

Health Care Ethics USA

A resource for the Catholic health ministry

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Moving Ethics into Ambulatory Care: The Future of Catholic Health Care Ethics in Shifting Delivery Trends

Rachelle Barina
Ethics Consultant
SSM Health Care
Saint Louis, MO
rachelle_barina@ssmhc.com

Emily K. Trancik
Ethics Consultant
SSM Health Care
Saint Louis, MO
emily_trancik@ssmhc.com

(Editor's Note: In an effort to further this conversation, we invite brief (500-700 word) responses/commentaries to this article dealing with 1) additional ethical issues in the outpatient setting, and/or 2) efforts being made to move ethics (or mission) into ambulatory care. As many responses/commentaries as possible will be published in the summer issue of HCEUSA. Responses/commentaries can be emailed to rhamel@chausa.org).

Introduction

Until recently, health care delivery tended to take place in inpatient settings. As the landscape of health care changes, a growing proportion of care is delivered in the outpatient setting. In outpatient (or ambulatory) care, the patient is admitted, treated and discharged on the same day. Outpatient visits include primary and preventive care through a range of services such as wellness exams, diagnostic procedures, minor surgeries, and cancer treatments.

Significant changes are occurring in the use of outpatient services. For example, inpatient

admissions to community hospitals decreased by 10 percent between 1987 and 2007, and the number of total inpatient days for admitted patients declined by more than 30 percent. Following this same trend, the percentage of outpatient surgeries at community hospitals rose from 44 percent to 63 percent between 1987 and 2007. Moreover, the shift from inpatient to outpatient care is manifest in revenue trends. In 1987, 19 percent of revenue for community hospitals was from outpatient visits. By 2007, the percentage of outpatient revenue doubled.¹ In 2011, there were over 100 million outpatient visits at Catholic hospitals.²

Several factors contribute to the shift from inpatient to outpatient care. First, although the expansion of outpatient care began prior to recent health reform initiatives, ongoing reform and the Affordable Care Act (ACA) will sustain the trends. As a result of the ACA, fewer patients will be uninsured and thus demand for services will increase.³ Pay-for-performance models (replacing fee-for-service models) incentivize preventive care delivered in outpatient offices.⁴ Moreover, Medicare reimbursement policies encourage reduction in readmissions to hospitals.⁵ Second, technological development contributes to increased use of ambulatory care. Better diagnostic tools enable providers to address issues before they require inpatient care, and minimally invasive surgery allows more procedures and treatments to be done without inpatient admission. Finally, chronic disease is rising across various demographics.⁶ Management of chronic disease increases demand for outpatient services and delivers better results than simply treating acute episodes. Because of the ACA, technological developments, and the rise of chronic disease, outpatient care is becoming and will remain the locus of patient care.

As outpatient settings become the primary site for care delivery, providers experience new kinds of ethical issues. Yet, ethics services (that is, the department or group of individuals that provide ethics education, consultation, and policy development in a given entity or group of entities, a.k.a., “ethics”) tend to lack a presence in outpatient facilities, and outpatient providers are often not aware of ethics services or how to access ethics resources. Ethics services should reach all providers in an organization and the resources that “ethics” provides should be applicable to

the particular contexts within which providers work.

In this article, we will first explain two aspects of outpatient care that give rise to new ethical issues. Then, we will argue for the necessity of developing new ethical tools and procedures to adequately address the kinds of ethical issues outpatient providers experience. We will conclude with some reflections on the sorts of tools and procedures that ethics may need to cultivate in order to improve and expand its presence in outpatient settings.

Ethical Issues in Ambulatory Care: A Sampling

Ethical norms and practices emerged in the second half of the 20th century in acute care facilities. The development of ethics within the acute care context had two primary effects on the structure and content of ethics. First, it caused the structure of ethics to take the form of the ethics committee and consultation service. With this structure, ethics resembles other medical specialties a hospital caregiver can consult for an expert’s opinion. In-person conversations and consultations are practically convenient because stakeholders are immediately accessible within the hospital. Second, the acute care context caused the content of ethics to emphasize a narrow range of issues pertaining to acute, inpatient crises at the beginning-of-life and end-of-life. It has tended not to focus on broader issues often encountered in outpatient settings, including practical issues such as managing chronic illness, and broader theoretical notions such as virtue, prudential judgment, or the meaning of healing.

As it currently stands, however, Catholic ethics lacks attention to outpatient care. The setting of care delivery shapes the ethical questions providers experience. Ethics services should be aware of the particular ethical questions and needs providers in different care settings experience and provide ethics resources across the entire continuum of care. Although some ethics topics such as informed consent, advance care planning, and privacy are relevant in both inpatient and outpatient care, the outpatient setting presents other distinct issues to which ethics must attend.

One challenge of the outpatient setting that has special relevance for ethics is coordination of care, compliance, and follow-up.⁷ In the inpatient setting, patient compliance is less challenging because of the controlled environment. In contrast, the efficacy of outpatient medical care relies upon patient compliance and disclosure. What are providers to do when patients continue to seek outpatient services but do not or cannot comply with the agreed upon treatment regimens? And, motivating and enabling providers to take time to do appropriate follow-up on patients, especially non-compliant patients, is challenging. Although a phone call is a small gesture that can dramatically improve compliance or coordination of care, providers cannot bill for this efficient means of follow-up.

Moreover, providing care in outpatient settings often results in a lack of communication between providers and thus a lack of coordination of treatment plans. Failure to coordinate care or help patients coordinate care is ethically problematic because it may lead to poor patient experience and outcomes.⁸ When patients face the

challenges of being bounced between providers, they may not only feel frustrated but also give up on pursuing care. Difficulties with the coordination of care are also problematic because they generate unnecessary use of repeat services.

A second new issue for outpatient providers concerns questions of justice and discrimination. Because of the 1986 Emergency Medical Treatment and Active Labor Act (EMTALA), inpatient providers are not personally responsible for determining whether or what kind of insurance is required for admission.⁹ In an outpatient setting, however, providers may confront the pressures of managing payments and excluding some patients more personally and directly. Outpatient providers must ensure their practice is sustainable. Managing the sustainability of a practice means choosing what kinds of insurance to accept and what to do about requests for care from patients without insurance. For example, providers may realize that their Medicaid patients are so numerous that the fiscal stability of the practice is jeopardized. Providers may be personally faced with the tension between sustaining their practice and discriminating against certain patient populations or insurance plans.

Coordinating care and sustaining outpatient practices are two of the many examples of the kinds of moral issues that arise in outpatient settings. In general, ethics does not reach outpatient providers very effectively or specifically. Ethics education tends to focus on inpatient cases and topics. Catholic health care must develop new moral tools, procedures and modes of engagement to

adequately address moral issues that arise in outpatient care.

The costs will be high if Catholic health care fails to cultivate ethics practices and resources specific to outpatient care. Equipping outpatient providers with moral tools and resources promotes quality patient care. Moreover, as more care is delivered in the outpatient setting, the coherency and internalization of organizational mission and ethics depends upon its presence. If ethics does not reach out to outpatient providers, it will become distanced from what is becoming the primary site of contact between patients and providers.

Expanding Ethics to the Outpatient Setting

Becoming aware of changes in health care delivery and new challenges for ethics in the outpatient setting is the first step in developing an ethics program that responds to ethical issues system-wide, across the whole continuum of care. Once aware of the deficiency in attention to outpatient settings, the first task of ethics must be to help providers recognize ethical dilemmas in those settings. The dilemmas that arise in outpatient care are not the flashy kinds of moral issues ethicists have discussed for the last forty or so years. Often, the dilemmas are easier to overlook or to write off as insignificant. Ethics services will need to initiate conversations with providers to raise awareness of moral issues and develop new ethics resources and procedures to make ethics accessible and useful beyond the hospital. In short, expanding ethics to the outpatient setting means that ethics services must begin to engage outpatient providers in conversation.

Structural differences between inpatient and outpatient settings create practical challenges for the expansion of ethics to outpatient care. Whereas the structure of the hospital enabled the delivery of education through large ethics programs during grand rounds or over lunch, the delivery of ethics educational programs throughout many small, disparate, independently functioning outpatient offices raises practical challenges. In addition to education, ethics also needs to provide a consultation resource for outpatient providers when they face a taxing dilemma for which some assistance would be helpful. The consultation formats of the interdisciplinary ethics committee or the in person consultant both seem inapplicable for outpatient providers because of the practical and geographical hurdles of the more isolated context of outpatient care. Providers working in disparate locations may connect most easily on conference calls or video meetings. Perhaps a virtual gathering akin to the ethics committee could happen between outpatient providers. Or, a committee model may be altogether unrealistic. Perhaps a single professional ethicist should be hired to provide consultation and to facilitate collaboration and communication among outpatient providers.

Most importantly, ethics needs to be attentive to preserving, applying, and interpreting the content of its Catholic identity as it moves into the outpatient setting. One necessary way to do so will be to carefully examine how themes of Catholic moral theology, traditions in medical ethics, and in particular the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs) provide guidance in the context of outpatient care. Ethics may also realize that the ERDs are not currently

sufficient to addressing these new issues. For example, interpreting the tradition of ordinary and extraordinary means¹⁰ for a decision made prior to an acute crisis (as has occurred in recent discussions of advance directives and POLST forms) raises new questions.¹¹ Can the notions of ordinary and extraordinary be determined in the outpatient context such that an outpatient provider could write an immediately and universally effective DNR order? Understanding the meaning of these long-standing principles in the context of outpatient care will not only provide guidance in resolving moral dilemmas, but also become prescriptive for good practices and patient care. Conversation among clinicians, health care ethicists and academicians is crucial to developing new ideas for new situations based upon sustained moral ideologies.

Conclusion

The reality is that the ethics practices of education, committee meetings, and consultation have emerged because they are compatible and convenient within the context of the hospital. They are unrealistic ways for ethics to function well in the outpatient context. The procedures by which ethics will be practically able to expand into the outpatient setting require creative and innovative thinking. Ethics needs to provide more moral guidance on the more vague and underemphasized issues that arise in outpatient care. Ethics needs to help providers think about caring for patients with chronic diseases, managing the health of populations, dealing with non-compliant patients and relating organizational values to decisions about the provision of care. Most of all, ethics

needs to reach out to outpatient providers and support them with relevant resources. This move is of utmost importance. If ethics does not expand the content of moral reflection and the structure by which outpatient clinicians can engage ethics, it will fail to reach the bulk of care delivery and thus, underserve the mission and identity of Catholic health care.

(Ms. Barina and Ms. Trancik are also graduate students in health care ethics at Saint Louis University's Albert Gnaegi Center for Health Care Ethics).

¹ Tracy K. Johnson, "Ambulatory Care Stands Out Under Reform," *Healthcare Financial Management* 64 (2010): 57.

² "2011 American Hospital Association Annual Survey."

³ Kaiser Commission, "Medicaid and the Uninsured," <http://www.kff.org/uninsured/upload/1420-14.pdf>.

⁴ Johnson, "Ambulatory Care Stands Out Under Reform," 58-9.

⁵ Centers for Medicare & Medicaid Services, "Affordable Care Act Update: Implementing Medicare Cost Savings," <http://www.cms.gov/apps/docs/aca-update-implementing-medicare-costs-savings.pdf>.

⁶ Johnson, "Ambulatory Care Stands Out Under Reform," 59-61.

⁷ Ernlé W.D. Young, "Ethics in the Outpatient Setting: New Challenges and Opportunities," *Cambridge Quarterly of Health Care Ethics* 6 (1997): 294-5.

⁸ Perry A. Pugno, "Ethical Considerations of Electronic Communication in the Clinical Outpatient Setting," *The Journal of Clinical Ethics* 13, no. 4 (2002).

⁹ American Academy of Emergency Medicine, "EMTALA," <http://www.aaem.org/em-resources/regulatory-issues/emtala>.

¹⁰ USCCB, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, DC: USCCB, 2009), nos. 56, 57.

¹¹ Ron Hamel, "Ethical Currents: POLST Under Fire," *Health Care Ethics USA* 20, no. 1 (2012).

Treatment of Unexplained Subfertility in Catholic Health Care: Taking the Lead toward a Natural Approach

Gina Fullam
Saint Louis University
Albert Gnaegi Center for Health Care Ethics
gina.fullam@gmail.com

Editor's Note: Graduate students in health care ethics were invited to make submissions in a student essay contest. This essay is one of the entries. Several others will be published in subsequent issues of HCEUSA.

Introduction

Though in vitro fertilization (IVF) has become common treatment for unexplained subfertility,¹ concerns about the practice linger. The risks to women posed by all-too-common IVF-associated multiple pregnancies, and the heightened risks of prematurity and congenital disabilities for IVF-conceived babies, are troublesome to those of all moral sensibilities. Furthermore, spare embryos and the practice of fetal reduction are disconcerting to those even outside of anti-abortion circles. Finally, the costs of IVF treatment raise serious questions of justice and access. Surprisingly, a Cochrane review finds that the assumed efficacy of IVF for unexplained subfertility relative to other more natural treatments is not sustained by empirical evidence. Given these ethical concerns, and the unproven relative efficacy of IVF, I argue that standard care for unexplained subfertility should favor more natural options,

including expectant management. I also consider the promising preliminary evidence for Natural Procreative Technology (NaProTechnology), an infertility treatment approach that seeks to identify and address the underlying cause of a couple's infertility. Though I acknowledge the need for further empirical studies on NaProTechnology's effectiveness, I argue that couples seeking treatment for unexplained subfertility should at least be informed of NaProTechnology's methods. Moreover, Catholic health care can and should take a lead role informing patients of and treating patients using NaProTechnology's methods.

Standard Infertility Treatment

Infertility, the inability to become pregnant after one year (or six months if a woman is 35 years or older) of normal

sexual intercourse without contraception, affects an estimated 10 percent of couples of childbearing age in the United States.² Infertility can be devastating for a couple who wishes to have children of their own. Many couples feel that their marriage is unfulfilled if they do not have children, and involuntary childlessness may lead to “low levels of self-esteem and to feelings of anger, denial, depression and frustration.”³ Today, however, infertility need not mean a couple will never give birth to a child of their own. Mainstream medical practice has developed infertility treatments which enable the desires of some of these couples to become reality.

Generally when a couple is having difficulty conceiving, a family physician or gynecologist will encourage the couple to continue to engage in regular sexual intercourse for a few months.⁴ If the couple has not achieved pregnancy after that time, the doctor may suggest timed sexual intercourse and show the woman how to chart her body temperature (in order to more accurately know when she is fertile) and also perhaps start the woman on fertility drugs, such as clomiphene citrate, to regulate her cycle. If these attempts are also unsuccessful, the couple is recommended to a fertility specialist or clinic. Here both the man and woman are physically examined and their complete medical and social histories are taken. In further effort to identify the cause of infertility, blood tests, urinalysis, sperm analysis and postcoital tests are performed, and the woman will undergo a hysterosalpingography (X-ray of uterus and fallopian tubes).

At this point, some relatively simple procedures, such as artificial insemination in the case of male infertility due to poor sperm motility or low sperm count, may be attempted. In artificial insemination, a sample of the man’s or donor’s sperm is obtained, usually through masturbation, the sperm is “washed” so as to optimize chances of fertilization, and the washed sperm is injected into the woman’s vagina or uterus during the woman’s fertile period. Artificial insemination gained popularity in the United States in the 1960s.

If these efforts are still unsuccessful, more advanced assisted reproductive methods, in which both sperm and egg are handled, may be attempted.⁵ These assisted reproductive methods are known as artificial reproductive technologies (ARTs), and may make use of donor gametes and surrogate mothers. Sperm is retrieved and prepared in the same way as it is in artificial insemination. The egg retrieval process is lengthier and more invasive. Though even more invasive at one time, today a woman will take ovarian stimulation drugs (which must be injected) for three to four weeks, and then one or more of her eggs are retrieved through transvaginal ultrasound guided egg aspiration.

ARTs include, but are not limited to:

- (1) *In vitro fertilization (IVF) and embryo transfer*: Developed to remedy blocked or damaged fallopian tubes and first successful in 1978, today IVF is the most well-known and commonly

practiced ART. IVF involves the mixing of sperm and egg in a petri dish and the placement of one or more resultant embryos into the uterus 2-5 days after fertilization. Embryos not selected for placement into the uterus are discarded or frozen for later usage. When more embryos implant than would be healthy for the woman to carry to term, fetal reduction is recommended.

(2) *IVF with intracytoplasmic sperm injection (ICSI)*: A specific form of IVF developed to circumvent sperm-related infertility, ICSI involves the injection of a single sperm directly into an egg (*in vitro*), and the placement of the resultant embryo into the uterus.

(3) *Zygote intrafallopian transfer (ZIFT)*: A process similar to IVF, though only performed when infertility is not caused by tubal blockage, ZIFT involves the transfer of one or more zygotes (fertilized *in vitro*) to one of a woman's fallopian tubes immediately after fertilization with the hope that the zygote will then arrive and implant into the uterus naturally.

(4) *Gamete intrafallopian transfer (GIFT)*: In this process, sperm and egg are mixed *in vitro* but transferred to one of a woman's fallopian tubes before fertilization has occurred.

All of these procedures can be assisted by preimplantation genetic diagnosis (PGD) and prenatal genetic diagnosis, which test embryos for genetic disease prior to and after implantation, respectively.

The Centers for Disease Control and Prevention (CDC) estimates that slightly more than 1 percent of total U.S. births are the result of ART.⁶ The number of ART cycles performed in the United States nearly doubled from 1999⁷ to 2010⁸ (87,636 cycles in 1999 compared with 147,260 cycles in 2008).⁹ In 1999, 30,629 infants were born as a result of these ART cycles. The number of live births has also steadily increased, with 61,564 ART-conceived children born in 2010. Specific to this paper, couples with unexplained infertility are represented in 9.5 percent,¹⁰ or about 14,000, of these cycles, and about 4,700 live births. IVF and IVF with ICSI accounted for 99.9 percent of all ART cycles in 2010; hence the focus of this paper on IVF is warranted.

IVF: Risks to Women and Children

IVF and other related procedures are not without risk to either women participating in fertility treatment or the children to be created through these technologies. In 2010, for ART cycles using fresh nondonor eggs or embryos, the incidence of twins was 28.8 percent and the incidence of triplets or more was 1.5 percent.¹¹ For ART cycles using frozen nondonor embryos, the incidences of twins and triplets were 22.8 percent and 1.1 percent respectively. For ART cycles

using fresh embryos from donor eggs, the incidences of twins and triplets were 36.7 percent and 0.8 percent respectively. These numbers compare to a 1.05 to 1.35 percent rate of twins and 0.01 to 0.017 percent rate of triplets in the general population.¹² Maternal mortality is seven times greater in multiple pregnancies than in single pregnancies¹³ due to “increased incidence of preeclampsia, placenta previa, placental abruption, premature rupture of the membranes, postpartum hemorrhage, and Cesarean section.”¹⁴ Perinatal mortality rates quadruple for twins, and sextuple for triplets.¹⁵ Furthermore, twins are 9.6 times more likely than singletons to be very low birth weight, and thus susceptible to a multitude of problems, and triplets or more are 32.7 times more likely than singletons to be very low birth weight.¹⁶

Even singleton IVF babies, however, are at increased risk for preterm delivery, low and very low birth weight, Caesarean section, admission to neonatal intensive care unit, and perinatal mortality.¹⁷ ART-conceived children, including singletons, are two to four times more likely to have heart problems, cleft lip, cleft palate and abnormalities in the esophagus or rectum.¹⁸ Other studies indicate a link between ARTs and developmental delay, cerebral palsy, and autism spectrum disorders.¹⁹ It is important to note that the long-term effects of IVF are unknown, as the first IVF conceived baby is now only 34 years old.

Fetal Reduction and Spare Embryos

In an effort to reduce the risks to women and children, fetal reduction is often performed in the event that a multiple gestation pregnancy results from IVF. The practice of fetal reduction involves selecting the fetus or fetuses to be eliminated either by chromosomal abnormalities, ease of reach, or sex, and injecting a shot of potassium chloride into the heart of each selected fetus. The fetuses are left to be absorbed by the woman’s body. The CDC does not report the frequency of fetal reduction in ART treatment.²⁰ “This is a very sensitive topic,”²¹ explains David Grainger, now past president of the Society for Assisted Reproductive Technologies (SART). Nevertheless, investigative journalist Liza Mundy finds that the practice, though often unmentioned, is common.²²

Although the practice of fetal reduction associated with IVF has not received the same backlash from the anti-abortion movement as abortion—perhaps because fetal reduction is not as much in the public eye—even women who undergo fetal reduction do not do so without concerns. The procedure itself carries a 16 percent or greater risk that the remaining fetuses will be preterm, and the same degree of risk that the entire pregnancy will be lost before 24 weeks of gestation.²³ It is also not irrelevant that the most recent Gallup poll reports that 50 percent of Americans consider themselves pro-life, compared to 41 percent identifying as pro-choice.²⁴

The spare embryo issue related to IVF is also a bit of an anomaly in the typical divide between pro-life and pro-choice. It is not uncommon for ten embryos to result per IVF cycle; only one to three of which are typically implanted into the woman's uterus. The remaining embryos are then frozen and stored. The question, with which many couples and individuals with frozen embryos struggle, is what to do with these embryos. Their choices are: use for further reproduction, discard the embryos, donate the embryos for reproduction, and donate the embryos to science. Interestingly, one study found that 72 percent of couples, even after an average 4.2 years of storage, are unsure of what to do.²⁵ Their embryos remain frozen indefinitely, contributing to the estimated one half million frozen embryos in storage in the United States.²⁶ Couples cite discomfort with having another couple gestate and raise their children and the idea of their embryos as "virtual" children among their reasons for indefinite freezing.²⁷

Costs of IVF

The high costs of IVF treatment also raise noteworthy ethical questions. Per cycle estimates in the United States usually range between \$7,000 and \$11,000. The bulk of this cost is out of pocket, as many insurance companies do not provide IVF coverage. This cost in itself is prohibitive to many infertile couples. Interestingly, only 38.5 percent of infertile couples have ever used infertility services,²⁸ and not using infertility services is correlated with

lower income and lower education levels.²⁹ Mundy argues that those lower income couples (already disproportionately infertile due to lack of prior access to treatment for initially preventable infertility causes) who do seek infertility treatment are endangered by non-access to IVF and/or follow-up care.³⁰ When the only treatments lower income couples can afford are fertility drugs, which will be taken without monitoring or follow-up appointments, their risks for multiple pregnancies and ensuing complications are exceedingly high.

Even couples who can afford the base price tag associated with IVF, however, may not be able to afford IVF's associated costs. As Robert Blank correctly notes, an accurate figure must take into account the number of failed cycles often undergone before a live birth is achieved, as well as the "costs of all subsequent procedures that occur more often with IVF pregnancies, such as high-risk obstetrical care, Cesarean sections, and neonatal care."³¹ A 1994 estimated cost per live birth including such indirect costs was \$66,667 for successful birth after one IVF cycle, and \$114,286 for successful birth after six cycles.³²

Efficacy of IVF for Unexplained Subfertility

In the face of these concerns about risks to women and children, fetal reduction, spare embryos, and costs, it is worth asking if there are not other equally effective methods of treating infertility and, specifically, unexplained subfertility, which

is the focus of this paper. Given that IVF and fetal reduction are gravely contrary to the moral law,³³ it is especially important for Catholic health care to ask if there are not other equally effective methods of treating infertility. Surprisingly, a systematic Cochrane review has found that although IVF is a widely accepted treatment option for couples with unexplained subfertility, “its effectiveness has not been rigorously evaluated in comparison with other treatments.”³⁴ The Cochrane review assessed all randomized control studies that compared the effectiveness of IVF in achieving live birth to the effectiveness of one or more of the following: expectant management, clomiphene citrate, intrauterine insemination, intrauterine insemination with controlled ovarian stimulation, and GIFT. Randomized clinical trials are the “gold standard for experimental evaluation of medical or surgical infertility therapy.”³⁵

In comparison with expectant management, the Cochrane review found that IVF attained significantly higher clinical pregnancy rates (odds ratio 3.24; 95 percent confidence interval 1.07 to 9.8).³⁶ However, the review does not allow conclusions to be drawn from this data given the studies’ small sample sizes (35 and 51 participants) and inadequate follow-up with participants. The duration of follow-up was three months in the first study and six months in the second. The systematic review found no studies comparing IVF with clomiphene citrate.³⁷ Studies comparing IVF with intrauterine

insemination either without or with ovarian stimulation did not exhibit any difference in live birth rates (odds ratio 1.96; 95 percent confidence interval 0.88 to 4.4 and odds ratio 1.15; 95 percent confidence interval 0.55 to 2.4, respectively).³⁸ Though periodically updated, the Cochrane review’s conclusions have remained unchanged since 2005.

A 2008 randomized study³⁹ compared the effectiveness of expectant management, clomifene citrate, and unstimulated intrauterine insemination as treatment for unexplained subfertility. This study was not included in the Cochrane view as it did not examine the effectiveness of IVF relative to these treatments. However, I include the study here given the lack of data comparing IVF with clomiphene citrate noted in the Cochrane view. S. Bhattacharya et al. randomly assigned each of 580 couples with infertility for over two years to one of three study arms. Those assigned to the expectant management arm did not receive any follow-up treatment or advice. Differences in live birth rates after six months (17 percent for expectant management, 14 percent for clomiphene citrate, and 23 percent for unstimulated intrauterine insemination) across the three arms were not statistically significant.

Allowing the Bhattacharya study to inform the Cochrane review suggests an important point. Given that the Cochrane review finds no statistical difference in live birth rates between IVF and either unstimulated or stimulated intrauterine insemination,

and given that the Bhattacharya study finds no statistical difference in live birth rates among expectant management, clomifene citrate, and unstimulated intrauterine insemination, it may follow that there is no statistical difference between IVF and expectant management, clomifene citrate, or unstimulated intrauterine insemination.

Challenges of Research

In fairness, I note that there are unique challenges to research examining the efficacy of infertility treatments, and treatment for unexplained subfertility in particular, especially to meet the high standards of Cochrane reviews. If anything, however, these challenges give IVF an advantage over more natural treatment options in research studies.

D. Guzick and J. Queenan jr observe, for instance, that there is always a probability that a couple will achieve pregnancy during treatment that is not a result of the treatment under study.⁴⁰ Studies suggest spontaneous pregnancy rates as high as 60 percent.⁴¹ Additionally, large sample sizes are necessary to overcome differences in IVF success rates among fertility clinics.⁴² As such, randomized clinical trials require the cooperation of multiple fertility clinics. Thirdly, patients and physicians participating in studies may have preconceived notions of what constitutes “best” treatment.

This last challenge is evident in the Bhattacharya study. Bhattacharya et al.

found that 94 percent of women randomized to clomifene citrate and 96 percent of women randomized to unstimulated intrauterine insemination found the process of treatment acceptable, compared with 80 percent of women randomized to expectant management. Although differences in satisfaction rates did not correspond to any difference in anxiety and depression scores (these scores were even across the three groups), Bhattacharya et al. conclude that “women with infertility are reassured by active treatment and are less satisfied with an expectant approach.”⁴³

NaProTechnology: Unexplained Infertility

Having now observed the ethical concerns surrounding IVF, as well as the dearth of evidence demonstrating the efficacy of IVF relative to other treatments in achieving live births for couples with unexplained subfertility, I argue that standard care for unexplained subfertility should favor more natural options, including expectant management. Above all, standard care for unexplained subfertility in Catholic health care should favor natural options. Specifically, I recommend that the second step of standard infertility treatment, the period of time which involves testing and simple fertility treatments, be significantly expanded. At the same time, I urge further research into best treatment for unexplained subfertility, which again can and should be spearheaded by Catholic health care.

Pope John Paul II's *Donum Vitae* in 1987 and the Congregation for the Doctrine of Faith's *Dignitas Personae* in 2008 expound that sexual intercourse is not to be stripped of its unitive dimension via assisted reproductive methods which replace or substitute for the conjugal act.⁴⁴ The marriage bond, the dignity of the child, the right of the child to be conceived, carried in the womb, brought into the world and brought up within marriage, and the respect due to the child's origin all add additional weight to this teaching. Thus the Catholic Church rejects many mainstream infertility treatments, including AI, IVF, IVF with ICSI and ZIFT. The Church also condemns the destruction of spare embryos and practice of selective fetal reduction associated with IVF and related ARTs. Catholic health care, then, has a special obligation to inform patients of and offer natural options for treatment of unexplained subfertility, and a special obligation to invest in research into natural treatment for unexplained subfertility.

Both inside and outside of Catholic health care, it should be obvious that best treatment for unexplained subfertility would include diagnosis of the cause of subfertility. In fact, rarely does the medical professional encourage a band-aid treatment approach. Knee-replacement surgery, for instance, is not medically indicated when the functionality of the knee can be restored. Still, literature reports that fertility specialists diagnose between 25-30 percent of all infertility as "unexplained."⁴⁵ N. Gleicher and D. Barad

point out that the *diagnosis* of unexplained infertility is in fact a misnomer, as unexplained infertility only indicates that more diagnostic testing remains to be performed.⁴⁶ They urge: "A better effort should be undertaken to develop reliable tools to diagnose, hitherto often undiagnosed, conditions of endometriosis, tubal disease, premature ovarian ageing and immunological infertility, which are often misdiagnosed for UI [unexplained infertility]."⁴⁷

Unbeknownst to Gleicher and Barad, and in fact little known to the fertility field, Thomas W. Hilgers, MD and colleagues at Creighton University and Saint Louis University Schools of Medicine over the last thirty years have worked to develop Natural Procreative Technology (NaProTechnology), an approach to infertility that seeks to identify and address the underlying cause of a couple's infertility.⁴⁸ Though only a handful of studies demonstrating the effectiveness of NaProTechnology have been published, and at that, only one in a peer-reviewed journal, the success of NaProTechnology in diagnosing the underlying cause of a couple's infertility is promising.

In the *Journal of the American Board of Family Medicine* September-October 2008 issue, Drs. Joseph B. Stanford, Tracey A. Parnell, and Phil C. Boyle presented their study of 1,072 couples who received NaProTechnology treatment between February 1998 and January 2002 at a clinic in Galway, Ireland.⁴⁹ Table 2⁵⁰ shows the diagnoses of couples after

complete evaluation using the Creighton Model FertilityCare™ System’s charting method for ovulation in conjunction with timed blood samples and reproductive hormone testing. As indicated in Table 2, while 506 (47.2 percent) of couples’ infertility was unexplained prior to evaluation, only 5 couples’ (0.5 percent) infertility remained unexplained after evaluation. Boyle notes in a separate article that, “The timed hormonal blood tests for

both progesterone and estradiol help us to identify subtle deficiencies that are simply not diagnosed with a day 21 blood test [standard practice] that does not pay any attention to the time of ovulation.”⁵¹ The Ireland study indeed offers preliminary evidence that the more reliable methods to diagnose unexplained infertility that Gleicher and Barad urge can be, and in fact have been, developed.

Table 2. Common Diagnoses of Couples Receiving Treatment Before and After Evaluation with Natural Procreative Technology*

Diagnostic Category	Before NPT Evaluation (n [%])	After NPT Evaluation (n [%])
Unexplained infertility	506 (47.2)	5 (0.5)
Unexplained recurrent miscarriage	124 (11.6)	2 (0.2)
Anovulation	31 (2.9)	36 (3.4)
Polycystic ovarian syndrome	68 (6.3)	110 (10.3)
Endometriosis	209 (19.5)	208 (24.6)
Male factor	115 (10.7)	146 (13.6)
Limited cervical mucus	12 (1.1)	276 (25.7)
Suboptimal luteal progesterone	99 (9.2)	923 (86.1)
Suboptimal luteal estrogen	2 (0.2)	676 (63.1)

*This table is based on the 1072 couples that initiated evaluation. Diagnostic categories sum to more than 100% because couples could have more than one diagnosis (other than unexplained).

Efficacy of NaProTechnology in Achieving Live Births

Promisingly, the Ireland study suggests that NaProTechnology is not only successful in the identification of the underlying cause of a couple’s infertility, but also has live birth rates comparable to those of IVF. NaProTechnology’s methods include surgical means to restore fertility;⁵² however the Ireland study only evaluated NaProTechnology’s medical protocols (as surgical means were

unavailable at the clinic at the time). Richard Fehring provides insight into these medical protocols:

Treatment involved having the woman patient track her fertility with the CrM system [Creighton Model FertilityCare™ System] (which focuses primarily on the estrogenic changes in cervical mucus), assessing the timing of intercourse, evaluating the quality of cervical mucus production, measuring luteal phase lengths,

and determining levels of progesterone and estrogen on certain days of the menstrual cycle. When menstrual cycle deficits were detected, treatment included the use of clomiphene (to stimulate ovulation), medications to stimulate cervical mucus production, and progesterone supplementation.⁵³

The average female age of the study was 35.8 years.⁵⁴ Thirty-three percent of the couples had previously attempted ART treatment. Excluded from the study were couples whose infertility was the result of menopause or azoospermia, which NaProTechnology cannot treat. This is, of course, irrelevant to the present consideration of best treatment for *unexplained* subfertility.

For those couples that could be treated using NaProTechnology, the Ireland study two-year crude proportion live birth rate was 25.5 percent, and the adjusted proportion live birth rate (adjusted for couples who dropped out of the study as well as couples who were continuing treatment after the two year trial period) was 52.8 percent.⁵⁵ This success rate is indeed comparable to the estimated 13-28 percent live births resulting per cycle from IVF.⁵⁶ Especially interesting is that 16 percent of those couples who had previously attempted ART treatment were able to achieve pregnancy and carry the child to term using NaProTechnology.⁵⁷

Though there are no studies comparing couples' satisfaction rates for NaProTechnology to satisfaction rates for expectant management, the couple's participation in and understanding of the treatment, which is essential to NaProTechnology,⁵⁸ may very well help to overcome the research challenge of active versus non-active treatment. I also note that the Ireland study suggests NaProTechnology as a viable alternative to IVF for conditions other than unexplained subfertility.

It is obvious that one peer-reviewed study on NaProTechnology's effectiveness does not meet the standards of evidence-based medicine. Indeed, the Ireland report concludes that, "Large multicenter prospective studies are warranted to confirm these results, to explore further the characteristics associated with successful NPT [NaProTechnology] treatment, and to directly compare NPT to other forms of infertility treatment."⁵⁹ Nevertheless, the preliminary evidence of NaProTechnology's effectiveness in both identifying the cause of a couple's infertility and achieving live birth rates is promising. If no evidence demonstrates IVF's effectiveness over more natural methods such as expectant management for treatment of couples with unexplained subfertility, there is no reason why couples seeking treatment for unexplained subfertility should not also be informed of NaProTechnology during step two of their treatment.

Standards for innovative treatment in the field of reproduction are all but non-existent. As a result of a long-standing government ban on federal funding for research involving human embryos, the fertility field has developed virtually independent of Food and Drug Administration (FDA) or Institutional Review Board (IRB) oversight. Regardless, NaProTechnology possesses no risk of harm that would raise issues even by the standards for innovative treatment in other fields. In fact, the multiple birth rate in the Ireland study was only 4.5 percent, compared with the 23-37 percent⁶⁰ multiple birth rate associated with ART. Thus, in NaProTechnology, Hilgers and colleagues have developed an approach to fertility that is both in conformity with Church teaching and, at least preliminarily, scientifically sound.

Moreover, unlike IVF, NaProTechnology is often covered by insurance. Over 200 FertilityCare™ Centers featuring NaProTechnology exist throughout the United States and Canada, and additional centers have opened in Ireland, Poland, Taiwan, and Australia.⁶¹ NaProTechnology's methods are also easily accessible (for instance, to interested fertility specialists) in the 1244 page volume *The Medical & Surgical Practice of NaProTechnology* by Thomas W. Hilgers.⁶²

Conclusion

Given IVF's costs, risks to women and children, and the associated issues of fetal

reduction and spare embryos, and the lack of empirical evidence showing IVF's effectiveness over other treatments for unexplained subfertility, I agree that standard treatment for unexplained subfertility should favor more natural options, including expectant management. This argument has special urgency in Catholic health care, where treatment such as IVF is morally impermissible. I further submit that couples seeking treatment for unexplained subfertility should at least be informed of NaProTechnology's methods, and again, Catholic health care can and should take the lead in this.

¹ I will use "infertility" and "subfertility" interchangeably. Though some distinguish between "infertility" and "subfertility," the distinction is not relevant to the discussion in this paper.

² I will focus this paper primarily on treatment for unexplained subfertility in the United States. See Centers for Disease Control and Prevention, "Infertility," <http://www.cdc.gov/reproductivehealth/Infertility/index.htm#1>.

³ The New York State Task Force on Life and the Law, *Surrogate parenting: analysis and recommendations for public policy* (1988). 12.

⁴ Victor Groza and Karen F. Rosenberg, *Clinical and practice issues in adoption* (Westport, CT: Greenwood Publishing Group, Inc., 1998). 25.

⁵ Ibid.

⁶ Centers for Disease Control and Prevention, "2010 assisted reproductive technology: national summary report," (2012).

⁷ 1999 is the first year for which the CDC collected data.

⁸ 2010 is the most recent year for which data is available.

⁹ As the CDC only compiles statistics from reporting fertility clinics, and fertility clinics are not required to report, the true figures are likely higher.

¹⁰ The CDC reports 13.9 percent of cycles for couples with unexplained infertility making use of fresh nondonor eggs or embryos; cycles making use of fresh nondonor eggs or embryos represent 68.5 percent of all ART cycles. Couples' diagnoses are only reported for those cycles making use of fresh nondonor eggs or embryos, so the actual numbers may be higher.

¹¹ These numbers reflect live birth rates and do not include multiple pregnancies that miscarried or were reduced by fetal reduction. See Centers for Disease Control and Prevention, "2010 assisted reproductive technology: national summary report."

¹² MA Seoud et al., "Outcome of twin, triplet, and quadruplet in vitro fertilization pregnancies: the norfolk experience," *Fertility and Sterility* 57, no. 4 (1992).

¹³ R.C Wimalasundera, G Trew, and N.M Fisk, "Reducing the incidence of twins and triplets," *Obstetrics & Gynecology* 17, no. 2 (2003).

¹⁴ Robert H. Blank, "Assisted reproduction and reproductive rights: the case of in vitro fertilization," *Politics and the Life Sciences* 16, no. 2 (1997).

¹ Wimalasundera, Trew, and Fisk, "Reducing the incidence of twins and triplets."

¹⁵ B. Luke, "The changing patterns of multiple births in the united states: maternal and infant characteristics, 1973 and 1990," *Obstetrics & Gynecology* 84, no. 1 (1994).

¹⁶ F. M. Helmerhorst et al., "Perinatal outcome of singletons and twins after assisted conception: a systematic review of controlled studies," *British Medical Journal* 328, no. 7434 (2004); R. A. Jackson et al., "Perinatal outcomes in singletons following in vitro fertilization: a meta-analysis," *Obstetrics and Gynecology* 103, no. 3 (2004).

¹⁷ J. Reefhuis et al., "Assisted reproductive technology and major structural birth defects in the united states," *Human Reproduction* 24, no. 2 (2009).

¹⁸ Dorte Hvidtjørn et al., "Cerebral palsy, autism spectrum disorders, and developmental delay in children born after assisted conception: a systematic review and meta-analysis," *Archives of Pediatric & Adolescent Medicine* 163, no. 1 (2009).

²⁰ Centers for Disease Control and Prevention, "2010 assisted reproductive technology: national summary report."

²¹ David Grainger as quoted by Liza Mundy, *Everything conceivable: how assisted reproduction is changing men, women, and the world* (New York: Alfred A. Knopf, 2007). 254.

²² Ibid.

²³ Luke, "The changing patterns of multiple births in the united states: maternal and infant characteristics, 1973 and 1990."

²⁴ Gallup, "'Pro-choice' americans at record-low 41 percent," (May 2012).

²⁵ R. D. Nachtigall et al., "Parents' conceptualization of their frozen embryos complicates the disposition decision," *Fertility and Sterility* 84, no. 2 (2005).

²⁶ This is a 2007 estimate; numbers are likely higher now. See DI Hoffman et al., "Cryopreserved embryos in the United States and their availability for research," *Fertility and Sterility* 79, no. 5 (2003).

²⁷ Nachtigall et al., "Parents' conceptualization of their frozen embryos complicates the disposition decision."

²⁸ Infertility services are defined in the study as including any consultation or treatment for infertility.

²⁹ A. Chandra and E. H. Stephen, "Infertility service use among U.S. women: 1995 and 2002," *Fertility and Sterility* 93, no. 3 (2010).

³⁰ Mundy, *Everything conceivable: how assisted reproduction is changing men, women, and the world*: 222.

³¹ Blank, "Assisted reproduction and reproductive rights: the case of in vitro fertilization."

³² PJ Neumann, SD Gharib, and MC Weinstein, "The cost of a successful delivery with in vitro fertilization," *New England Journal of Medicine* 331, no. 4 (1994).

³³ *Catechism of the Catholic Church*, (New York: Doubleday, 1995). §2376 and 2270-2275.

³⁴ Zabeena Pandian, Ahmed Fathy Gibreel, and Siladitya Bhattacharya, "In vitro fertilisation for unexplained subfertility," *Cochrane Database of Systematic Reviews*, no. 2 (2005).

³⁵ D. Guzick and J. Queenan jr, "Evaluating the efficacy of intervention," *Endocrinology &*

Metabolism Clinics of North America 32, no. 3 (2003).

³⁶ Pandian, Gibreel, and Bhattacharya, "In vitro fertilisation for unexplained subfertility."

³⁷ Another Cochrane review finds that there is, in fact, "no evidence of clinical benefit of clomiphene citrate for unexplained fertility." See E Hughes et al., "Clomiphene citrate for unexplained subfertility in women," *Cochrane Database of Systematic Reviews*, no. 1 (2010).

³⁸ Pandian, Gibreel, and Bhattacharya, "In vitro fertilisation for unexplained subfertility."

³⁹ S. Bhattacharya et al., "Clomifene citrate or unstimulated intrauterine insemination compared with expectant management for unexplained infertility: pragmatic randomised controlled trial," *British Medical Journal* 337, no. aug07 2 (2008).

⁴⁰ Guzick and Queenanjr, "Evaluating the efficacy of intervention."

⁴¹ HKA Snick et al., "The spontaneous pregnancy prognosis in untreated subfertile couples: the walcheren primary care study," *Human Reproduction* 12, no. 7 (1997).

⁴² Guzick and Queenanjr, "Evaluating the efficacy of intervention."

⁴³ Bhattacharya et al., "Clomifene citrate or unstimulated intrauterine insemination compared with expectant management for unexplained infertility: pragmatic randomised controlled trial."

⁴⁴ Congregation for the Doctrine of Faith, "Instruction *donum vitae* on respect for human life at its origins and for the dignity of procreation," (1987); Congregation for the Doctrine of Faith, "Instruction *dignitas personae* on certain bioethical questions," (2008).

⁴⁵ N. Gleicher and D. Barad, "Unexplained infertility: does it really exist?," *Human Reproduction* 21, no. 8 (2006).

⁴⁶ Ibid.

⁴⁷ Ibid.

⁴⁸ Thomas W. Hilgers, *The medical & surgical practice of NaProTechnology* (Omaha, Nebraska: Pope Paul VI Institute Press, 2004).

⁴⁹ J. B. Stanford, T. A. Parnell, and P. C. Boyle, "Outcomes from treatment of infertility with natural procreative technology in an Irish general practice," *Journal of the American Board of Family Medicine* 21, no. 5 (2008).

⁵⁰ Ibid.

⁵¹ Phil C. Boyle, "NaProTechnology and pregnancy following failed ART," in *The Medical & Surgical Practice of NaProTechnology*, ed. Thomas W. Hilgers (Omaha, Nebraska: Pope Paul VI Institute Press, 2004), 673.

⁵² See Hilgers, *The medical & surgical practice of NaProTechnology*. and Thomas W. Hilgers, "Near adhesion-free reconstructive pelvic surgery " *Journal Of Gynecologic Surgery* 26, no. 1 (2010).

⁵³ Richard J. Fehring, "Current medical research winter 2008-spring 2009 " *The Linacre Quarterly* 76, no. 4 (2009).

⁵⁴ Stanford, Parnell, and Boyle, "Outcomes from treatment of infertility with natural procreative technology in an Irish general practice."

⁵⁵ Ibid.

⁵⁶ Pandian, Gibreel, and Bhattacharya, "In vitro fertilisation for unexplained subfertility."

⁵⁷ Stanford, Parnell, and Boyle, "Outcomes from treatment of infertility with natural procreative technology in an Irish general practice."

⁵⁸ Hilgers, *The medical & surgical practice of NaProTechnology*: 22.

⁵⁹ Stanford, Parnell, and Boyle, "Outcomes from treatment of infertility with natural procreative technology in an Irish general practice."

⁶⁰ Centers for Disease Control and Prevention, "2010 assisted reproductive technology: national summary report."

⁶¹ Chuck Weber, "The state of NaProTechnology," *The Catholic World Report*, February 2011.

⁶² Hilgers, *The medical & surgical practice of NaProTechnology*.

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Physicians in a New Health Care Context: Two Reflections

Editor's Note: The following reflection was delivered as part of a panel at the CHA-sponsored Theology and Ethics Colloquium on March 22, 2013.

Ethical Challenges and Opportunities in Physician Employment: A Brief Reflection

John Paul Slosar, Ph.D.
Vice President, Ethics Integration & Education,
Ascension Health
Vice President, Ethics
Ascension Health Care Network
jslosar@ascensionhealth.org

Whether due to an inevitable move toward population health management, the passage of the Affordable Care Act, or a combination thereof, there has been a significant trend of late toward physician employment by hospitals and health systems, including Catholic systems. As with most things, this trend brings both opportunities and challenges. In this brief reflection, I will offer an initial identification of what I see to be the most pressing challenges and opportunities related to physician employment. In addition to the ethical challenges and opportunities, I will begin by briefly exploring the concept of physician employment itself and end with a brief observation regarding a practical implication to which Catholic ethicists should attend.

The first question we must ask as we begin to think about this topic is how do we understand the very concept of

employment in the context of physicians? Physicians are indeed a special breed of persons (please don't take offense if you are a physician; I am heading somewhere with this). Likewise, one might assert that physicians are a special breed of professionals. Their authority to practice medicine, after all, does not come from their employment status but from the authority that states grant them through the licensure process. To put it more succinctly, physicians are physicians first and employees second. Likewise, nearly, if not all, states have some type of legal regulation prohibiting hospitals from engaging in the practice of medicine and from controlling the practice of medicine by any physician, including those employed by the hospital. This is true whether or not that hospital is in a state that has a formal anti-corporate practice of medicine statute. In this way, physicians have a greater sphere of professional and moral agency than other types of

employees might normally enjoy in their relationship with their employer. Physicians simply are not limited in their professional capacity to acting as an agent of their employer. This has implications for how we understand what physicians can do on their own, that is, as their own moral and professional agents, what we as Catholic health care can do with our employed physicians, and what we can, should, or must do for them.

While employment establishes greater opportunity for influence, this influence is not achieved through the direct exercise of control. The influence we gain through employment is primarily achieved in two other ways. First, as hospitals and health systems we have influence through the control of what *we as Catholic organizations* will or will not actively participate in, permit, or provide the means for within our facilities. Second, our influence is also established through the alignment with the employed physicians that comes from compensation structures and other non-financial benefits, such as alleviating physicians from the burden of managing the “business” of medical practice and allowing them more time to care for patients, which is why they went into medicine in the first place. These considerations give rise to conceptual questions regarding just how much control and how much influence is garnered through an employment relationship. Does it even make sense to speak in terms of control, or are physicians such a special breed of professionals that we must limit our conceptual understanding of the opportunities and

challenges that physician employment brings in terms of influence alone?

The fact that we inherently must partner with physicians, whether that partnership takes the form of employment or some other form of alignment, in order to live out our healing mission raises some classic questions of cooperation in intrinsically evil, i.e., objectively immoral, acts. Given that employment does not necessarily establish control over physicians’ practice of medicine, and physicians therefore retain some professional and moral agency independent of the employing institution, these issues will persist in the new landscape of health care. These are not new issues, and for the purpose of this brief reflection I need not spend substantial time on the cooperation questions related to employing physicians who might prescribe contraceptives in the course of a well-woman visit or physicians who might want to retain the ability to perform tubal ligations or vasectomies independently of and outside the scope of their practice with a Catholic health care institution. These questions alone could constitute the substance and breadth of an entire book. However, for the purpose of this reflection, all I really need to say is that whether our approach to structuring physician-employment agreements and the support services we provide to their practice will remain essentially the same in this respect or will need to be somehow different in the new health care landscape largely depends on how one understands the independence of physician agency in light of the balance between control and influence that results from a physician-employment relationship.

Of course, challenges are not the only consequence of physician employment. In fact, I would suggest that the challenges are not even the primary consequence. To the contrary, the alignment and influence that come along with physician employment bring about many more opportunities to advance the Catholic identity of the healing ministry than it does challenges. Ultimately, I would argue that these opportunities to have a positive moral influence on the practice of physicians strengthens the ability of the Catholic health ministry to be a prophetic voice and pay public witness to Catholic values within and for the good of society, which itself constitutes a proportionate good that justifies most (if not all) of the instances of *mediate* material cooperation that may result from employing physicians.

In particular, physician employment provides unique opportunities to have positive influence in three key areas of moral concern to the healing ministry. First, there is evidence, at least anecdotal, of an increasing trend in some markets of physicians who are unwilling to take Medicaid or Medical Assistance patients (and there are likely many rational reasons for this with two of the most significant being pressure to meet RVU goals and the cost of a medical education today). Along with this hesitancy comes difficulty in finding physicians to take on-call duty for the ED. Physician employment offers the opportunity to incentivize these physicians through their compensation structures to care for more patients who are poor and vulnerable. This will also be a significant advantage once reimbursement moves to a

pay for performance model in which many physicians may have concerns about caring for the underinsured who often present with greater acuity, multiple comorbidities and increased complexity.

Second, by providing a combination of more practice management services, quality and efficiency protocols, data analytics, network development and care-design models, we will be able to have significant influence on the type and way that employed physicians actually provide care to patients. Specifically, we will be able to offer physicians the environment and capabilities to provide holistic, person-centered care of the highest quality and safety. Of course, it takes more than just incentives and infrastructure to provide such care; it also takes the desire and will to do so.

This brings me to the third key area of opportunity for influence--physician formation in the context of Catholic culture and values. In addition to helping physicians see the value in holistic person-centered care, physician formation programs can offer opportunities to provide more adequate education around Catholic values, spirituality and anthropology as well as to restore the physician's connection to her original sense of vocation and to a robust understanding of the philosophy of medicine, all of which ultimately improves patient care. In the end, employment offers a meaningful context within which to care for the physicians who care for our patients.

FROM THE FIELD

I would like now to conclude with a brief observation regarding an important implication of physician employment, specifically, the question of values-compatibility. The question of whether and how we screen for values-compatibility in our processes of hiring physicians—whether we give these considerations serious weight in the selection process or simply leave the selection of physicians solely to the whim of market forces and referral patterns—becomes of increasing importance in the new landscape of health care. As Accountable Care Organizations, “Narrow Networks” and Integrated Delivery Systems become the norm, we will find ourselves doing even more with and for our employed-physician partners. As ethicists, we must be persistent in support of our strategy, business, and operations leaders to help them understand what it means for physicians to be values-compatible and the importance of selecting for values-compatibility, even as the concept of values-compatible physicians itself evolves in response to this new landscape.

Physician Blessing in Health Care Reform

Kelly Stuart, MD, MPH, MTS
 Medical Director, Clinical Ethics
 Bon Secours Virginia HealthSource Inc.
kelly_stuart@bshsi.org

The same night he got up and took his two wives, his two maids, and his eleven children, and crossed the ford of the Jabbok.

²³ *He took them and sent them across the stream, and likewise everything that he had.*

²⁴ *Jacob was left alone; and a man wrestled with him until daybreak.* ²⁵ *When the man saw that he did not prevail against Jacob, he struck him on the hip socket; and Jacob's hip was put out of joint as he wrestled with him.*

²⁶ *Then he said, "Let me go, for the day is breaking." But Jacob said, "I will not let you go, unless you bless me."* ²⁷ *So he said to him, "What is your name?" And he said, "Jacob."*

²⁸ *Then the man said, "You shall no longer be called Jacob, but Israel, for you have striven with God and with humans, and have prevailed."* ²⁹ *Then Jacob asked him, "Please tell me your name." But he said, "Why is it that you ask my name?" And there he blessed him.* ³⁰ *So Jacob called the place Peniel, saying, "For I have seen God face to face, and yet my life is preserved."*

(Genesis 32:22-30 NRS)

I have a confession to make. When the Affordable Care Act first passed and was signed into law, I cried. I felt sick. Yes, I am an absolute believer that all of humanity should care for each other, and all people deserve medical care, regardless of ability to pay. Yes, I believe we, physicians, should share our gifts and our

wealth with those in need. Yet I found myself in crisis over the health care reform bill. Many say that the frustration physicians feel about the bill stems from being left out of the debate, and this is true for a good number of physicians. I believe there is more to it than that. I did not know it at the time, but *I was mourning our profession's inability to recognize and participate in the full blessing.* There has been so much talk about the rights that individuals have to medical care that there has been little or no regard for *the blessings that all of humanity has to gain from caring for each other.* Sure, it is obvious to most people that healthy societies have the best chance at flourishing, but it is not as obvious to many people that how we get there matters.

The United States government is concerned with addressing the health needs of its citizens, and thus it has determined that physicians are just going to get on board with reform or be left out entirely. Indeed, health care reform already failed in the nineties, and the legislative majority and executive branch were not going to take the chance that any opposition would prevent the current reform. While essentially leaving

dissenting physicians out of the debate violates the leadership concept of subsidiarity, it may be understandable for a government looking to meet the health needs of a population groaning under the weight of widening disparity.

Still, there is more at stake than medical needs and services. There is opportunity here for real benefit beyond physical wellness. *Willingly caring for all humanity holds the potential for profound reciprocal blessing for physicians and patients*; our government simply is not equipped to concern itself with that aspect of reform.

Fortunately, Catholic health care has the means and the perspective to do better by its providers. We can take this opportunity to embrace physicians' struggles and encourage their volitional participation in service to humanity – the blessing of right relationship, friendship, love.

There is a lot of discussion today about health care as a basic human right. Catholic health care organizations have always tended to the needs of the poor and disenfranchised of the world who are unable to represent their own needs, and this caring for humanity stands grounded in sound biblical and theological foundations. So when did the notion of health care as a basic human right enter into the modern conversation for Catholic health care? In 1963 Pope John XXIII issued the encyclical *Pacem in Terris*. In it, he beautifully presents the cosmic truth that in order for humanity to thrive in creation, we must tend to one another's

needs by acknowledging and respecting certain rights. Included in these rights is medical care – particularly, “the right to be looked after in the event of ill health” and “disability stemming from [a person's] work” (11).¹ This encyclical had significant meaning at a time in which the world populations were just beginning to make progress in the struggle against social injustice in the face of seemingly endless world resources and abundance. The sixties brought the face of global crimes against humanity and the American civil rights movement into the forefront. For this and other reasons, rights language emerged as relevant and helpful. Drew Christiansen notes, “In the 1960s most educated Catholics and even more non-Catholics assumed that natural law was consistent with the language of duties but not with the language of rights. So the encyclical's recourse to rights language itself constituted an intellectual challenge. For some it seemed a capitulation to the Enlightenment; to others it amounted to an overdue encounter with the secular (western) world.”² Rights language functioned as both a means of expressing humanity's need to rid the world of oppression and to align the language of the Catholic Church with other groups that had the same goals.

But *Pacem in Terris* does not simply refer to rights alone; duties remain important. Specifically, there is a duty of society to recognize and support each person's rights. “Hence, to claim one's rights and ignore one's duties, or only half fulfill them, is like building a house with one hand and tearing it down with the other”

(9,30).³ The Christian duty to care for humanity is foundational. More specifically, emphasis on the duty to care for those without the means to care for themselves (widows, orphans, aliens, family members, prisoners, neighbors) shines through both Old and New Testaments. This duty, as acknowledged, affirmed and accepted by caretakers, is the spine that allows rights to stand erect. We should not discuss rights without discussing duties. Frederick Bauerschmidt illustrates the dangers of taking rights language out of the context of duties language in his discussion on abortion, for “what seems like common ground, human beings as possessors of rights, yields virtually nothing by way of agreement on the question of abortion. Whatever the merits of ‘rights talk’ in other contexts, in the context of abortion it has proved perplexingly unfruitful.”⁴ In a similar, though less obvious way, *rights language may be detrimental to gaining constructive physician participation in health care reform.*

Yet, rights language dominates the conversation today. While the sixties birthed human rights as a concept in the face of abundance and hopeful liberation, the third millennium is heralded by the global realization that our resources are limited, and our rights, while theoretically considered equal for all, really compete. In contrast to the 60s’ androcentric view of creation and economics, today’s environmentalists remind us that we must be good stewards of our interdependent natural resources, and medical professionals are particularly sensitive to

finite health care resources. For this reason, it is imperative to include another core concept of the encyclical: volition. Although *Pacem in Terris* clearly expresses that every person must freely choose to do what is good, without coercion (9, 34), there is little written on this portion of the document.⁵

Humanity’s relationship with God has always allowed for our failure, while remaining hopeful of our good choices. There was no fence around the tree in the middle of the garden, and there can be no real relationship without the possibility of failure. If we only discuss rights without considering duties and volition, then we are left with unresolved conflict – competing interests – and the course of action is lost in the dogged determination to assert exclusively one’s individual or group interests. According to the *Catechism of the Catholic Church*, “as long as freedom has not bound itself definitively to its ultimate good which is God, there is the possibility of choosing between good and evil, and thus of growing in perfection or failing and sinning. This freedom characterizes properly human acts. It is the basis for praise or blame, merit or reproach.... The more one does what is good, the freer one becomes.”⁶ Advancing the idea of rights without concomitantly emphasizing duties and volition sets us up for failure because, if the goal is God, humanity must *choose* to tend to its duties in support of others’ benefit, rather than one’s own, and choosing that option once, leads to choosing it many times.⁷

How important is human will – physician will – in health care reform? Is volition really essential to the blessing of right relationship in health care or is this notion just the obstinate insistence of one willful physician? At a foundational level, humans retain the same free will that God wove into the first couple in the garden, but is that a good thing? Augustine of Hippo asserted early in the fifth century that free will is a good thing that God bestowed upon humans in order to enable us to “live rightly.”⁸ Still, why is there even an option to live wrongly? Simple answer: God wants a genuine relationship with humanity. We are to be God's servants, but we are not intended to be God's minions or drones. The difference in being God's willing servants and being a drone is not just in the exertion of will, but in the richness of relationship. We see in Genesis 1 that God is omnipotent and can create and control from a distance, but we see in Genesis 2 and 3 that God actually touches and walks in the garden with Adam. It is not so much that God allows Adam and Eve to fail and fall as it is that God cultivates a real relationship, and that is a risky venture. Indeed, God's desire for and investment in relationship with humanity is superlatively exemplified by the incarnation of Jesus.

Augustine's equivalent of a minion or drone in its simplest form is a stone. Both a stone and a human may move, but a stone does not will its movement in any direction. Augustine refers to the stone's passive movement as “natural,” but “nothing can make the mind a slave to inordinate desire against its own will...the

movement by which the will turns from enjoying the Creator to enjoying his creatures belongs to the will itself.” For this reason, Augustine refers to the mind's movement as “voluntary.” There is nothing blameworthy or praiseworthy about natural movements; only voluntary movements can be so described.⁹

Still, patients might be better served than they currently are even with unwilling, forced participation of physicians, right? Yes, patients' physical health might still be better served, but is it not reasonable to hope that care providers also benefit from the fullness of relationship? Unidirectional service cannot be the only goal.

God knows and has always known that we will frequently fail, but apparently God delights in the few moments of success in our relationships with each other, and therefore with God, enough to constantly and repeatedly endure our failure and offer grace. The reason it is important to willingly see the face of God in every patient is that our relationships with patients are really modeled after and indicative of our relationship with God. We were not created as drones, but we were created, seemingly intentionally, as willing servants, and authentic relationship should be our goal. As Aquinas explains, there is an ultimate end (goal) for human life, which is good, and that end is sought through our willing relationship with our creator: “For man and other rational creatures reach their ultimate end by knowing and loving God.”¹⁰

The current state of overall health in America begs the question – does the medical system we operate in today help or harm our nation’s overall health? Somehow all our effort, education, and resource investment do not translate to a healthier population or better outcomes. The richest potential aspects of relationship seem to be unrealized, for the most part, in American medicine. Trust, concern, and intimacy are no longer assumed to be integral to the interaction, and the relationship has become less genuine and less fulfilling for both parties. As physicians, the reason we must willingly perform our duty to uphold society’s right to health care is that we then work toward our own blessing within the context of humanity, and it is in cultivating relationships that Catholic health care can improve on reform. We can acknowledge with physicians that, whatever the new legislation imposes, *there is no relationship without willing service*, and God’s example to us is relationship. For this reason, we must train our wills to strive for unchangeable good rather than temporal good.

Little commentary exists about the concept of volition in Pope John XXIII’s encyclical, but there is commentary on another aspect of *Pacem in Terris* that can only be considered as volitional – love. “That is, Christian love enables one to see in the ambiguous historical developments opportunities and positive accomplishments...which contribute to the growing unity in the human family.”¹¹ Without love we are caught in a downward spiral of competing rights:

humanity can assert its right to health care, but physicians have the right to compensation for their work, and physicians have the right to refuse to work. This battle of competing rights makes no progress toward the blessing that willingly caring for each other approaches. *The opportunity for rich, interdependent blessing - for right relationship - in health care delivery gets lost in the midst of the seemingly perpetual struggle for individual or collective rights.*

If we discuss rights in the context of duties and volition, we become relational and less confrontational; choices become clearer, and our will is drawn to unchangeable good. We see our goal through a different lens and realize that all of humanity has a right to medical care, and all of humanity has a duty to care for each other. Then the question that confronts physicians is: are you willing to care for humanity, regardless of social status, ethnicity, citizenship and ability to pay? In short, can you participate in the right relationship that Aquinas called friendship by offering Christian love? The conversation becomes richer, as does the potential blessing of doing the transformational work we accomplish together each day in Catholic health care.

If physicians are to will well by Aquinas’ standards -that is, if physicians are to choose Christian love and friendship and God over competing interests, then Catholic health care needs to do what the Church has done well for centuries. We must be pastoral in our language and recognize that physicians need shepherding just like the rest of the flock.

In particular, physicians facing uncertainty need shepherding now. Aquinas explains that, while the ultimate end of the will is reached by knowing and loving God, “one need not always be considering the ultimate end when desiring or doing something.”¹² Indeed, for the ultimate end to be achieved we need to develop “well-disposed affections” because we frequently “mistakenly seek [it] in other things” and “turn away from that in which the ultimate end is truly found.”¹³ That is, we sin.

The language of the Affordable Care Act presumes that physicians already have “well disposed affections.” This legislation is not the equivalent of determining new traffic regulations or interstate commerce. This legislation demands that one particular profession rethink its affections. Catholic health care can improve on the limited, linear language of legislation by recognizing and validating the profound moral struggle many physicians are experiencing with health care reform. *Rights language alone is not pastoral, but rights coupled with duties and volition allows us to occupy a moral space, a relationship.* So, physicians may reframe the above question from their own perspective: do I value and seek to offer and receive the blessing?

What about the danger of failure? What about the physicians who choose not to participate willingly in health care reform? That is the risk of relationship. The book of Genesis further illustrates the willing struggle of man following God’s call in the person of Jacob. When God called Jacob

to leave Laban’s house and return with his family to the land of his birth, Jacob knew that he would have to face Esau, the twin brother that he essentially swindled out of both birthright and blessing. Jacob was scared of Esau’s strength and likely resentment. As Jacob neared his homeland, he became more worried about following God’s call. Finally, Jacob reached the Jabbok River that marked the entrance to his homeland. He sent his family and possessions across, but he remained another night on the safe side of the river. A man - or spirit, or will - approached in the dark, and Jacob wrestled with him until morning when the man declared that Jacob had prevailed and should let go. Even though the man had dislocated Jacob’s hip, Jacob refused to let go until the man blessed him. So, the man blessed and then renamed Jacob Israel, which means “strives with God.” Indeed, Jacob prevailed not in defeating the spirit of God but in enduring pain and staying in the struggle through the darkness of night and into the light of day – the day that marked the brothers’ peaceful reunion, the mending of their relationship. We all wrestle with our own spirits and bear the scars of the blessings we seek. Indeed, the only way to achieve the blessing is to continue to strive, to struggle, with our own spirits and our own wills in our relationship with humanity and God.

After about a generation of rewarding smart business practices as much or more than good medical skills, our country now demands that physicians change their entire way of practicing and receiving

compensation. Physicians are being told to change their culture and to reconsider what we value, but if we are to change our values we should probably change our language, too. If we are to consider health care a right and accept this change as our duty and calling, we should struggle with our spirits, come to the conclusion of love, and find our blessing in willing relationship with humanity and God. Jacob did not defeat the spirit but rather struggled with it until the morning came. Similarly, physicians rather than defeating health care reform might insist on our blessing in it. Some doctors have crossed the river with their hands ready to work, but others are still struggling on the safe side. Like the United States government, Catholic health care is concerned with the physical well-being of its patients, but Catholic health care is not limited to that end or that language. Using rights language without acknowledging duties and volitional love fails to convey blessing. If we allow and encourage providers to struggle with their spirits and willingly come to the blessing, we will do so much more than address our physical needs. Pope John XXIII described more than peoples' right to medical care. *Pacem in Terris* puts forth a plan for the full blessing. Isn't that the real reason we became doctors?

¹ Pope John XXIII. "Pacem in Terris," www.vatican.va/.../hf_j-xxiii_enc_11041963_pacem_en.html

² Drew Christiansen, "Commentary on *Pacem in Terris*," in *Modern Catholic Social teaching: Commentaries and Interpretations*, ed. Kenneth R. Himes, (Georgetown University Press: Washington, DC, 2005): 224.

³ *Pacem in Terris*, no. 30.

⁴ Frederick C. Bauerschmidt, "Being Baptized: Bodies and Abortion," in *The Blackwell Companion to Christian Ethics*, ed. Stanley Hauerwas and Samuel Wells (Blackwell: Malden; 2006): 250.

⁵ *Pacem in Terris*, no. 34.

⁶ Article 3: Man's Freedom. *Catechism of the Catholic Church*, United States Catholic Conference (Liguori: Liguori MO, 1994): 430, nos. 1732-3.

⁷ Thomas Aquinas, "Treatise on Happiness," *Summa Theologica*, trans John Osterle (University of Notre Dame Press reprint 1983. Prentice Hall; Englewood Cliffs, 1964): 8-14

⁸ Augustine, "On Free Choice of the Will," trans Thomas Williams (Hackett; Indianapolis, 1993): Book 2, nos. 1 and 18, pp. 30, 64.

⁹ Augustine 72-3; Book 3, sections 1, 2.

¹⁰ Aquinas, "Treatise on Happiness," *Summa Theologica* trans John Osterle (University of Notre Dame Press reprint 1983. Prentice Hall; Englewood Cliffs, 1964) 8-14.

¹¹ Christiansen, 226.

¹² Aquinas, 12.

¹³ Aquinas, 13.

Moving Health Care Ethics into the Future

In this issue of *Health Care Ethics USA*, Rachelle Barina and Emily Trancik call for more work on ethical issues arising in the outpatient setting and greater efforts to move ethics into that context. Much the same could be said about ACOs, the emphasis on population health and employed physicians and physician groups. There is a paucity of literature in these areas that deals with ethical concerns as well as how ethics can be integrated into these newer realities. These alternative structures for health care delivery are ripe for new initiatives.

Another emerging area in health care ethics is “green bioethics.” At this year’s Theology and Ethics Colloquium, the winner of the graduate student essay contest, Christina Richie from Boston College, delivered her essay titled “Building a Framework for Green Bioethics: Integrating Ecology into the Medical Industry.” Richie states that the *telos* of green bioethics is “to promote green medical developments, techniques and procedures and reduce or eliminate ecologically harmful medical developments, techniques and procedures.”¹ She proposes four priorities to achieve this goal. The first is to place human needs before wants in order to reduce resources. The second is simplicity before complexity. “I suggest that approaches to treating and healing disease rely on simple measures before complex, expensive, or multi-step procedures are

undertaken.” The third priority expands our health care system’s scope of concern, that is, how it affects the weak and disadvantaged in this country and beyond. A green bioethics calls for global medical justice. Finally, a green bioethics promotes compassion and justice above marketing medical developments, techniques, and procedures for monetary gain. Such an approach would allow the medical industry “to focus less on production and more on conservation.” Obviously, much more could be said about each of these priorities as well as the theological and ethical grounding of green bioethics. All that is intended here is to signal another developing area in health care ethics that is ripe for further work.

Another emerging area that is fertile for further exploration is nanomedicine. “Nanomedicine’ is a field comprising medical applications of nanotechnology, while ‘nanomedicines’ are pharmaceutical products that comprise an enabling nanotechnological component, often a carrier, or vector, for the drug itself.”² And “nanotechnology” is understood “to refer to the manufacturing, characterization, and use of man-made devices with dimensions on the order of 1-100 nanometers(1nanometer [nm] = 1 billionth of a meter).”³ Nanotechnology is likely to become of considerable importance in personalized medicine where there is a desire to provide a particular therapy to a particular location in a patient’s body at a particular time in the course of a disease. “In such a detailed situation, it becomes necessary to have

tools that are very specific, controllable in time and space, and responsive to therapeutic needs as the patient progresses through therapy.”⁴ This is especially true of cancer therapy. “For example, nanoparticle vectors can enable site-selective delivery of therapeutics. Nanochannel systems can be used to produce ‘nanoglands’ that release drugs from implants to enable timed-release and triggering of beneficial responses. ... The engagement of the body’s healing processes and the ability to enhance these processes is at the very heart of regenerative medicine, and nanotechnology and nanomaterials have an essential role in providing stimulatory and protective scaffolds where stem cells can rebuild, repair, and regenerate dysfunctional and damaged tissue.”⁵

Nanomedicine is not without its ethical issues, though, as the authors point out, the vast majority are similar to if not identical with ethical concerns raised by other advances in medicine. “[I]n all respects explored in the field, the ethical questions posed by nanomedicine are the identical counterparts of questions that have arisen in multiple other domains of medicine and medical research: no new categories of bioethical thoughts have emerged to date.”⁶ This is not to say, however, that there are no ethical issues that have to be surfaced and addressed.

They range from risks and benefits to patients, to the use of the extensive information gained by molecular profiling of individuals enabled by nanotechnology, to equitable access, especially in poor areas and developing countries and much else in between.⁷

Obviously, there are other developing areas in medicine and science that require ethical analysis, neuroscience, for example. All of these and other areas call for attention. They call us beyond the confines of our usual issues. Neglecting them will once again mean that science and medicine outpace ethics, by leaps and bounds. And we will inadequately serve those who look to us for assistance.

R.H.

¹ Christina Richie, “Building a Framework for Green Bioethics: Integrating Ecology into the Medical Industry,” unpublished manuscript, 2013.

² Rebecca Hall, Tong Sun, and Mauro Ferrari, “A Portrait of Nanomedicine and Its Bioethical Implications,” *Journal of Law, Medicine, & Ethics* (Winter 2012): 764.

³ *Ibid.*, p. 763.

⁴ *Ibid.*, p. 766.

⁵ *Ibid.*, p. 767.

⁶ *Ibid.*, p. 776.

⁷ *Ibid.*, pp. 767-776. See also Dresser, Rebecca, “Building an Ethical Foundation for First-in-Human Nanotrials,” *Journal of Law, Medicine, & Ethics* (Winter 2012): 802-808.

Of Note

Study: Boost in Hospice Visits by Way of the ICU

A recent study published in the *Journal of the American Medical Association* found that more Medicare patients are using hospice care, from 22 percent in 2000 to 42 percent in 2009. Although this appears to be good news, the details of the research tell a different story. Researchers found that many patients were only in hospice for a few days and usually entered after stays in the ICU. The number of patients transferred from one setting to another in their last three days has increased as well. Study author Joan Teno said that moving patients near the end of life can cause agitation, disruption of vital pain medication, and additional stress on the family. Researchers concluded that, "Short lengths of stay raise concerns that hospice is an 'add-on' to a growing pattern of more utilization of intensive services at the end of life." The Institute of Medicine has formed a task force called Coalition to Transform Advanced Care (C-TAC) to examine end-of-life care in light of the aging population and 2010 national health care law. (Joanne Kenen, *Politico*, Feb. 6, 2013)

Assisted Suicide on Legal Agenda in Several States

Although a ballot initiative to allow physicians to help terminally ill patients die failed in Massachusetts, the

conversation has spread across the country. State legislatures in Connecticut, New Jersey, New York, Vermont, Kansas, Arizona, Montana and Hawaii are all considering bills that would legalize assisted suicide. Connecticut legislature is set to hear at least two bills that could make it the first state legislature to legalize the practice. A bill allowing physicians to prescribe a lethal dose of medication has passed the New Jersey state Assembly and awaits voter approval. Although thirty-four states prohibit assisted suicide and seven have banned it, Montana's Supreme Court ruled that assisted suicide is medical treatment and Oregon and Washington passed right-to-die laws via voter referendum.

In Connecticut there are groups on both sides of the issue. Peter Wolfgang, directors of the Family Institute, believes that this is not the will of the people of Connecticut but out-of-state advocacy groups trying to influence Connecticut lawmakers. Dr. Gary Blick, a doctor who treats patients with HIV and AIDS, believes it is time for the state legislature to discuss this issue. "This is not for everybody. We realize there are people that do not believe in this for religious beliefs, and I respect that. But there are those subsets of people that do not want to go through the suffering that they have to go through." (Susan Haigh, Associated Press, Feb. 8, 2013)

Alzheimer's 'Epidemic' Now a Deadlier Threat to Elderly

Alzheimer's disease has become the sixth leading cause of death in the United States. Susan Mitchell, professor of medicine at Harvard, believes that the number of deaths caused by Alzheimer's may be much greater than recorded. She says that other medical problems are often listed as a cause of death when Alzheimer's is the actual cause. After conducting a study of patients with advanced dementia, Mitchell found that as the disease progresses it damages the brain in such a way that normal body functions are affected such as swallowing, balance and walking. Due to the disease's ability to diminish the body's defenses, the most common cause of death is infection. "The body is so debilitated, frail and weak at the end of dementia that some of the usual immunological and metabolic factors that can protect a healthy body from infections and fevers really become susceptible," Mitchell stated. These findings are important for families to know when making decisions regarding the care of their loved ones suffering from the later stages of dementia. (Jon Hamilton, *National Public Radio*, March 19, 2013)

New Data to Consider in D.N.R. Decisions

A recent study published in the *New England Journal of Medicine* looked at what happened to elderly patients who were discharged following an in-hospital cardiac arrest. Of those studied, 58.5 percent were still alive and 52 percent had

moderate or severe neurological damage. After leaving the hospital, 60 percent went to nursing homes, rehabilitation facilities or hospice. Dr. Paul Chan, lead author of the study, believes there is hope for resuscitation survivors. Improvements in hospital resuscitation such as use of therapeutic hypothermia to reduce brain swelling, quicker response times, and advances in performing CPR can significantly change outcomes. The quality of health post-cardiac arrest was not explicitly measured in the study. Study authors encourage doctors to share these findings with patients when discussing medical plans concerning cardiac arrest and resuscitation. (Judith Graham, *New York Times*, March 14, 2013)

Should Family Members Watch as their Dying Loved Ones Get CPR?

Researchers theorized that family presence during resuscitation might have positive results. Witnessing CPR might allow the family to know that all possible efforts were implemented to try to save the life of the patient. Family witness could also give loved ones an opportunity to say goodbye. Lastly, witnessing CPR could eliminate unrealistic expectations and end suspicion surrounding closed-door efforts. The study, published in the *New England Journal of Medicine*, supported the researchers' theories. The study found that family members who did witness CPR were less likely to have post-traumatic stress disorder or symptoms of anxiety and depression. The medical teams were concerned that family witnesses would be

in the way or lead to more lawsuits but this was not the case. Only 3 percent of those who witnessed CPR said they regretted it and one witness wrote a thank-you letter to the medical team. (Karen Kaplan, *LA Times*, March 13, 2013)

Key Long-Term-Care Insurer to Raise Women's Premiums

Long-term care insurance is not subject to the provision in the Affordable Care Act which prohibits insurers from charging premiums based on gender. Starting this spring, Genworth Financial, the country's largest long-term care insurance provider, will increase premiums for women who buy new individual policies by 20 to 40 percent. An increase in premiums is not a surprise because two of every three insurance claim dollars go to a woman. Other factors play a role such as women live longer than men, women act as caregivers keeping men's health care costs lower, and a lack of family caregivers who take care of women. Although the Affordable Care Act does not apply to Genworth, Colorado and Montana have state laws that prohibit premium costs based on gender. Advocates see this as an opportunity to encourage other states to adopt similar laws. (Michelle Andrews, *Kaiser Health News*, Feb. 26, 2013)

Hospitals Clamp Down on Dangerous Early Elective Deliveries

Delivering babies before 39 weeks without a medical reason is dangerous for both baby and mother. Babies have a higher

likelihood of breathing or feeding problems, infections and developmental problems later in life. Mothers who deliver early have higher rates of infection due to an increase in the occurrence of Caesarian sections. The Leapfrog Group, a group of the country's largest corporations that buy health care for employees, found that the national average of elective deliveries before 39 weeks decreased from 14 percent in 2011 to 11.2 percent in 2012. Although the decrease is promising there is still more to be done. Individual states have taken a role in lowering the number of early elective deliveries. The Midwest Business Group on Health has assisted Illinois lower the early deliver rate to 7 percent. South Carolina and Texas Medicaid stopped reimbursing for early elective deliveries. (Phil Galewitz, *Kaiser Health News*, Feb. 21, 2013)

Cell Therapy Shows Promise for Acute Type of Leukemia

A study published in the journal *Science Translation Medicine* gives great hope for the use of T-cell therapy to treat adults suffering from acute lymphoblastic leukemia. The treatment consists of extracting patients' T-cells and genetically engineering the T-cells to recognize and kill all B-cells which carry the protein CD19. The side effect of destroying all B-cells, even those that make antibodies, is treatable. Of the five patients studied, three are in remission, one died in remission from a blood clot and the fifth patient died after relapsing. All four of the patients that went into remission also received a bone marrow transplant. It is

unclear if the bone marrow transplant was necessary or if the T-cells would have been enough. Since a bone marrow transplant is standard, withholding that treatment would have been unethical. Dr. Michel Sadelain, senior author of the study, said “We’re creating living drugs. It’s an exciting story that’s just beginning.” (Denise Grady, *The New York Times*, March 20, 2013)

Students from the Center for Health Law Studies at Saint Louis University School of Law contributed the following items to this column. Amy N. Sanders, Assistant Director, Center for Health Law Studies, supervised the contributions of health law students Srishti Miglani (JD/MPH anticipated '15) and Michael K. Morton (JD anticipated '14).

The following submissions are by Srishti Miglani

Robot Watson to Provide Health Care

IBM’s Watson supercomputer is the next big IT breakthrough in health care delivery. It can process information and make recommendations much more quickly and intelligently than any machine that preceded it. It can make diagnoses and recommend treatments while giving a series of possibilities, each with its own level of confidence. Dr. Marty Kohn, the clinical leader of the IBM team training Watson for health care applications, said that in addition to primary care, Watson can help in specialized fields such as oncology. Unlike humans, Watson has the ability to process large amounts of information. Watson’s

abilities don’t end at diagnosis and suggesting treatment options- it also has an application to submit treatment proposals to managed-care companies for instant approval, thereby reducing administrative time for getting payment authorizations.

There are, however, some areas in which Watson still needs work. Before it becomes an integral part of the health care system it has to learn to extract relevant information and relationships from cases, understand and analyze medical information, and understand the various terminologies used by different people in the medical field. Some people are afraid that Watson might increase the cost of health care because it would suggest multiple possible diagnoses per patient which the doctor would want to further investigate with additional medical tests. Watson is currently being tested and developed at Memorial Sloan-Kettering Cancer Center and the Cleveland Clinic. In addition, WellPoint has begun testing Watson as a support tool for nurses who make treatment-approval decisions. IBM is very optimistic about Watson’s future prospects but it does not claim that Watson will replace doctors. Instead it sees Watson as a “clinical support tool rather than a decision-making tool.” (“The Robot Will See You Now” Jonathan Cohn, *The Atlantic*, Feb. 20, 2013 <http://www.theatlantic.com/magazine/archive/2013/03/the-robot-will-see-you-now/309216/>)

Where the Sequestration Cuts Are in HHS

Since Congress and the White House failed to agree on targeted levels of deficit reduction, The Budget Control Act of 2011 put sequester into effect. Budget cuts resulting from the sequester went into effect on March 1, 2013. On March 4, 2013 its effects began to be felt when the program offices of Department of Health and Human Services (HHS) began their cuts. The Office of Management and Budget reported that HHS programs, large and small, will be subjected to a 5.1 percent spending cut in this fiscal year.

Medicare and Medicaid are not subjected to the full budget cuts. Physician payments under Medicare were cut by 2 percent, while Medicaid did not suffer any budget cuts. On April 1, 2013 cuts in physician reimbursement went into effect resulting in \$11 billion in lost revenues. But other programs under the Centers for Medicare and Medicaid Services (CMS) will be subjected to budget cuts related to the sequester.

Budgets of other agencies will also be reduced during this fiscal year. For example: The National Institutes of Health (NIH) by \$1.5 billion, Centers for Disease Control and Prevention (CDC) by \$289 million, the Office of the National Coordinator for Health Information Technology by \$1 million, the Food and Drug Administration (FDA) by \$209 million, the Substance Abuse and Mental Health Services Administration by \$168 million, and the Indian Health Service by \$198 million. ("HHS Officials Begin Implementing Cuts in Federal

Health Programs Under Sequester" Ralph Lindeman, *BNA's Health Care Policy Report*, March 11, 2013
http://news.bna.com/hcln/HCLNWB/split_display.adp?fedfid=29966540&vname=hcpnotallissues&fcn=3&wsn=498759500&fn=29966540&split=0

Drug Costs Are Down but Increases on the Horizon

In 2012, for the first time in over fifty years, spending on prescription drugs dropped 1 percent to \$325.7 billion. Spending on commonly used medications, such as those used to control high blood pressure and high cholesterol, dropped by 1.5 percent. This drop has been attributed to the increasing use of generics. The use of generics was increased when dozens of brand name drugs, like Plavix and Lipitor, lost their patent protection.

The question is whether this drop in spending will continue; predictions say that it will not. Fewer drugs are set to lose their patent protection in the next several years. The use of generic drugs has been said to reach its saturation point at 84 percent and it is not estimated to go higher than 86 percent or 87 percent.

Despite the drop in the cost of traditional drugs, the spending on specialty drugs by commercially insured patients increased by 18.4 percent. These drugs tend to cost more than other prescription drugs and can cost up to \$200,000 per patient. IMS Health has predicted that the spending on drugs will increase by 4 percent in 2014 because fewer brand name drugs will lose

their patent protection and health care utilization will increase under the Affordable Care Act. That increase will be followed by a small dip in spending in 2015, with a subsequent rise of 4 percent in 2016. Steps are being taken to reduce spending and insurance companies and drug-benefit managers are either recommending patients to try the less expensive treatments first or they are seeking prior approval for higher-priced drugs. In addition, biosimilars, which are considered the generic version of biologics and cost 30 percent to 50 percent less than biologics, might be available in the United States in the near future. (“U.S. Drug Costs Dropped in 2012, but Rises Loom” Katie Thomas, *The New York Times*, March 18, 2013 <http://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?pagewanted=all&r=0>)

The President’s Brain Mapping Initiative

President Obama asked Congress to put \$100 million next year towards the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative. This funding would support the research at the National Institutes of Health (NIH), the Defense Advanced Research Projects Agency (DARPA), and the National Science Foundation. President Obama also urged the private sector to get involved with government agencies to further this research.

Even though the specific goals of this project are unclear, the ultimate goal is to understand the workings of the brain by tracking the activity of the individual cells and the neuronal connections. This research will hopefully facilitate better understanding of neurological and psychiatric disorders such as autism. The BRAIN initiative is hoped to be a return on investment and a much needed effort to understand, treat, and cure various neurodegenerative and psychiatric diseases. (“Obama Proposes Brain Mapping Initiative” Nedra Pickler & Malcolm Ritter, *Huffington Post*, April 2, 2013 http://www.huffingtonpost.com/2013/04/02/obama-brain-initiative_n_2999027.html)

Hospitals May Be Making Money from Errors

A study reported in *The Journal of the American Medical Association* (JAMA) showed that hospitals profit from their own mistakes because insurers reimburse them more for longer hospital stays and the extra services provided to patients to treat preventable surgical complications.

The study’s conclusion was based on a survey of the medical records of 34,256 people who had surgery in 2010 at one of 12 Texas Health Resources hospitals. Of these patients, 1,820 had preventable complications resulting in longer hospital stays. That resulted in hospital revenue averaging \$30,500 more for patients with complications than those without. Hospitals were reimbursed at a higher rate

by private insurers than by Medicare, Medicaid, or patients who paid for their bills out of pocket. The authors of this study used the contribution margin, a measure of a hospital's income and ability to cover its costs, to understand the relationship between services rendered and the resulting revenues. When complications arose, it tripled for patients with private insurance and doubled for Medicare patients.

The problem is the fee-for-service system which rewards quantity more than quality; the current payment system does not reward hospitals for performing better. To the contrary, it provides a disincentive for better training and improvements in hospital care because both cost money. The researchers not only urged for a quality-based payment system but for increased transparency in hospitals' reporting of their quality performance measures.

It should be noted that the study did not claim that the current payment system causes hospitals to deliberately cause complications in patients. Instead, it concluded that the payment system rewarded hospitals for the increased quantity of health care services provided as a result of complications when it should instead focus on rewarding hospitals that make improvements to reduce complications. ("Hospitals Profit From Surgical Errors, Study Finds"
Denise Grady, *The New York Times*, April 16, 2013
<http://www.nytimes.com/2013/04/17/health/hospitals-profit-from-surgical-errors->

[study-finds.html?emc=tnt&tntemail0=y&r=0\)](http://www.nytimes.com/2013/04/17/health/hospitals-profit-from-surgical-errors-)

The following submissions are by Michael K. Morton

Stem Cell Breakthroughs May Revolutionize Heart Failure Therapy

Heart attacks and heart failure often turn the human body's most powerful muscle into an inefficient circulation tool. Millions of heart cells are lost during heart attacks and other failure due to heart disease. In the absence of those cells, dense, unworkable scar tissue forms. This extreme reduction in healthy heart cells and increase in scar tissue negatively affects the rate at which the heart can pump blood through the body. However, research breakthroughs regarding harvesting and utilizing a patient's own stem cells can reverse the damage done by heart failure.

Beginning in 2009, a research team at the University of Louisville, had successfully harvested and reproduced stem cells taken from patients' own hearts who have experienced heart failure. Stem cells are vital to the reproduction of heart cells after a heart attack or other type of heart failure; however, this process only takes place within the body for up to two weeks after an attack. That short time frame does not adequately make up for the damage done by the heart attack. The ability to harvest and reproduce the stem cells outside of the body has given the research team the opportunity to discover whether this recovery period within the heart can

be lengthened by additional stem cell infusions.

After reproduction, the native stem cells are then pumped back into a patient's coronary artery through a catheter. While the experimental community is small – this has only been attempted on 16 patients – the results are positive and the outlook on future implications on heart failure recovery are exceedingly bright. In the sixteen patients who received this experimental native stem cell treatment, an 8 percent increase was seen in the amount of blood that the heart was pumping through the body after four months. This was compared to a control group of patients, who had received the standard treatment for heart failure, consisting of primarily beta blocker injections, resulting in 0.1 percent increase in pumping efficiency.

Impressively, analysis a year after this stem cell treatment revealed an average of a 30 percent reduction in scar tissue in the 16 patients receiving this breakthrough treatment. (A Change of Heart: Stem Cells May Transform Treatment for Heart Failure, Ferris Jabr, *Scientific American*, April 3, 2013

<http://www.scientificamerican.com/article.cfm?id=change-heart-stem-cell-treatment-heart-failure>)

Injecting Humanity into Medical Education

As medical schools hurry to keep up with the ever-changing world of medicine with additions to their required curricula, schools are also taking a step back to look

at patient care from a more holistic perspective. To that end, many medical schools are beginning to “teach” compassion and empathy, by adding required courses in the arts and humanities to their grueling sets of medical science courses.

The University of Chicago Pritzker School of Medicine has added a creative writing course to its curriculum. At Northwestern University's Feinberg School of Medicine, students are required to take two courses from the University's Humanities and Bioethics program in order to graduate. According to research done by Penn State University's College of Medicine, every medical school in the United States requires some coursework in medical ethics, while almost half now push their students to delve into the world of art and humanities.

While the old guard of medical education looks down upon such deviation from the standard scientific medical education, both younger educators and current practitioners have endorsed this new portrait of medical education in the United States. (Teaching Compassion, Lisa Pevtzow, March 20, 2013, *Chicago Tribune* http://articles.chicagotribune.com/2013-03-20/health/ct-x-medical-school-arts-20130320_1_doctors-humanities-students)

Failure to Warn Regarding Premature Subjects Leads to Reprimand

Death of premature babies who had taken part in a large research study has led to the Office for Human Research Protections (OHRP), a federal agency, notifying over 20 research institutions that their informed consent procedures did not adequately warn infant subjects' parents of the dangers of this given study. The study – named Support – was established to analyze the optimal amount of oxygen that should be administered to infants born prematurely. Oxygen support is crucial to premature infants, as their lungs are not yet fully formed; however, unnecessarily high levels of oxygen support lead to blindness in these same patients. This research was charged to find at what exact level in the American Academy of Pediatrics' standard of 85 percent to 95 percent oxygen concentration was most advantageous for survival future health of premature babies.

Based on past scientific endeavors, it was known that higher concentration levels in oxygen would result in an eye disease in premature subjects often leading to blindness. For the study to work, some of the infants would necessarily need to be exposed to higher concentrations within the set standard. However, in the study's informed consent forms and procedures, parents were not notified that these higher levels of oxygen meant a greater possibility of eye troubles for their infants.

Researchers argue that since even the highest oxygen levels to which any of their premature subject were exposed was in the

set standard of care, the odds that blindness would occur in these subjects compared to premature babies outside of the study were just as severe. However, the OHRP argues that, although within the standard of care, it is known within this research community that any increased level of oxygen concentration leads to an increased possibility of eye disease; therefore, the parents should have been warned during the consent period.

Violations of OHRP informed consent policy can have serious consequences. Punishment can range from corrective actions being promulgated from the agency itself, to federal funding being pulled from the institutions at issue that conduct human subjects research. (Crucial Studies, Fragile Subjects, Sabrina Tavernise, April 16, 2013, *New York Times*
<http://www.nytimes.com/2013/04/16/health/balancing-risks-and-benefits-in-clinical-trials.html?pagewanted=1&r=0&ref=ethics>)

High-risk Insurance Pools Established by PPACA Already Drying Up

The Pre-Existing Condition Insurance Plan – an insurance pool for individuals with high-risk health conditions run by the federal government – has been forced to stop accepting applications due to lack of funding. Established by the Patient Protection and Affordable Care Act in 2010, this high-risk insurance plan was supposed to act as a bridge for historically sick individuals until the bulk of health

care reform took effect in 2014. However, the \$5 billion that Congress appropriated to the high-risk plan is on the verge of being exhausted. About \$2.3 billion of the original appropriation remains, which is only enough to cover the existing 100,000 individuals who have already enrolled in the high-risk plan. As of March 2, the federal government will be forced to reject any new application submitted by an individual.

The reason for the shortfall, according to individuals within the Department of Health and Human Services' Center for Consumer Information and Insurance Oversight, is that the majority of the 100,000 individuals that had originally enrolled in the Pre-Existing Condition Insurance Plan have proven to be more costly to insure than originally calculated. By extrapolating the numbers of applications that the federal government had received during the last few months – about 4,000 new applications per month – tens of thousands more Americans would have applied for coverage under this plan, had more funds been available. According to the Department of Health and Human Services, additional appropriations from Congress for this high-risk plan will not be sought. (Funds Run Low for Health Insurance in State "High-Risk Pools," N.C. Aizenman, Feb. 16, 2013, *Washington Post* http://www.washingtonpost.com/national/health-science/funding-is-running-low-for-health-insurance-in-state-high-risk-pools/2013/02/15/cb9d56ac-779c-11e2-8f84-3e4b513b1a13_story.html)

RESOURCES

Gun Violence as a Health Care Issue A Select Bibliography

Editor's Note: CHA is a member of the Faiths United to Prevent Gun Violence coalition, which is working through the interfaith community to enact common-sense gun control measures that would make our nation safer and reduce violence in our communities. Several CHA members and other Catholic organizations are also part of the coalition. The following resources provide helpful information about gun control for our readers.

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(Prepared by CHA intern Jenna Herron.)

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Editor’s Note: These materials provide timely information about immigration and can provide helpful background for CHA’s April 18, 2013 webinar, “Our Immigrant Neighbors, Catholic Health Care and the New World of Health Care Reform.”

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(Prepared by CHA intern Lori Ashmore-Ruppel.)

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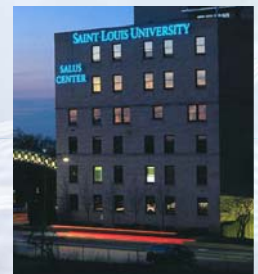


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