicaid, and utilizes excess funds to improve patient care, improve facilities, and advance medical education.

The Internal Revenue Service rules governing 501©(3) charitable status emphasize the need for community oversight and transparency, holding boards to a high
standard. Governance boards best know their local community needs. Governance boards are inherently linked to the distinguishing characteristics of volunteer governance, community accountability, and “ownership.” They serve as the community, and “give back” to the communities in which they live. Such leadership can help “stay the course” when seeing programs to fruition or deciding the best course of community action. For example, it is critical for physicians to be engaged in their organization’s mission. Such relationships do not occur randomly or haphazardly. Rather, it is imperative to mission that physicians are nurtured in relationships that enable them to see themselves as partners in ministry so that their ethical investment will benefit the greater good.

In 2008 the IRS revised its Form 990 creating a new Schedule H (especially part VI) for hospital organizations to complete. The new federal reporting obligation provides nonprofit organizations the opportunity to reaffirm their commitment to community benefit. Hospitals are instructed to provide information about how the organization furthers its exempt purpose by promoting the health of the community. Here hospitals can report their endeavors within the community that enhance community well being.

Form 990 Schedule H consists of six parts. First, Charity Care and Certain other Community Benefits at Cost: this includes the cost of doing community work, unreimbursed Medicaid and other government means-tested programs, and health professional education. Second, Community Building Activities: this includes the cost of environmental improvements. Third, Bad Debt, Medicare, and Collection Practices: these include bad debt expenses and charity care. Fourth, Management Companies and Joint Ventures: this includes entities of which the organization is a partner or shareholder.
Fifth, Facility Information: this includes the type and designation of the facility, for example if it is a teaching hospital, a children’s hospital, and/or a critical access hospital, and whether it operates emergency services. Sixth, Supplemental Information: this includes how the organization serves its community, providing the opportunity to explain previous answers and information on how the public is served.77

The new IRS 990 Schedule H provides important opportunities for the Catholic healthcare ministry. The Catholic Health Association Board of Trustees emphasizes that community benefit is integral to the mission of Catholic healthcare. While secular organizations can remain committed to their fiduciary responsibilities, there remains a conceptual difference in how and why Community Benefit remains central to Catholic healthcare. In Catholic healthcare, Boards are provided an opportunity to assess the use of community resources to ensure that the organization is meeting their community benefit responsibilities.78 The reporting mechanism emphasizes the fiduciary responsibilities of Boards as well as their stewardship to address community needs.79 Here Boards can provide tangible evidence that they are representing the community’s best interests. It is an occasion to show that tax-exempt, community-oriented organizations are transparent and accountable.80

Hence, there is a variety of tasks that Boards should undertake. They should be involved in how community needs are assessed and prioritized. They should be reviewing and approving the community benefit plan, providing information and insight into community need and resources, and helping set priorities for what their local community needs to address.81 They must ensure that services are targeted to the areas of greatest need, and be confident that their program is making a difference in the overall health of
the community. They should pay particular attention to charity care and may be active in setting the charity and community benefit budget. By appointing qualified staff to lead community benefit programs, by ensuring adequate financial resources are deployed, and by being advocates inside and outside the organization, board members establish a standard for executive leaders to excellence in their mission.

This reporting requirement enables Catholic healthcare to connect its mission and its commitment to community service. Catholic healthcare organizations do not provide community benefits because of external pressures, such as challenges to tax-exempt status. The motivation of Catholic health care organizations to provide community benefit arises from their Catholic identity. It’s such an understanding that reinforces their mission of being organizations whose core principles are to take care of the poor and the under-served, reflected in their operational model of embracing healing.

6.c. Conclusion.

In light of the mission of Catholic healthcare and in compliance with the reporting requirements to the Internal Revenue Service, nonprofit organizations in Catholic healthcare must be responsive to their community needs and provide Community Benefit programs. Given the importance of this trend that focuses on community benefit programs for nonprofit organizations in healthcare, and given its fit with Catholic mission and its social tradition, there is an urgent need for intensive Sponsorship and Governance oversight in Catholic healthcare to provide leadership for community benefit programs – without which Catholic healthcare as nonprofit could be in jeopardy.
This chapter has discussed intensive oversight of the public good focusing on community benefit programs. As discussed previously, there are emerging trends that are pivotal for healthcare and require intensive Sponsorship and Governance oversight. The previous chapter examined a pivotal trend from the perspective of patient care. This chapter examines another pivotal trend that deals with the public good, the issue of community benefit programs. This requires intensive Sponsorship and Governance oversight because Catholic healthcare could lose its nonprofit status if this characteristic of tax-exemption is not honored. The next chapter considers another pivotal trend in Catholic healthcare that deals with the public good, Sponsorship and Governance oversight of conflicted organizational partnerships.
Notes


5 David Seay, *Beyond Charity Care* (St Louis: CHA, 2007), 8.


12 David Seay, "Beyond Charity Care," *Catholic Health Association*, (St Louis: CHA, 2007).


15 Lawrence Prybil et al, Governance in High Preforming Community Health Systems: A report on trustee and CEO Views (Chicago: Grant Thorton LLP, 2009), 6


18 Lawrence Prybil et al, Governance in High Preforming Community Health Systems: A report on trustee and CEO Views (Chicago: Grant Thorton LLP, 2009), 22


20 Gerard Magill and Lawrence Prybil, "Stewardship And Integrity In Health Care: A Role For Organizational Ethics," Journal of Business Ethics no. 50 (2004, January 01): 226


31 Gerard Magill and Lawrence Prybil, "Stewardship And Integrity In Health Care: A Role For Organizational Ethics," *Journal of Business Ethics* no. 50 (2004, January 01): 229


39 Prybil et al, *Governance in High Performing Community Health Systems: A report on trustee and CEO Views* (Chicago: Grant Thorton LLP, 2009), 12


64 Catholic Health Association, *Healing Communities and the Environment: Opportunities for Community Benefit Programs* (St Louis: Catholic Health Association of the United States, 2013), 31.


68 Catholic Health Association, *Healing Communities and the Environment: Opportunities for Community Benefit Programs* (St Louis: Catholic Health Association of the United States, 2013), 14-17.

69 Catholic Health Association, *Healing Communities and the Environment: Opportunities for Community Benefit Programs* (St Louis: Catholic Health Association of the United States, 2013), 33.

70 Catholic Health Association, *Healing Communities and the Environment: Opportunities for Community Benefit Programs* (St Louis: Catholic Health Association of the United States, 2013), 23.


74 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 6.

75 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 4.

77 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 8.

78 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 16.

79 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 5.

80 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 24.

81 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 17.

82 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 18.

83 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 22.

84 Catholic Health Association, *The IRS Form 990, Schedule H; Community Benefit and Catholic Health Care Governance Leaders* (St Louis: Catholic Health Association of the United States, 2009), 12.

Introduction.

Chapter 7 discusses intensive oversight of conflicted organizational partnerships. In addition to the pivotal trends that focus on patient care (patient care quality and safety) and on the public good (community benefit programs) there is another trend that is pivotal for Catholic healthcare in the U.S. – the increasing need to develop organizational partnerships between Catholic healthcare and other-than-Catholic institutions that involve practices forbidden by Catholic teaching. This clash of values means the organizational partnerships are conflicted. As with the trends focusing on patient safety and community benefit, the pivotal nature of this trend dealing with conflicted organizational partnerships requires intensive Sponsorship and Governance oversight.

Hospitals across the nation are being swept up in the biggest wave of mergers since the 1990s, a development that is creating giant hospital systems. Analysts predict that 1,000 of the nation’s roughly 5,000 hospitals could seek out mergers in the next few years. The reality is that instead of being paid on volume, being rewarded for filling beds and performing more tests and procedures, hospitals are becoming responsible for more of the total cost of a patient’s care. This combination of the delivery of care (via hospitals) and the financing of care (via insurance companies) is referred to as integrated healthcare organizations. As a result, the incentive to keep patients healthy more than ever before reflects both the delivery and financing aspects of healthcare.¹
In this fast-changing context, Catholic healthcare increasingly faces organizational challenges about survival. As a result, there is a pivotal trend to create organizational partnerships with other-than-Catholic facilities, some of whose values conflict with the Catholic tradition. This trend is pivotal from the perspective of Catholic healthcare retaining its mission and identity. Hence, there is need for intensive Sponsorship and Governance oversight of this trend. Fortunately, there is a long-standing ethical principle in the Catholic social tradition that can provide guidance for this controversial issue: the ethical principle of cooperation.

It is claimed that there is no more difficult question in Catholic moral theology than the principle of cooperation. The principle differentiates the action of a wrongdoer from the action of a cooperator. In the context of healthcare partnerships, the principle can differentiate between a Catholic organization (as the so-called cooperator) and an other-than-Catholic organization (that provides services prohibited by Catholic teaching) with which it cooperates.

To understand how the principle of cooperation functions it can help to explain another principle upon which it can be based, the principle of double effect. In other words, to understand the significance of the principle of cooperation for conflicted partnerships in Catholic healthcare, the principle of double effect has to be grasped. Double effect is applied in bioethics to distinguish between what one intends and what one foresees and accepts but does not intend as a side effect. This marks the difference between impermissible and the permissible that is so important for using the principle of cooperation.

The principle of the double effect is one of the most practical in the study of moral theology. As a principle it is important not so much in purely theoretical matters as in the application of theory to practical cases. Although it is a fundamental principle, it is far from a simple one and ethicists widely recognize its complexity. However, when applied it can be an efficient guide to prudent moral judgment in solving the more difficult cases. The principle is used extensively in the Catholic tradition.4

The principle is often invoked to explain the permissibility of an action that causes a serious harm as a side effect of promoting some good end. It states that sometimes it is permissible to cause such a harm as a side effect (or “double effect”) of bringing about a good result even though it would not be permissible to cause such a harm as a means to bringing about the same good end. Not surprisingly, the principle is used to address new and complex cases in medicine that arise because of the increasing capacity of technology. Hence, the principle and its application to complex new cases needs intensive Sponsorship and Governance oversight to ensure its use is consistent with the Catholic tradition. The following sections explain the basic categories of the principle and apply it to cases in medicine that are controversial for the Catholic tradition.

7.a.(i). The Principle’s Four Categories.

Thomas Aquinas (1225–1274) is credited with introducing the principle of double effect in his discussion of the permissibility of self-defense in the Summa Theologica (II-II, Qu. 64, Art.7).5 Here Aquinas uses the term to refer to the duality of the results of a single human action. A person performing an action that is foreseen to have a multiplicity
of results can have very different interests in them – from serious commitment to bringing about a result to reluctant acceptance of a result that is unwanted but unavoidable. Since actions are purposeful, at least one of the results of an action must be intended, but others, although knowingly and voluntarily caused, can be outside the agent’s intention, foreseen but unintended consequences. Aquinas made this distinction in discussing killing in self-defense: one who uses lethal force for defense against attack need not intend the assailant’s death; that can be outside the agent’s intention.  

Aquinas also elaborates that it can be justifiable if one unintentionally causes the death of attackers while using the least amount of force necessary to ward them off. Aquinas is typically taken to be in accordance with St. Augustine in legitimating lethal self-defense. Neither allows one intentionally to kill one’s attacker on the basis of a general claim of self-defense, but causing death in self-defense is acceptable. Also, both Augustine and Aquinas emphasize the centrality of charity and expected the Christian will always seek the least evil effect in their action. Later versions of the double effect principle emphasize the distinction between causing a morally grave harm as a side effect of pursuing a good end.  

Aquinas’ treatment of killing in self-defense was developed and widely used in casuistic arguments through the period of high casuistry and classical moral theology onwards. This development places the principle of double effect in an important role in applied ethics in every area of bioethics from beginning of life withholding or withdrawing futile treatment at the end of life. Many secular moralists recognize that the Catholic approach to double effect captures basic elements of common sense morality. Today, double effect is applied in bioethics to understand moral reasoning in which the
distinction between what one intends in acting and what one accepts as a side effect of acting. The principle helps to distinguish between what is impermissible and what is permissible.⁹

After Aquinas the principle of double effect was developed in a long period called the manualist tradition of moral theology. This is the period of classic moral theology, extending from the Council of Trent 1563 until Vatican II in 1963. The Council of Trent had legislated the establishment of seminaries and the discipline of theologia moralis, an approach that was developed to train priests to administer the sacrament of penance. Cases of conscience were studied by seminarians to develop skills based in casuistry and necessary to be prudent confessors. This approach explored the nature of sin, intentions and attitudes of the penitent, the pursuit of and possibility of perfection in Christian life, the nature of good and evil actions, and which actions are absolute are intrinsically evil. Even more specifically, the approach also considered whether it is possible always to perform good actions, or whether sometimes one can only do the lesser evil. This centuries long approach is no longer operative,¹⁰ but one of its basics principles remains, the principle of double effect.

By the nineteenth century the manualist tradition in casuistry refined and formulated Aquinas’s reasoning into a set of rules useful for giving practical moral advice. These rules became known as the doctrine of double effect, or the principle of double effect. They were generally formulated as necessary conditions for the permissibility of actions to distinguish them from similar actions that are impermissible. The classic formulation of the PDE is presented in Jesuit moralist J. B. Gury’s Compendium theologiae moralis in 1869.¹¹ He explained: “It is licit to posit a cause
which is either good or indifferent from which there follows a twofold effect, one good
the other evil, if a proportionately grave reason is present, and if the end of the agent is
honorable – that is, if he does not intend the evil.”

Gury elaborated what were previously three conditions into four conditions by
distinguishing intention into two components. The first component addressed the
distinction between a means and a side effect: if the bad effect – that is, the result which
would render that action simply wrong were it intended – is the means to the good effect,
then it cannot be a side effect and is intended. Thus, the key requirement that the good
effect be brought about “immediately,” that is, not by means of the bad effect. The
second component – that one intends only the good effect – excludes cases in which the
bad effect is not brought about as a means to the good effect, but is nevertheless intended
because it functions as an independent goal.

Hence, Gury developed the PDE into four conditions, all of which together are
required for an act to be licit. His conditions are as follows. First, the agent's end must be
morally acceptable. Second, the cause must be good or at least indifferent. Third, the
good effect must be immediate. Fourth, there must be a grave reason for positing the
cause. Catholic moral theology continued to add nuance to these conditions and prior to
Vatican II the Jesuit Gerard Kelly explained the conditions in this manner. First, the
action considered by itself and independent of its effect must not be evil. Second, the evil
effect must not be the means of producing a good effect. Third, the evil effect is sincerely
not intended, but merely tolerated. Fourth, there must be proportionate reason for
preforming the action, in spite of its evil consequences. More recently, David F. Kelly
articulated the categories or conditions of the principle of double effect in the following
manner. The first condition is that the act in itself must not be morally wrong. This condition deals with the object of the action and asks whether or not an act is right or wrong. The second condition is that the bad effect must not cause the good effect. This condition deals with material cause of the action. The third condition is that the agent must not intend the bad effect as an end to be sought. This condition deals with the agent’s intention requiring that only the good effect must be intended. The fourth condition is that the bad effect must not outweigh the good effect. This condition stipulates proportionality between the intended good effect and the permitted but unintended evil.¹⁶

Roman Catholic moral theology has also attributed important moral significance to the distinction between what a person intends in acting and what a person accepts as a side effect of intentionally acting for another result. The principle applies to the scenario where a doctor administers to a woman (suffering from dangerously high fever) a drug which will have the two-fold effect of lowering her temperature and producing an abortion. If it is a case where the doctor merely intends to save the woman’s life by lowering her temperature the act is lawful. However in an identically similar case the doctor may wish the child to die and administers the same drug in exactly the same way but this time with the intention of producing an abortion. In this case the act is manifestly evil; the doctor deliberately wills to produce an abortion and acts to achieve that end. The fact that the act has also the good effect of lowering the woman’s temperature will not make it a good act. Here the same act performed in identical circumstances can have different intentions and moral significance. The crucial difference between the two acts
lies in the different intentions with which they were performed. The evil intention in the second case makes the act evil.\textsuperscript{17}

Perhaps the most important reminder for medical ethics that emerges from the principle of double effect is that actions cannot be morally judged solely in terms of their consequences. The intention with which an act is carried out is a vital aspect of its moral assessment. Also, there is a distinction between moral evaluation of the state of affairs that results from a person's action, moral evaluation of the action independently of its results, and moral evaluation of agents themselves. A person may have a fundamentally good or bad character and yet take specific actions that are atypical of their character.\textsuperscript{18}

Critics misconstrue PDE when they suggest that it is simply a rule that enables one to decide whether one potentially harmful action is preferable to another. This is not true. The rule of double effect is not simply an instrument of consequentialist reasoning, i.e., determining the moral status of an action on the basis of net utility. One does not begin double effect reasoning by first examining the consequences of a proposed action and then decide whether the net consequences are such that there might be a good reason to override some prima facie prohibition against the action. Rather, an individual must set out to do a morally good action, taking full account of the foreseeable consequences. If the action conforms to the conditions of the rule of double effect, one may proceed even under circumstances in which that action might have dangerous side effects.\textsuperscript{19}

The purpose of discussing the principle of double effect here is to set the stage for understanding the principle of cooperation, each distinguishing between what is permissible and what is impermissible in related ways. However, it is important also to recognize the need for intensive Sponsorship and Governance oversight of how Catholic
healthcare applies the principle of double effect insofar as the principle engages complex
dilemmas that deal with the Church’s prohibition of abortion. The following cases can
illustrate the significance of this principle and the accompanying need for intensive
oversight.

7.a.(ii). Case Examples of Double Effect.

The principle of double effect distinguishes between the direct (intended) and
indirect (unintended) features of moral action. To illustrate the principle a classic
example can be considered: the removal of a cancerous uterus from a pregnant woman.20

First, the act itself must not be morally wrong. The removal of the cancerous
uterus involves the foreseen, unavoidable, and unintended death of the developing fetus.
Second, the bad effect must not cause the good effect.21 The hysterectomy does not abort
the fetus to cure the cancer; rather it cures the cancer while also bringing about the
foreseen but unintended side effect of the removal and unavoidable death of the fetus.22
Thirdly, the agent must not intend the bad effect. Assuming that the woman does not
intend the death of her fetus, the third condition of PDE is met.23 Finally, the bad effect
must not outweigh the good effect. The surgery does not directly target the life of the
unborn child. The hysterectomy is minimally necessary to save the woman’s life. Hence,
the fourth condition of proportionality is fulfilled.24

This principle can be applied to a more recent case that is referred to as the
Phoenix Case. In this case, a woman suffered from pulmonary hypertension that was
exacerbated by her pregnancy to the point of imminently threatening her life. The
diagnosis was dire, including severe pulmonary arterial hypertension from which two
other pathologies emerged, right-sided heart failure and cardiogenic shock that can result in cardiac arrest. The only way to save her life was to remove the placenta that was exacerbating the pulmonary hypertension. But to remove the placenta unavoidably involves killing the developing embryo. To resolve the case a D&C was undertaken, removing the offending placenta and the developing embryo. This highly controversial case was pivotal for Catholic healthcare. This is because the case insofar was construed by some, including the local Bishop in whose diocese the hospital was situated, as an abortion that is forbidden in Catholic teaching. However, the PDE can be applied to justify this intervention. Close scrutiny of the case is needed to see how the principle applies.

The D&C procedure to remove the placenta was directly intended as necessary to resolve the pathological condition of the mother. The good effect and the bad effect occurred simultaneously. The good effect was directly intending to save the mother by removing the placenta and the amniotic membranes. The bad effect was the unintended but foreseen death of the fetus contained within the amniotic membranes. This is permitted by the second condition of the principle of double effect. Just as in the case of removing a cancerous uterus the fetal death is a side effect. Similarly, in the hypertension case, removing the placenta as the offending organ unavoidably brings about the death of the fetus. This death is a foreseen but unintended side effect. In each case the moral intent is focused on removing the offending organ to resolve the woman’s pathological condition. There is proportionality in the case of the cancerous pregnant womb and in the hypertension case. In the latter, the placenta and amniotic membranes containing the fetus
were removed legitimately because the mother’s life was in imminent danger. The death of the fetus was foreseen but unavoidable and unintended.\textsuperscript{27}

In the third case example, there is a debate among Catholic ethicists about the use of Salpingostomy, Salpingectomy, and Methotrexate to deal with ectopic pregnancy. In essence a Salpingostomy is the longitudinally slicing of the fallopian tube and the portion containing the damaged area and the ectopic pregnancy is removed. Salpingectomy involves surgically removing the entire fallopian tube containing the ectopic pregnancy. This can also be done partially where the ends of the tube are sutured back together. Methotrexate inhibits DNA synthesis in the trophoblast. Those who are opposed to them argue that the procedures involve the direct attack on nascent human life and therefore cannot be justified under the principle of double effect.\textsuperscript{28} However, this paper contends that in applying the principle of double effect, it can clearly distinguishes between the direct (intended) and indirect (unintended) features of moral action. Such application can foster an acceptable moral resolution.\textsuperscript{29}

Ectopic pregnancy is defined as a conceptus implanting outside the uterine endometrium and remains the leading cause of death in the first trimester of pregnancy. The most common implantation site is within the fallopian tube (95.5%), followed by ovarian (3.2%) and abdominal (1.3%) sites.\textsuperscript{30} Two hundred years ago, the mortality rate of ectopic pregnancies was greater than 60%. Today, it has decreased to 9% of pregnancy-related mortality and less than 1% of overall mortality in women. Despite a 5-fold increase in the incidence of ectopic pregnancy from 1970 to 1992, the mortality has been reduced by more than 90%. Until 1970, greater than 80% of ectopic pregnancies were not diagnosed before rupture, leading to a high rate of morbidity and
mortality.\textsuperscript{31} Owing to the advances made in transvaginal ultrasound and an increased vigilance by clinicians with more experience of diagnostic laparoscopy, more than 80% of ectopic pregnancies are now diagnosed intact. This allows a more conservative management and is responsible for the decline from 35.5 deaths to 3.8 per 1000 ectopic pregnancies. The decrease in mortality is due to early diagnosis and treatment.\textsuperscript{32} The costs of treating ectopic pregnancy are considerable, with direct costs estimated at $1 billion in the U.S. alone. There are also intangible costs, such as ongoing infertility, to consider.\textsuperscript{33}

In the etymology of pregnancy, usually the oocyte and the sperm meet in the ampullary of the fallopian tube where impregnation takes place. The growing morula moves slowly towards the uterus cavity while differentiating into the embryoblast and trophoblast. Normally, implantation in the uterine cavity usually takes place after 6 or 7 days. However in about 2% of all cases the zygote implants outside the uterine cavity.\textsuperscript{34} The word ectopic literally means “out of place” from the Greek ek (out of) and topos (“place”). As these pregnancies advance, the tubal pregnancy may either diminish in size and spontaneously resolve, or increase in size and eventually lead to tubal rupture, with consequent maternal morbidity and mortality.\textsuperscript{35}

There are no reliable clinical, sonographic, or biological indicators that can predict rupture of tubal ectopic pregnancy. Thus treatment options for tubal ectopic pregnancy are: (1) surgery, e.g. salpingectomy or salpingostomy, performed either laparoscopically or by open surgery; (2) medical management, with a variety of drugs, most commonly with methotrexate, that can be administered systemically and/or locally by various routes; (3) expectant management.\textsuperscript{36} However, if a patient has signs and
symptoms of tubal rupture, surgery must be performed immediately. Two types of surgery are used to resolve the ectopic pregnancy. A conservative approach, Salpingostomy, preserves the tube but bears the risk of incomplete removal of the pregnancy tissue (persistent trophoblast), which then needs additional treatment and the patient runs the risk of a repeat ectopic pregnancy in the same tube in the future. Or a more radical approach, salpingectomy, which bears no risk of persistent trophoblast and limits the risk of a repeat tubal pregnancy, but leaves only one tube for reproductive capacity.

Salpingectomy is the surgical procedure to remove the fallopian tube. It involves either the total or partial removal of a fallopian tube with the embryo inside. This procedure is morally acceptable in Catholic teaching under the principle of double effect. The PDE can be applied in a similar fashion to that of the pregnant woman with a cancerous womb. The four categories of PDE must be met: the act itself cannot be morally wrong; the bad effect cannot cause the good effect; the agent must not intend the bad effect as an end to be sought; the bad effect must not outweigh the good effect. The USSCB’s Committee on Doctrine supports for the removal of a cancerous uterus during pregnancy can apply in a similar manner to ectopic pregnancy by using these categories of the PDE. With both ectopic pregnancy and the cancerous uterus there is an urgent need for a medical procedure which indirectly and unintentionally, although foreseeably, results in the death of an unborn child. The surgery in both cases directly addresses the life-threatening health problem of the woman, the cancerous uterus or ectopic pregnancy. The surgery does not directly target the unborn child. The child, in both cases, will not be
able to live long outside the mother’s body, but the death of the child is an unintended and unavoidable side effect and not the aim of the surgery.\textsuperscript{40}

Hence, managing an ectopic pregnancy by means of a total or partial salpingectomy is morally acceptable, by applying the principle of double effect. If an embryo continues to develop in the fallopian tube, rupture of the tube and possible death of the mother and child could occur. When the fallopian tube, or a portion of it, is removed, the death of the unborn child is an unintended secondary effect. However the removal of the tube containing the unborn child will end the mother’s fertility if the opposite tube is occluded or surgically absent.\textsuperscript{41} However, this risk of sterilization can be avoided by salpingostomy. Studies have shown that salpingectomy may result in lower fertility rates when compared to salpingostomy or methotrexate.\textsuperscript{42} However, Salpingostomy has elicited controversy from the Catholic perspective. In the analysis that follows, the argument is that there is no moral difference between salpingectomy and salpingostomy from the perspective of applying PDE.

The application of principle of double effect provides a mechanism that distinguishes between the direct and indirect features of the moral action. Each of the categories of the principle can be applied specifically, as follows. First, the act itself must not be morally wrong. With ectopic pregnancies, implantation of the embryo in the uterus has not occurred and the tubal implantation is life-threatening, not only for the child but also for the mother. The moral action is the removal of the damaged tissue and the stopping of the enzymatic activity of the trophoblast. That enzymatic action would be normal and proper in the uterus, but in this case it causes severe damage in an abnormal
site, that is in the tubal lining. As a result, the loss of the embryo is foreseen but unintended.

Second, the bad effect must not cause the good effect. In the intervention, whether surgical or chemical, there is equal casual immediacy regarding the good effect (removal of the pathology) and the bad effect (death of the fetus) which is foreseen but unintended. Here the unborn child is tragically implanted in the fallopian tube, a medical condition that is life-threatening for the mother. It is morally licit to take effective measures to end this life-threatening medical condition even though the unborn child will die. Third, the agent must not intend the bad effect as an end to be sought. In ectopic pregnancy in the attempt to save the only life that can be saved, that of the mother, the intent is good. The fourth condition is that the bad effect must not outweigh good effect. The medical intervention does not target the life of the unborn child. In such situations the medical intervention is the minimum need to save the mother's life. The condition of a proportionality is fulfilled.

Salpingostomy is a therapeutic intervention for healing exactly the same pathology as Salpingectomy. The only difference is that Salpingostomy prevents secondary disease of the fallopian tube. It is performed so that the fallopian tube and the woman's ability to bear children can be preserved. The tubal pregnancy itself is the actual pathology. In both procedures the embryo is transferred from a place where it cannot survive, to another place, outside the tube, where it cannot survive either. It's dying, however, is not the result of human action but of a pathological situation. The medical intervention is therefore not responsible for the death of the embryo that occurs as a result
of the procedures. In other words, there is no morally relative distinction between Salpingostomy and Salpingectomy.\textsuperscript{48}

To understand how the principle of double effect can be applied to justify salpingostomy it is helpful to recall the process in the early development of the embryo. The outcome of fertilization is the division of the fertilized egg into cells accompanied by duplication of the nucleus. At about four days after fertilization, this development enters the blastocyst stage. This stage is unique since it develops the trophoblast and the cytoblast. The trophoblast is an outer extraembryonic layer that later becomes membranes surrounding the embryo, later developing to form a part of the placenta. The cytoblast is a group of formative cells called the inner cell mass (ICM) that develops into the embryo.\textsuperscript{49}

Salpingostomy involves detaching the trophoblast from the fallopian tube. However, the trophoblast should not be considered an organ of the embryo for several reasons. First, there is the trophoblast’s unique ability to continue to survive following the death of an embryo. In contrast to other organs of the body a trophoblast often continues its natural growth hours, days, and even weeks after the death of an embryo. Second, organs of the human body (heart, lungs etc.) have a mutually beneficial action for the good of the body and each other. By contrast the trophoblast, and later the placenta, simply benefits the embryo: there is no mutual benefit as is typical with other organs. This indicates that the trophoblast is not a part of the embryo. Finally the fact that the embryo needs the trophoblast to survive does not necessarily indicate that it is a vital organ of the embryo. The embryo also needs the mother to survive, but she is not a vital organ of the embryo.\textsuperscript{50} The fact the embryo and the trophoblast share DNA also does not
indicate that the trophoblast is a vital organ, for many other parts of an organism, such as hair, share DNA but are not vital organs.\footnote{This distinction is important for the justification of salpingostomy. It is the trophoblast that burrows into the wall of the fallopian tube. Because this occurs in a location contra to normal human development, it is the trophoblast that is the cause of the life-threatening pathology, not the cytoblast that develops within the trophoblast. It is the trophoblast that causes the damage that eventually leads to severe hemorrhaging and life-threatening condition of the mother. In salpingostomy the trophoblast is separated from the tube lining leaving the tube intact. The loss of the fetus due to the loss of the cytoblast meets the conditions of the PDE. The trophoblast, which is causing the hemorrhage, is medically addressed. The object of the procedure is detaching the trophoblast from its incorrect and life-threatening location in the fallopian tube and not the removal of the fetus. Therefore, the first condition of the PDE is met. Insofar as the good and the bad effect occur simultaneously, and the intent is to save life that would otherwise lead to death, the second and third conditions are met. And the fourth condition is met insofar as resolving the ectopic pregnancy is a necessary intervention to save the mother’s life.\footnote{In addition to salpingectomy and salpingostomy, there is another treatment for ectopic pregnancy. Instead of these surgical procedures, there is a chemical intervention that can be effective, the use of methotrexate (MTX). Since the 1980’s, methotrexate (MTX) has been used in the medical treatment of ectopic pregnancies. It is administered systemically by intramuscular (IM) injection, locally via laparoscope, or under ultrasound guidance. This chemotherapeutic agent arrests the growth of the trophoblast by inhibiting DNA synthesis.} Methotrexate acts to inhibit the trophoblastic cells to synthesize DNA}
as required, producing proteins digesting enzymes necessary for the implantation of the embryo into the tubal tissue.\textsuperscript{55}

Methotrexate is the predominant drug used in ectopic pregnancy for patients with high operative risk, patients who have contraindications to anesthesia or who are poor surgical candidates.\textsuperscript{56} It works by inhibiting the growth of the trophoblast, the forerunner to the placenta, and has an 82\% to 95\% rate of success from a single dose. It also has the medical advantage of preserving the tube, thereby improving further fertility.\textsuperscript{57} In other words, Methotrexate disrupts the rapidly dividing trophoblastic cells to detach it from the fallopian tube. It is the trophoblast that causes the life-threatening hemorrhage. Methotrexate achieves its effect by impacting the trophoblast, not the cytoblast. Hence, the loss of the cytoblast, which is eventually absorbed by the body, is a foreseen but unintended consequence of a procedure upon the trophoblast.\textsuperscript{58}

The principle of double effect can be applied to Methotrexate, just as occurs with the surgical interventions of salpingectomy and salpingostomy. The first category of PDE is that the action must not be wrong. The use of MTX constitutes a healing act to prevent further damage to the fallopian tube, and as such is a good intervention. That is, the moral object is good insofar as MTX is used as to stop the destructive enzymatic activity of the trophoblast. The second category is that the good and bad effects must be at least simultaneous in the sense that the bad effect may not be permitted to cause the good effect. In the use of Methotrexate, the good and bad effect occur simultaneously, and hence this condition of PDE is met. The third category is that the bad effect must not be intended. In using Methotrexate, the unavoidable death of the embryo is a foreseen but unintended outcome. The death of the embryo while foreseen and tragic is not the reason
for ending the life-threatening activity of the trophoblast. Similar to the removal of a pregnant cancerous uterus, the use of MTX prevents the death of the mother while the death of the child is a foreseen but unintended side effect. The fourth category of the PDE requires a proportionality between the intended good effect and the permitted but unintended evil effect. In an ectopic pregnancy Methotrexate is a minimally invasive intervention to save the life of the mother, thereby meeting the condition of proportionality. Not surprisingly, there is continued debate about the ethical legitimacy of Methotrexate. Some traditional Catholic ethicists consider the use of methotrexate as impermissible (for example Charles E. Cavagnaro, Thomas W. Hilgers, and Bernard Nathanson), whereas other conservative Catholic ethicists consider methotrexate to be permissible (such as Albert Morzaczewski O.P., Benedict Ashley, O.P., Patrick Norris, O.P., and Peter Clark, S.J.). At this point in time official Catholic teaching has not forbidden the use of Methotrexate.

This explanation of the PDE highlights that there is one agent with two effects (a good and a bad effect). However, this principle sets the stage to understand the principle of cooperation that involves two agents each engaging a distinct and separate action. The principle of cooperation explains how the cooperator’s action can be justified when it intersects with the wrongdoing of another agent. The principle of cooperation is similar to the principle of double effect in this sense: both principles discuss the problem when good and evil intersect in moral action to differentiate between what is permissible and what is impermissible.

It is claimed that there is no more difficult question in Catholic moral theology than that of cooperation with wrongdoing. In the 18th century, St Alphonsus Liguori introduced the principle of cooperation. Principles in moral theology are understood, to be general norms that when applied to a particular event or activity, offer a plan of behavior that seeks to avoid sin and fosters virtue. Hence, the principle of cooperation seeks to differentiate the action of a wrongdoer from the action of a cooperator when their actions combine. The theory developed to help individuals determine to what extent they could legitimately perform their own good actions when they intersected with others who were acting wrongly.

Akin to the principle of double effect that deals with the moral agency of one individual whose action has two effects, the principle of cooperation deals with two moral agents with good and bad actions that intersect. The Catholic moral tradition developed a moral compass to guide when the actions of two agents intersect, one action being morally good and the other being morally wrong. That compass is the moral principle of cooperation. However, the principle can be difficult to apply. The basic premise is that if an individual intends to cooperate in the wrong action of another the individual is morally culpable. But if an individual is unavoidably connected with the wrong action of another without intending that wrongdoing, the individual may not be morally culpable.

It can help to provide an illustration to clarify the main distinctions that follow. In a bank robbery, the primary agent who robs the bank intends wrongdoing and enacts a morally wrong action of robbery. Similarly, the getaway driver may not have technically been in the bank for the robbery, but is nonetheless morally culpable: the getaway driver
intends the wrongdoing and participates in the moral action of robbery – this is formal cooperation. However, if the bank robber when escaping hijacks an innocent passerby in a car and threatens to shoot if not driven away, the passerby does not intend the wrongdoing, does not participate in the moral object of robbery, but nonetheless is materially involved in the escape. This constitutes material cooperation.\textsuperscript{69}

The principle of cooperation differentiates the action of the wrongdoer from the action of the cooperator through two major distinctions. The first is between formal and material cooperation, focusing on the intention of the agents. The second distinction deals with the object of the action and is expressed by the immediate and mediate material cooperation.\textsuperscript{70} These crucial distinctions are discussed in the following sections.

7.b.(i) Formal Cooperation.

The first distinction in the principle of cooperation is whether the cooperation is formal or material. To intend the wrongdoing of others occurs when individuals freely and directly participate in the objectionable acts of others. They must intend the wrongdoing, sharing in the moral object of that intent.\textsuperscript{71} One is guilty of formal cooperation when one shares the intention of the individual who is doing wrong. The critical factor here is intention or voluntariness. An example is when a husband approves and pays for his wife’s abortion, (like the getaway driver who intentionally participates in the crime).\textsuperscript{72} However, the intentionality that is associated with formal cooperation can be subtle, such as occurs in the category of implicit formal cooperation. That is, since intention is not simply an explicit act of the will, formal cooperation can also be implicit.
Implicit formal cooperation occurs when the cooperator denies intending the principal agent’s wrongdoing, yet no other explanation can distinguish the cooperator’s action from the principal’s wrongdoing. That is, the cooperator’s action in the concrete situation can have no other meaning than intending the wrongdoing of the principal agent. An example would be if a Catholic hospital merged with a secular hospital simply to provide access to direct sterilizations that are impermissible in a Catholic hospital. In this case, the merger of the Catholic hospital could not be separated from intending the wrongdoing of direct sterilizations in the secular hospital with which it merged. The U.S. bishops explained that closeness with wrongdoing in this way; "Implicit formal cooperation is attributed, when, even though the cooperator denies intending the wrong doer's object, no other explanation can distinguish the cooperator's object from the wrong doer's object." However, if the cooperator does not intend the object of the wrongdoer’s activity, the cooperation is material and can be morally licit.


Formal cooperation is distinguished from material cooperation principally in the matter of intention. Material cooperation occurs when the cooperator clearly does not intend the immoral object that another agent undertakes, yet is involved in circumstances that materially intersect with that wrong action. Whether material cooperation would be permissible depends on further distinctions as discussed below.

One type of material cooperation is what is referred to as immediate material cooperation. Insofar as immediate material cooperation refers to an action of a cooperator without which the wrongdoing of the other agent could occur, it constitutes a type of
implicit formal cooperation. Hence, immediate material cooperation is morally illicit. However, a subtle distinction can be drawn between immediate material cooperation and implicit formal cooperation. Implicit formal cooperation deals with the intention of the cooperating agent, as explained previously. However, immediate material cooperation deals with the action (moral object) undertaken by the cooperating agent. In other words, a cooperating agent may be involved in a situation where the cooperation involves an implicit intent to undertake the wrongdoing in addition to performing an action (moral object) without which the wrongdoing could not occur. Because of the close affiliation between these concepts of intention (implicit formal) and the moral object (immediate material), they are typically aligned with each other. For example, if a Catholic hospital undertakes the action (moral object) of providing a surgery suite for direct sterilizations (forbidden by Catholic teaching), there is an accompanying desire (intention) to perform the direct sterilizations. The moral object refers to immediate material cooperation; the intention refers to implicit formal cooperation. Typically, they are aligned together.

However, there is a substantive difference between immediate cooperation and material cooperation. Immediate material cooperation contributes to the essential circumstances of the wrongdoing. In contrast, mediate material cooperation is cooperation with an evil act that does not share the intention of the agent (i.e., is not formal) and which is not essential to the execution of the act (i.e., is not immediate). Mediate material cooperation can be morally tolerated if there is a great good to be preserved or a grave evil to be avoided. Mediate cooperation is morally licit under three key conditions, all of which must be met in order to proceed in good conscience: duress, proportionality and avoiding scandal.
First, there must be external duress. There must be duress to force the cooperator to undertake an action that intersects with the wrongdoing of another. For example, for a Catholic hospital to survive it needs to merge with a secular hospital that provides direct sterilizations – but the catholic hospital genuinely does not want to provide sterilizations. Second, there must be proportionality. There must be a proportionate good to be attained that cannot be attained in any other way than through cooperation. An example would be maintaining Catholic healthcare services for poor populations. Third, scandal must be avoided. Scandal can be defined as leading others into evil, error, or confusion. In the U.S. Bishops’ Ethical and Religious Directives, number 71 explains the following: “The possibility of scandal must be considered when applying the principles governing cooperation. Cooperation, which in all other respects is morally licit, may need to be refused because of the scandal that might be caused. Scandal can sometimes be avoided by an appropriate explanation of what is in fact being done at the health care facility under Catholic auspices. The diocesan bishop has final responsibility for assessing and addressing issues of scandal, considering not only the circumstances in his local diocese but also the regional and national implications of his decision.”

The illustration of a bank robber might clarify these concepts. The getaway driver does not rob the bank but formally cooperates with the bank robber and intends the wrongdoing: this is formal cooperation. In contrast, if the bank robber hijacks an innocent passerby to drive the getaway car, the passenger materially cooperates with the robber but is not morally complicit. This is a material cooperation as the passerby does not intend the wrongdoing. Still, if the father of the bank robber coincidently passes by and sees his son fall while running and stops to drive his child to the hospital there is no cooperation,
just paternal assistance. However, after discovering a robbery has occurred, and the father
does not report his child to the authorities, the father is now so immediately involved with
the wrongdoing as to be morally complicit. This would be immediate material
cooperation, which is implicitly equivalent to formal cooperation and therefore wrong. 85

In addition to the crucial distinction between immediate and mediate material
cooperation, there are further conditions about mediate material cooperation that need to
be addressed for the principle to be applied properly – the distinction between proximate
and remote cooperation.

The distinction between proximate and remote action is important to understand
how the principle of mediate material cooperation should be applied. If the cooperator’s
involvement is remote, a lesser reason is required to justify the cooperator’s involvement.
But if the involvement is closer or proximate a stronger reason is necessary. 86 Mediate
material cooperation is proximate if the cooperator’s act is close to the wrongdoing of the
principal agent, and remote if more distant from the wrongdoing of principal agent. 87 An
example of proximate mediate material cooperation could be the recovery room nurse
who cares for all postsurgical patients, including those who may have undergone morally
illicit procedures. An example of remote mediate material cooperation would be the clerk
who processes the scheduling details at a distant site for patients, including those
undertaking illicit procedures. 88 Other distinctions also can be applied to the principle of
mediate material cooperation, but the above ones are the pivotal distinctions that must be
implemented.

In sum, the principle of double effect helps to enlighten the principle of
cooperation in the Catholic tradition. Both deal with the intersection between good and
evil action. Furthermore, the specific distinctions within the principle of cooperation are used to clarify what is permissible and what is impermissible. These distinctions help to enlighten the following cases of conflicted organizational partnerships. Although these cases have now been resolved, they illustrate the need for intensive Sponsorship and Governance oversight of emerging dilemmas that cause Catholic organizations to become entangled with the wrongdoing of others.

7.c. Organizational Partnerships: Conflicted Cases.

In today's competitive market, many Catholic hospitals find that mergers and joint ventures allow them to become more efficient using shared resources that provide a great advantage for struggling institutions. Such affiliations often cause conflicted organizational partnerships. For instance, a hospital’s Catholic identity might be questioned if the hospital entered into a merger or joint venture with a non-Catholic provider that engaged in activities judged to be morally wrong by the church. The Directive 69 in the ERDs governing cooperation between Catholic and non-Catholic partners states: "If a Catholic health care institution is considering entering into an arrangement with another organization that may be involved in activities judged morally wrong by the church, participation in such activities must be limited to what is in accord with the moral principles governing cooperation." The ERDs employ the principle of cooperation to evaluate and guide institutional relationships. The Congregation for the Doctrine of the Faith has specifically allowed the use of this principle for healthcare institutions; and the principle has been applied to guide conflicted organizational partnerships as discussed below. The reason why the
principle of cooperation is relevant for organizations is because what pertains to individuals (for whom the principle of cooperation was originally designed) also applies analogously to institutions. The next section discusses how the principle of cooperation justifies the intersection of actions between Catholic and other-than-Catholic organizations in situations that create conflicted organizational partnerships.

7.b.(i). Seton Medical Center, Austin, Texas.

Since 1884, the city of Austin has had a public hospital, Brackenridge Hospital that treated patients regardless of their ability to pay. In a state where one in five people had no health coverage, leaving public and charity hospitals to assume most of the resulting cost, the burden of a crushing $38 million debt became too great for Brackenridge Hospital. The solution in 1995 was to lease Brackenridge Hospital to Seton Hospital which was a Catholic facility owned and operated by the Daughters of Charity of St. Vincent De-Paul, a Catholic health system.

The stated purpose of the transaction was to “ensure the continuation of essential health care services, including trauma, women's and reproductive services, and children services, for all citizens of Austin and Travis County, regardless of their financial means.” The partnership arrangement became conflicted because Austin city insisted that Brackenridge Hospital would retain its reproductive services (except for abortions which had never been performed there).

The lease stipulated that Brackenridge Hospital would retain ownership of its facility and that Seton Hospital would not identify Brackenridge as a Catholic institution. For the sake of the contract allowing it to serve the poor and for the sake of
continuing to prevent abortions at Brackenridge, Seton Hospital agreed to permit surgical sterilizations to continue at Brackenridge. To do so Seton Hospital designed a plan to ensure that Seton personnel would be removed from any type of culpable cooperation.

However, a crucial problem emerged. The Vatican found the details of the arrangement to be objectionable. While Seton Hospital isolated its personnel and funding stream from cooperation, it had not sufficiently isolated its hospital management from what was construed to be formal cooperation. Insofar as the management arrangements established by the agreement ensured that the direct sterilizations would continue to take place at a different campus from Seton Hospital, Church authorities construed that Seton Hospital’s management intended the wrongdoing of sterilizations by virtue of orchestrating the off-campus arrangements. Hence, the conflicted organizational partnership was deemed to constitute formal and hence illicit cooperation. The Vatican found this arrangement objectionable.

Contracted ethicists prepared a position paper analyzing the partnership from the perspective of church teachings and ethical principles. Their argument built upon the Catholic tradition of social justice and the 1994 Ethical and Religious Directives, specifically, Directive 69, which stated that Catholic institutions could participate in networking arrangements that included cooperating, in a limited way, with the provision of services such as sterilization that Catholic teaching prohibited. This did not include abortions. They circulated the paper among clergy to help prevent the possibility of scandal. It built on the Catholic tradition of social justice and the ERDs. In the fiscal year ending June 30, 1998, Seton had delivered $17 million in charity healthcare. The projection for the fiscal year 1999 was $50 million.
The principle of material cooperation was used to develop a new arrangement to ensure that the management of Seton Hospital would not be complicit in arranging off-campus sterilizations. The arrangement was simply to accede to the reality that Brackenridge Hospital would continue to use a floor in its hospital for sterilizations – this was arranged by the city of Austin, not by Seton Hospital. Hence Seton Hospital was involved only with material and not formal cooperation.

An analysis of the conflicted organizational partnership sheds light on how the principle of cooperation functions. If Seton Hospital had supported sterilization services as morally acceptable, then it would have been guilty of formal cooperation. Seton did not approve of the illicit procedures or intend them to occur. Therefore, there was no formal cooperation by Seton. However, Seton Hospital was obligated by the contract with Breckenridge Hospital to let sterilizations continue on one of the floors of the Breckenridge Hospital. It is important to note that because the city reserved powers over Brackenridge Hospital, the facility was clearly not Catholic. The lease agreement did not give the facility a Catholic identity. Furthermore, those performing the services considered illicit would not be Seton Hospital personnel.99

The Vatican accepted the revised partnership, satisfied that the requirements of the principle of cooperation were honored.100 In 1998, the arrangement included the important point that the city of Austin would directly pay the healthcare workers at Brackenridge Hospital who providing reproductive healthcare, thus creating a fiscal “wall of separation” between them and Catholic management.101 In 2001 the city agreed to construct a separately licensed and managed women’s hospital on the top floor of Brackenridge Hospital that could be reached only by a separate elevator built up the side
of the hospital. The operating agreement between Seton Hospital and the city allowed for the continued provision of sterilization at Brackenridge Hospital as a matter of mediate material cooperation. The so-called carve-outs were designed to guarantee that the sterilization would be the responsibility of the city alone. Without this arrangement, Seton could have been seen as providing sterilizations in the merger and therefore be guilty of illicit formal cooperation.

Conceptually, the revision of the Seton/Brackenridge Hospital lease agreement was not complicated. The city of Austin agreed to assume management of the portion of the Brackenridge Hospital that provided the sterilizations, as a hospital within a hospital. Texas law allows a “hospital within a hospital” arrangement to which licensure is granted to separate but unrelated corporate identities which operate in the same building. The city holds the license for its hospital that has its own separate managers and governing body. The separate floor at Brackenridge Hospital handles all sterilizations and contraceptive services. It also houses the labor and delivery area for low-income women who want to deliver and have access to sterilization.

As a result of this arrangement using the principle of cooperation, some aspects can be identified as being potentially formal cooperation and other aspects can be identified as being legitimate material cooperation. If Breckenridge Hospital had not acceded to the arrangement of a hospital within a hospital that the city managed for sterilizations, Seton Hospital could have been guilty of formal cooperation by being seen to plan or coordinate the sterilization services. In contrast, other aspects of the merger were legitimate forms of material cooperation. For example, Seton’s provision of electricity and water would not contribute anything essential to Brackenridge Hospital’s
surgical sterilizations. However, the provision of sterilized surgical kits would have contributed something essential, as would the provision of pharmacy or laboratory services. Hence, Seton excluded those functions from the Ancillary Services Agreement, as well as anything else that might be seen as contributing essentially to inappropriate cooperation in the isolated floor at Brackenridge Hospital.  

7.b.(ii). St. Vincent’s Hospital, Denver, Colorado.

Another conflicted organizational partnership can illustrate the need for and application of the principle of licit material cooperation. In February of 1998, St. Vincent’s Hospital in Denver, sponsored by Catholic Health Initiatives, entered into an organizational partnership with the Arkansas Women’s Health Center, a non-religious institution located nearby. Prior to the purchase, physicians at the Health Center had performed abortions and tubal ligations. After the acquisition of the Health Center, St. Vincent Hospital ordered a halt to abortion services but allowed direct sterilizations to continue in a room across the hall from the obstetrics ward. This room at the new St. Vincent Doctors Hospital was leased by Arkansas Women’s Health Center, which paid rent to St. Vincent’s Hospital along with a set fee for each sterilization to compensate the hospital for supplies used.  

At the time, the sterilization unit was seen as a way of remaining competitive in a marketplace increasingly controlled by managed care companies pressuring hospitals to provide such services. This agreement was based on an argument that tried to apply the principle of cooperation in the following manner. The argument was made that the principle of cooperation permitted participation in an act of wrongdoing (sterilizations) in
times of duress if that participation is for the greater good. The source of duress was the pressures of managed care; the greater good was the hospital’s financial health to keep its doors open.\textsuperscript{108} This decision was based on the 1995 appendix of the ERD’s on duress. The articulation of the principle of cooperation in the 1995 ERDs was in line with the then U.S. bishops’ Commentary on the Congregation for the Defense of the Faith’s statement on sterilization, Quaecumque Sterilizatio.\textsuperscript{109} However, the Congregation for the Doctrine of the Faith eventually ruled against using the argument of duress.\textsuperscript{110}

These 1975 norms from the Holy See appeared to use the principle of material cooperation to permit direct sterilizations in Catholic hospitals in some circumstances. These norms recognized the fact that hospitals could be corporations under civil law and hence under civil pressure. It included a paragraph which stated: “The traditional doctrine regarding material cooperation, with the proper distinctions between necessary and free, proximate and remote, remains valid, to be applied with the utmost prudence, if the case warrants.”\textsuperscript{111} This clause specifically understood that duress meant the threat of closing a Catholic facility: that threat could justify sterilizations within the Catholic facility using the principle of proximate material cooperation.

At that time, the meaning of duress was understood to include personal or societal pressure including physical, economic, or psychological stress. An example of the sort of analysis that supported this stance is as follows: in material cooperation, the will of the cooperator does not move toward the evil action for its own sake, but on account of something else, that is, in order to avoid an evil which is feared; if the person cooperating with the evildoer assents neither to the objective evil being performed nor to the evil
intention of the person performing it, the cooperation is not formal but material. In other words, the cooperator contributes to the evil action under duress.\textsuperscript{112}

In the Vatican norms, duress threatening the closure of a Catholic facility was listed as an example of justifying sterilizations within a Catholic facility. The rationale was that such participation would preclude greater harms from occurring, for example, the closing of a Catholic hospital. It was understood that with serious duress and irreparable harm that could result from not cooperating, there were sufficient reason to justify mediate material cooperation with the provision of direct sterilizations.\textsuperscript{113}

However, a revised version of the ERDs trumped the Vatican norms and took a very different stance. The Vatican norms were superseded by Directive 70, as follows: “Catholic health care organizations are not permitted to engage in immediate material cooperation in actions that are intrinsically immoral, such as abortion, euthanasia, assisted suicide, and direct sterilization.”\textsuperscript{114} In other words, the U.S. Bishops have developed their thought on how to apply the principle of cooperation to conflicted organizational partnerships in healthcare. In the 1995 edition of the ERDs there was an appendix on cooperation that was subsequently removed in the 2001 and 2009 editions. The 1995 appendix permitted immediate material cooperation in some circumstances, whereas the 2001 and 2009 editions of the directives forbid immediate material cooperation with actions deemed to be intrinsically immoral.\textsuperscript{115} The 1995 appendix makes this statement: "Immediate material cooperation is wrong, except in some instances of duress. The matter of duress distinguishes immediate material cooperation from implicit formal cooperation."\textsuperscript{116}
To understand this development two directives are important in the 2001 and 2009 editions of the ERDs, chiefly directives number 69 and 70. First, immediate material cooperation is prohibited with regards to intrinsically evil actions: “Catholic health care organization are not permitted to engage in immediate material cooperation in actions that are intrinsically immoral such as abortions, euthanasia, assisted, and direct sterilization.”117 Second, mediate material cooperation may be permitted: “If a Catholic Health Care organization is considering entering into an arrangement with another organization that may be involved in activities judged morally wrong by the Church, participation in such activities must be limited to what is in accord with the moral principles governing cooperation.”118 It is clear that the 1995 appendix permitted immediate material cooperation in some circumstances, while the 2001 and 2009 editions of the ERDs forbid immediate material cooperation with actions deemed to be intrinsically immoral.

The 1997, the commentary of the US bishops on the Vatican norms about permitting sterilizations in Catholic facilities specifies the circumstance of threat of closure as justifying an application of mediate material cooperation to permit direct sterilizations in Catholic hospitals: "material cooperation will be justified only in situations where the hospital because of some kind of duress or pressure cannot reasonably exercise the autonomy it has (i.e., when it will do more harm than good).”119 In addressing duress the bishops explained in the 1997 commentary: "Direct sterilization is a grave evil. The allowance of material cooperation is extraordinary cases are built on the danger of even more serious evil, e.g., the closing of the hospital could be under circumstances a more serious evil.”120
In other words, the external duress of a Catholic hospital being threatened to close could be sufficient cause to justify direct sterilization in the Catholic facility using the principle of immediate material cooperation.\textsuperscript{121} To emphasize that cooperation in this situation is material and not formal, the bishops emphasized that the justification must be external to the reason for sterilization; "if the cooperation is to remain material, the reason for the cooperation must be something over and above the reason for the sterilization itself."\textsuperscript{122} This remark stands in stark contrast to the theoretical explanation of the principle of cooperation earlier in this chapter that presents immediate material cooperation as unacceptable. That theoretical explanation reflects the more recent stance of the U.S. Bishops whose thought has changed and become more cautious on the meaning and applicability of this controversial principle.

Nonetheless, there remains ambiguity on the meaning of duress. In 1995 the bishops were convinced that one form of duress, the threat of closing a Catholic hospital, as potentially justifying cooperation with direct sterilization. Why were the later editions of the ERDs changed so significantly (from permitting to forbidding this scenario) from the 1995 edition? The introduction to part six in the 2001 and 2009 edition of the directive provides a rationale: "The new edition of the ethical and religious directives omits the appendix concerning cooperation, which was contained in the 1995 edition. Experience has shown that the brief articulation of the principle of cooperation that was presented there did not sufficiently forestall certain possible misinterpretations and in practice gave rise to a problem in concrete application of the principles."\textsuperscript{123}

Such a change raises significant questions about ecclesial process and doctrinal truth, including the following: what was the historical precedent in the Catholic tradition
to justify defending immediate material cooperation with wrongdoing in some instances of duress; and in light of that historical tradition and official church teaching, what was the doctrinal rationale for the subsequent prohibition of immediate material cooperation by the US bishops; perhaps the doctrinal teaching in the 1995 appendix was subsequently seen to be erroneous, thereby requiring its removal; if erroneous, on what basis, using what criteria, and what implications result for understanding the authority of the official teaching of the bishops in the document such as the ERDs?  

Catholic moral theology is based on natural law and not merely on Episcopal and Vatican decree. It is unclear whether these changes in the ERDs are intended to represent changes in natural moral law, or in its interpretation, or simply to be new disciplinary rules. What is clear is that from such significant ambiguity Catholic healthcare institutions are in a quandary when it comes to making the difficult decisions about conflicted organizational partnerships.

In applying the principle of moral cooperation, the authorities determined that the Women’s Health Center in Denver would not have existed had St. Vincent’s Hospital not participated in its creation. It was established for the sole purpose of providing sterilizations within the hospital. St. Vincent’s Hospital leaders opposed the wrongdoing but justified their involvement as a condition of its conflicted organizational partnership.

There is now an understanding that immediate material cooperation cannot be justified for such conflicted organizational partnerships. There has been discussion among ethicists who claim it may be justified for individuals in situations of duress, such as when one’s life is at stake. However, the Congregation for the Doctrine of the Faith
clarified that individually experienced duress does not apply to institutions, explaining that nothing on the institutional level, not even financial ruin or failure, is analogous to the loss of one’s life. Institutional decisions become enshrined in contractual agreements that may have no definitive end in sight. This perpetuates a supposedly tolerated evil, making it part of daily operations in a long-term sense – unlike the temporary duress an individual may experience when life is threatened. Hence, from the Vatican’s current perspective, no prudential weighing of goods and evils can justify immediate material cooperation in conflicted organizational partnerships. The Denver case was concluded by St. Vincent’s Hospital complying with the Vatican’s ruling and closed its sterilization suite.

7.d. Conclusion.

This chapter has discussed the need for intensive Sponsorship and Governance oversight of conflicted organizational partnerships. The preceding chapters considered the need for such intensive oversight with regard to patient care (patient care quality and safety) and the public good (community benefit programs). This chapter has focused on another dilemma that deals with the public good to explore the significance of the principle of cooperation.

To understand how the principle of cooperation functions, the analysis considered another principle upon which it can be based the principle of double effect. That is, to understand the significance of the principle of cooperation for conflicted partnerships in Catholic healthcare, the principle of double effect has to be grasped. Double effect is used to distinguish between what one intends and what one foresees and accepts but does not
intend (as a side effect). This marks the difference between the permissible and the impermissible. The purpose of discussing the principle of double effect was to set the stage for understanding the principle of cooperation, each distinguishing between what is permissible and what is impermissible in related ways.

There is a need for intensive Sponsorship and Governance oversight of how Catholic healthcare applies the principle of double effect insofar as the principle engages complex dilemmas, especially those that deal with the Church’s prohibition of abortion. And that need for intensive Sponsorship and Governance oversight extends to the application of the principle of legitimate material cooperation in dilemma situations involving conflicted organizational partnerships, especially those that deal with direct sterilizations.
Notes


76 Kevin O’ Rourke, Philip Boyle, Medical Ethics: Sources of Catholic Teachings (Washington DC: Georgetown University Press, 1999), 146.


79 Peter Cataldo, "Compliance with Contraceptive Insurance Mandates: Licit or Illicit Cooperation in Evil?," National Catholic Bioethics Quarterly 1 (Spring 2004): 106.


81 Peter Cataldo, "Compliance with Contraceptive Insurance Mandates: Licit or Illicit Cooperation in Evil?," National Catholic Bioethics Quarterly 1 (Spring 2004): 106.


Chapter 8. Conclusion: Implications of Governance and Sponsorship Oversight.

This concluding chapter considers implications that Sponsorship and Governance oversight in Catholic healthcare can have for secular healthcare in the U.S. The meaning of Sponsorship and Governance oversight is explained within the broader context of the Catholic social tradition and organizational ethics. That explanation has relevance for secular healthcare insofar as the underlying concepts are amenable to secular reasoning.

The Catholic social tradition upholds the dignity and sanctity of the human being in relationship with the community and emphasizes the public good. Sponsorship and Governance oversight in Catholic healthcare must address both patient care and the public good. The approach to organizational ethics that is adopted combines patient care and the public good, reflecting the Catholic social tradition’s emphasis of these crucial components. This connection between social justice and organizational ethics is relevant for secular healthcare.

A distinction was drawn between enhanced and intensive oversight to explain the following. Enhanced oversight requires more attention to current issues that Catholic healthcare typically engages insofar as those issues have changed slightly reflecting revised Church teaching or changing science or secular awareness. Intensive oversight requires much more vigorous attention to deal with emerging trends that are pivotal for Catholic healthcare in the sense of potentially threatening its continued existence, such as can arise by the changing landscape of healthcare itself. Those basic concepts also pertain to secular discourse insofar as governance in secular healthcare needs to be attentive to
trends that arise from changing science or civic awareness (such as the shift in models of autonomy and informed consent in the genomics environment where communities may be affected by patient diagnoses) or indeed trends that can threaten their survival (patient safety and community benefit are shared topics in this regard).

The analysis explained the need for enhanced Sponsorship and Governance oversight of current issues related to patient care (such as end of life care) and current issues related to the public good (such as rationing in healthcare). Furthermore, the analysis highlights the need for intensive Sponsorship and Governance oversight of emerging trends related to patient care and to the public good (focusing upon patient care quality and safety, community benefit programs, and conflicted organizational partnerships). These issues are relevant for oversight in secular healthcare insofar as they can bring pressure upon or threatens the survival of healthcare organizations across the nation. Broadly, then, the argument about oversight in Catholic healthcare has implications for secular healthcare by addressing the combination of patient care and the public good as defining a role for organizational ethics for healthcare generally.

8.a. Organizational Ethics for Sponsorship and Governance Oversight.

The dissertation explored the meaning of sponsorship and governance oversight within the context of the Catholic social tradition in a manner that adopts the lens of organizational ethics to integrate patient care and the public good. A relational concept of inherent human dignity conveys the point that dignity is best understood and respected in interdependent relationship. This stance, reflecting the nature and dignity of human persons and their authentic human development as individuals and as community
together, is as relevant for secular healthcare as for Catholic healthcare. An obvious example is how this approach can be used to justify the basic right to healthcare that is so prominent in the Affordable Care Act’s efforts to extend access to all.

Organizational ethics has traditionally combined the ethical principles of solidarity and subsidiarity that characterize the Catholic social tradition. These are integral components of the principle of organizational integrity. This integration of solidarity and subsidiarity provides a moral compass that reflects the mission and values of organizations across healthcare, whether Catholic or secular. Adopting this moral compass is crucial for organizational leaders in all of healthcare to address the ethical challenges in healthcare.

The integration of the Catholic social tradition with organizational ethics inspires the integration of Sponsorship oversight (that deals with the Catholic social tradition) and Governance oversight (that deals with organizational ethics). Sponsorship has been explained as being responsive to the Catholic social tradition that combines the need for patient care and the public good in healthcare. In the past, the concepts of sponsorship and ownership were intertwined. Catholic religious congregations, for example, were understood to own the healthcare institutions they sponsored. Today, however, many congregations sponsor institutions without having any direct ownership rights over them. On the topic of Sponsorship, Catholic healthcare is distinctive: this form of organizational oversight does not exist in secular healthcare.

In contrast to sponsorship oversight that deals with an organization’s mission and identity reflecting the Catholic social tradition, Governance oversight deals with organizational ethics, integrating the focus on patient care and the public good that also
characterizes that tradition. Governance oversight should be responsive to the Catholic social tradition that integrates these crucial components of healthcare. Together, Sponsorship and Governance oversight functions in an integrative manner in Catholic healthcare organizations.

In secular healthcare the focus upon governance oversight alone can reach similar conclusions. Hospitals deal with fundamental matters of human wellbeing; their services are not just a commodity in the marketplace. Historically, management of hospitals is the responsibility of a team of healthcare professionals, and governance is the responsibility of a volunteer board of community members. Traditionally these board members were called Trustees. Trustees were entrusted with oversight responsibility to ensure that hospitals stayed true to their purpose as a community resource, holding goods and services of the hospital in trust for the community. Today, board members are responsible not only for thinking about the quality of care and community engagement, but also about strategic alignment to deal with local and regional competition.

Sponsorship and Governance oversight functions in an integrative manner in Catholic healthcare organizations to combine patient care and the public good in healthcare. That combination also pertains to secular healthcare as explained above. The different chapters have explored this integrative responsibility by discussing both current issues and emerging trends that require Sponsorship and Governance oversight of patient care and the public good. Chapter 3 and 4 address current issues that need enhanced oversight, chapter 3 dealing with issues related to patient care and chapter 4 focusing on issues related to the public good. Chapter 5, 6, and 7 discuss emerging trends that require intensive Sponsorship and Governance oversight, chapter 5 dealing with issues related to
patient care (quality and safety), chapters 6 and 7 focusing on issues related to the public good (community benefit programs and conflicted organizational partnerships).

The distinction between enhanced and intensive oversight can be explained in this way. Enhanced oversight requires more attention to current issues that healthcare (secular or Catholic) typically engages insofar as those issues have changed significantly reflecting changing science or secular awareness. In contrast, intensive oversight requires much more vigorous attention to deal with emerging issues and trends that are pivotal for healthcare (secular or Catholic) insofar as they can threaten the continuing viability of an organization, such as can arise by the changing landscape of healthcare itself.

8.b. **Enhanced Oversight of Patient Care and the Public Good.**

Two chapters were dedicated to the discussion of enhanced Sponsorship and Governance oversight of patient care and the public good. The discussion of patient care focused on patient autonomy in end of life care and the legitimacy of withdrawing futile treatment. Sponsorship and Governance oversight is needed to keep a fine balance between what the Catholic tradition permits and what is forbidden, reflecting changing Church teaching, such as on when artificial nutrition and hydration may be withdrawn. Patient autonomy is respected as a function of human dignity and sanctity, reflecting the Catholic social tradition.

There is consensus that not all life-prolonging measures are of benefit to the patient, hence not every medical treatment that prolongs life is morally required. The ethical distinction between mandatory and optional measures reflects the traditional distinction between ordinary and extraordinary means. Sponsorship and Board oversight
has to ensure that the decision about applying this distinction to treatment options focuses upon the patient and their proxy decision makers while also respecting the nuances and changes in Catholic teaching. Also, advanced directives are based on the principle of autonomy in that they allow our medical wishes to be known ahead of time, including the right to refuse medical care. Sponsorship and Governance oversight needs to be attentive to changes in advance care planning that can elicit some controversy within Catholic organizations. These ethical distinctions and observations are as pertinent for secular as for Catholic healthcare.

Respect for patient autonomy also justifies the withdrawal of futile treatments at the end of life while prohibiting assisted suicide and euthanasia. This topic relates the meaning of suffering with regard to circumstances in which withdrawing futile measures is justified to avoid the extremes of assisted suicide or euthanasia. Sponsorship and Governance oversight needs to be more attentive to recent nuanced changes in Church teaching about when life-sustaining measures become morally optional. The debate has been exacerbated with regard to patients in a persistent vegetative state (PVS), such as occurred in the case of Terri Schiavo in Florida. That case generated a revised version (the 5th edition) of the Ethical and Religious Directives for Catholic Health Care Services (ERD) in 2009, introducing a nuanced change in Catholic teaching about medically assisted nutrition and hydration, especially for PVS patients. The nuanced teaching clarified when futile measures including artificial feeding become morally optional, including for PVS patients. This debate is also relevant for secular healthcare, even though the specifics about nuances in Catholic teaching would not apply.
Assisted suicide and euthanasia constitute the intentional termination of the life of a person who requests the deed to be assisted or undertaken by someone else (typically a physician). There seems to be an increased trend in the US to permit assisted suicide and the trend in Europe also includes euthanasia. In the Catholic tradition, the decision to withdraw or withhold treatment is based on the principle of autonomy, reflecting not only the human dignity of the patient, but also reflecting the patient’s relationship with God. However, secular discourse that justifies these actions also makes an argument based upon respect for autonomy of the individual patient. But this argument needs to be substantively repudiated through Sponsorship and Governance oversight, not least because illness places the patient in a vulnerable relationship with the physician. Once again, the ethical issues in this discussion are relevant broadly for discourse in secular healthcare.

Briefly, there needs to be enhanced Sponsorship and Governance oversight of continuing developments around end of life care in Catholic healthcare. This enhanced oversight needs to be attentive to advances in science or health care as well as to nuanced changes in Church teaching about when life-sustaining measures may become morally optional while at the same time avoiding any confusion with the secular shift to permit assisted suicide or euthanasia. Furthermore, other areas in Catholic healthcare were discussed to illustrate the need for enhanced Sponsorship and Governance oversight in Catholic healthcare, especially from the perspective of influencing public policy. These topics included rationing in healthcare, minorities in research, mandatory vaccinations, and over-use of antibiotics. Each of these topics has relevance for discourses in both secular and Catholic healthcare.
Three chapters were dedicated to the discussion of intensive Sponsorship and Governance oversight of patient care and the public good. This discussion shifted from a patient care focus to addressing pivotal dilemmas in public health that also require enhanced Sponsorship and Governance oversight in Catholic healthcare. Each of these topics is relevant for secular healthcare. The topic of patient care quality and safety and the topic of community benefit responsibilities are self-evidently relevant for secular healthcare – the ethical analysis does not have a distinctively religious basis. The topic of conflicted organizational partnerships is relevant insofar as secular healthcare needs to be attentive to the ethical distinctions in order to facilitate successful partnerships with Catholic organizations when there is a conflict of organizational values at stake.

The first topic that was discussed was patient care quality and safety. The topic requires intensive oversight because of new Medicare penalties that can accrue to an organization that incurs serious issues regarding patient safety resulting from the Affordable Act. Healthcare must be of high quality and be safe for patients. The problem of medical error has been recognized as one of the top public health problems in the developed world. According to The Joint Commission, leadership failure in healthcare organizations is one of the most frequent causes of sentinel events, thereby requiring much more effective organizational oversight to protect and foster patient safety. In light of the widespread awareness of patient safety endeavors to prevent medical error as an emerging pivotal trend, there needs to be intensive Sponsorship and Governance oversight in healthcare to foster a culture of safety across the organization. Intensive
oversight is needed to engage the issue and to ensure that senior administrative leadership implements appropriate measures for evidence-based safety practices, including monitoring staff and caregivers.

There are two general approaches to addressing injuries that reflect different cultures and philosophies about mistakes. The professional sanctions model places practitioners in charge, being held personally responsible for patient injuries. This approach blames and punishes individuals but does little to improve the delivery system. In contrast, the patient safety model recognizes that individuals make mistakes, but they do so typically not because they are insufficiently trained or sanctioned but because systems work against them. The patient safety model addresses medical error by seeking changes in the systems and processes that lead to or cause individuals to make medical mistakes. There is a crucial shift from fixing blame upon individual professionals to fixing problems and implementing system-related change.

To foster patient care quality requires an organizational approach that seeks to avoid medical errors in healthcare by fostering a culture of patient safety. According to the Institute of Medicine, the biggest challenge to patient care quality and safety is changing the organizational culture from blaming individuals for medical errors to one in which medical errors are treated not as personal failures, but as opportunities to improve the system to prevent recurrence and future harm. Professional and organizational cultures in healthcare must undergo a transformation in the interests of promoting systems for safer patient care. Developing a culture of patient safety requires intensive Sponsorship and Governance oversight in healthcare, secular and Catholic.
Quality patient care is inextricably related with patient safety. This trend to enhance safety in patient care is pivotal for healthcare across the U.S. and requires intensive Sponsorship and Governance oversight in healthcare. Developing a culture of patient safety is very complex and requires astute and robust leadership. Catholic healthcare is especially well positioned to provide leadership nationally with regard to this trend insofar as the focus upon patient care quality and safety reflects the integration of organizational ethics with the Catholic social tradition. To ensure that this system-wide organizational change occurs, intensive Sponsorship and Governance oversight is needed for the foreseeable future.

The second topic that was discussed was community benefit programs. These require intensive oversight because of the new and stringent reporting requirements in the IRS 990 Form that can endanger the tax-exempt status of healthcare organizations. Nonprofit healthcare organizations need to be increasingly attentive to institutional integrity. The founders of mission-driven health care organizations were called by their values and civic duty to meet pressing health needs in their communities. Government recognized the benefits that these charitable organizations provided and granted them exemption from taxes so that those resources can be used to benefit the public. In return for this tax exemption, hospitals are expected to provide specific community benefits along with other legal requirements. Hence, community benefit programs can be seen as a litmus test of organizational integrity from the perspective of compliance with tax code for nonprofit status and from the perspective of an organization’s nonprofit mission.
The connection between board oversight and the mission of an organization allows boards to successfully respond to community benefit as an organizational ethical imperative. This responsibility fits well with the social tradition that requires Catholic healthcare institutions to have a prophetic role in service to the needy. Catholic healthcare emphasizes that within the marketplace where healthcare functions there are indispensable social responsibilities. Catholic healthcare commits itself to defend human dignity, care for poor and vulnerable people, promote the common good, provide sound management of resources, all being components of community benefit programs. This approach can be adopted easily in secular discourse using secular ethical terms.

Given the importance of this emerging trend that focuses on community benefit programs, and given its fit with the Catholic social tradition, there is an urgent need for intensive Sponsorship and Governance oversight in Catholic healthcare to provide leadership for community benefit programs – without which Catholic healthcare as nonprofit could be in jeopardy. This also pertains to secular healthcare. Developing plans and monitoring progress of community benefit programs represents a basic indicator of effective Sponsorship and Governance oversight. Catholic healthcare is especially well positioned to provide leadership nationally insofar as the focus upon community benefit programs reflects the integration of organizational ethics with the Catholic social tradition.

Briefly, given the importance of this trend that focuses on community benefit programs for nonprofit organizations in healthcare, and given its fit with Catholic mission and its social tradition, there is an urgent need for intensive Sponsorship and Governance oversight.
oversight in Catholic healthcare to provide leadership for community benefit programs – without which Catholic healthcare as nonprofit could be in jeopardy.

The third topic that was discussed was conflicted organizational partnerships between Catholic healthcare and other-than-Catholic institutions that involve practices forbidden by Catholic teaching. This clash of values between the organizations means the organizational partnership is conflicted. This trend is pivotal from the perspective of Catholic healthcare retaining its mission and identity. This topic requires intensive Sponsorship and Governance oversight because of the increasing need to integrate the delivery and financing of care, thereby requiring Catholic healthcare to partner with other-than-Catholic organizations to combine hospitals and insurance in an intricate manner.

There is a long-standing ethical principle in the Catholic social tradition that can provide guidance for this controversial issue: the ethical principle of cooperation. It is claimed that there is no more difficult question in Catholic moral theology than the principle of cooperation. The principle differentiates the action of a wrongdoer from the action of a cooperator. In the context of healthcare partnerships, the principle can differentiate between a Catholic organization (as the so-called cooperator) and an other-than-Catholic organization (that provides services prohibited by Catholic teaching) with which it cooperates. To understand how the principle of cooperation functions it can help to explain another principle upon which it can be based, the principle of double effect. In other words, to understand the significance of the principle of cooperation for conflicted partnerships in Catholic healthcare, the principle of double effect has to be grasped. Double effect is applied in bioethics to distinguish between what one intends and what
one foresees and accepts but does not intend as a side effect. This marks the difference between impermissible and the permissible that is so important for using the principle of cooperation. The is discussion set the stage for understanding the principle of cooperation, each distinguishing between what is permissible and what is impermissible in related ways.

There is a need for intensive Sponsorship and Governance oversight of how Catholic healthcare applies the principle of double effect insofar as the principle engages complex dilemmas, especially those that deal with the Church’s prohibition of abortion. And that need for intensive Sponsorship and Governance oversight extends to the application of the principle of legitimate material cooperation in dilemma situations involving conflicted organizational partnerships, especially those dealing with sterilizations that forbidden in Catholic healthcare. Even though secular healthcare may not oppose these services, it needs to be attentive to the distinctions in the ethical principles in situations when secular and Catholic organizations need to partner to survive in the competitive healthcare marketplace.

In summary, Sponsorship and Governance oversight functions in an integrative manner in both Catholic and secular healthcare organizations to combine patient care and the public good in healthcare. The different chapters have explored this integrative responsibility by discussing both current issues and emerging trends that require Sponsorship and Governance oversight of patient care and the public good in healthcare. Chapter 3 and 4 addressed current issues that need enhanced oversight, chapter 3 dealing with issues related to patient care and chapter 4 focusing on issues related to the public good. Chapter 5, 6, and 7 discussed emerging trends that require intensive Sponsorship
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