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Flu Vaccination and the Ethical Ishihara

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Over 90 years ago, Dr. Shinobu Ishihara developed the well-known screening test for color blindness that still goes by his name. The fact that I routinely fail this test does not make me a bad person. It does make for interesting debates about color in our home—which my wife always wins!

The incidence of color blindness or deficiencies in the USA is about eight percent in males and 0.4 percent in females. If news stories are any indication, ethical blindness is far more prevalent than color blindness. While color blindness can often be predicted based on genetics, ethical blindness may be anticipated based on education, occupation and other factors that shape one’s world view. Using the equivalent of an ethical Ishiraha test to identify ethical blindness may be a useful way to compensate for differences in perception that undermine mutual understanding and block constructive solutions.

A case in point, to illustrate the use of an ethical Ishihara, is the appallingly low rate of influenza vaccinations among health care providers (HCPs). Despite the fact that the Centers for Disease Control and Prevention has recommended annual flu vaccinations for HCPs since 1981, and the documented benefits of HCP influenza vaccination on patient outcomes and HCP absenteeism as well as reducing influenza infection among staff, fewer than half of HCPs are vaccinated. The unions (or individuals) that adamantly oppose mandatory flu vaccinations for HCPs are not evil—they simply have a variant of ethical blindness that needs to be recognized, addressed and compensated for.

The traditional principles of American medical ethics (beneficence and nonmaleficence) toward the patient, patient autonomy, fidelity toward the patient, and justice make it clear that HCPs have a moral/ethical/professional obligation to be vaccinated to avoid harming patients and to stay true to what is in patients’ best interests. A concern for the common good and for community well-being further underscore such an obligation. We could even legitimately argue that to honor patient autonomy, patients should be informed as to the vaccination status of health care workers so they can choose whether or not they want to be treated by that provider. In light of the underlying ethical issues at stake, it is a scandalous failure that
vaccination rates are so low among HCPs. The union perspective of seeing everything as an opportunity to advocate for worker’s rights is blind to the ethical principles that should guide the behaviors of health care providers.

If there are contraindications and the risk (or perceived risk) to the health care worker (competing values) is greater than the potential benefit to the patient, then the decisional balance changes. Clearly there are exceptions and in those situations the values and rights of all parties can be respected by having non-vaccinated providers wear masks. Unfortunately, some unions are even opposed to unvaccinated HCPs being required to wear masks during flu season. Reflexively defending the freedom and autonomy of workers to the exclusion of all other values (medical ethics), rights (of patients not to be harmed) and professional responsibilities is not an intentionally malevolent act by unions. However, the consequences of this ethical blindness are bad for patients, health care workers and unions (whose unbalanced behavior only undermines their credibility and effectiveness).

Unlike color blindness, for which there is not yet any commercially available cure, there is a potential remedy for ethical blindness. In the Ishihara color blindness test, accentuating the contrast between different colors allows even color blind people (like me) to see the hidden letters/numbers, etc. By clearly spelling out and accentuating the contrast between the different ethical issues (“colors”), even those who have ethical blindness will be able to see.

The specific ethical issues involved need to be identified, named, illustrated and contrasted “so that he who runs may” see. In the case of flu vaccination for HCPs, worker rights and autonomy must be contrasted with the ethical obligations of nonmaleficence and fidelity as well as justice and the common good. Where these are in conflict, honorable solutions can be found. Unfortunately, when we have different perspectives, the tendency to dig our heels in and attribute negative motives, intentions or characteristics to the opposition does not lead to constructive solutions. Getting stuck in arguments about right and wrong, blue and green, is not useful when based on totally different perceptions and realities.

The ethical Ishihara can just as easily be applied to the deteriorating dialogue on health care reform or any problem where differences in perspective have created an unconstructive impasse. At times, in certain situations, we all suffer from varying degrees of ethical blindness. The point of the ethical Ishihara is not to manipulate others to see things our way but to honor what everyone sees, recognize and name what is not seen and create contrasts that everyone can recognize. The quality of the dialogue and probability of desirable outcomes can increase significantly with this approach.

While it’s fun to occasionally banter with my wife about colors, we are able to move on because, thanks to Dr. Ishihara, I
understand she is always right on this topic.

NOTES


Attempting to Establish Standards in Ethics Consultation for Catholic Health Care: Moving Beyond A Beta Group

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Columbia St. Mary’s Hospital
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In the Winter 2008 issue of *Health Care Ethics USA*, I contributed an essay analyzing 196 clinical ethics consultations from 2003 to 2007 in an attempt open a dialogue regarding standards for the ethics consultation process. In conjunction with that essay, the Catholic Health Association established a Beta group, consisting of several ethicists from across the country, who agreed to utilize the software that I was employing in order to capture, measure, and evaluate ethics consultations at their respective ministries. The intention was to develop a broader consensus on standards for the practice of ethics consultation along with measures for quality and effectiveness, and to spur dialogue on what criteria should constitute qualifications for practitioners within Catholic health care. Given the significant dialogue on these topics outside of Catholic health care, it seemed most appropriate to begin to address these issues in the context of our own ministry. This piece will reflect on the creation of the Beta group, its place in the ongoing dialogue on quality and effectiveness in clinical ethics consultation in relationship to the Clinical Ethics Credentialing Project, and end with a plea for collaborative next steps with health care institutions inside and outside the Catholic health care ministry.

Current Discourse Outside the Ministry: Where is Catholic Health Care?

In the October 2009 issue of the *Cambridge Quarterly of Healthcare Ethics*, all articles focused on a central theme: ‘[A]lthough still in a formative and dynamic phase of development, clinical ethics is now sufficiently mature to be open to critical self-examination, including empirical investigation.” Agich and Reiter-Theil’s call should not fall on deaf ears in Catholic health care, given our ministry’s directed attention to ethics consultation:

An ethics committee or some alternate form of ethical consultation should be available to assist by advising on particular ethical situations, by offering educational opportunities and by review and recommending policies. To these ends, *there should be appropriate standards for*
medical ethical consultation within a particular diocese that will respect the diocesan bishop’s pastoral responsibilities as well as assist members of ethics committees to be familiar with Catholic medical ethics and, in particular, these Directives [emphasis added].

It is clear from Directive #37 of the Ethical and Religious Directives for Catholic Health Care Services (ERDs) that the Catholic health care ministry should already be able to demonstrate the integrated role of ethics consultation into particular consultative contexts, education opportunities and policy development. Additionally, it is also clear that Directive #37 requires that appropriate standards for such consultation should be informed by a robust understanding on the part of committee members of the principles of medical ethics found in Catholic moral tradition as well as the principles derived from that normative tradition and given greater specificity in the ERDs. Were it the case that the Catholic health care ministry has achieved these standards in its ethics consultation services across the ministry, there would be much we could offer our non-Catholic partners in these regards. It does not seem, however, that Catholic health care has embodied these standards. Moreover, we seem to be lagging behind the constructive dialogue occurring outside Catholic health care on the matter of “standards for medical ethical consultation” despite the prescriptive language found in Directive #37.

Returning to the October 2009 issue of the Cambridge Quarterly of Healthcare Ethics, George Agich opens the issue by suggesting that despite the increasing accountability to quality in every other area of health care, clinical ethics consultation has therefore been heretofore somehow exempt. He suggests that the field must foster a “robust internal commitment to quality” alongside an external accountability in order to be a responsible practice. Agich’s focus on clinical ethics consultation as a responsible practice forms the basis for his approach and for the expectations of full accountability derived from it. According to Agich, the development standards that constitute responsible practice should not be, and need not be, hampered by a general lack of consensus on the right model for ethics consultation (e.g., individual, subcommittee or ad hoc group). In fact, a quality assessment can and should occur whatever an institution’s particular model of clinical ethics consultation.

Robert D. Orr and Wayne Shelton, in the Spring 2009 issue of The Journal of Clinical Ethics, propose a process and format for clinical ethics consultation and teaching graduate students on how to do clinical ethics consultation. Their approach appeals to a standardization of components of a clinical ethics consultation process wherein, regardless of consultant model (i.e., individual, subcommittee or ad hoc group), the
methodology assures that relevant data are gathered and analyzed before any recommendation is made. Additionally, Orr and Shelton argue for a standard in documentation of the clinical ethics consultation that demonstrates that a “systematic and thorough investigation has been made into the question or problem that has been presented to the consultant” with an eye toward utility for the clinical team.  

An article by Douglas J. Opel et al., in the Fall 2009 issue of *The Journal of Clinical Ethics* moves beyond the question of whether ethics consultation ought to be subject to quality assessments to the matter of recommending a quality improvement tool. Of note is these authors’ unequivocal position that ethics consultation must be assessed from a quality standpoint. Further, the real debate lies in how. They propose using a tool familiar to risk management, namely, root cause analysis. For these authors, the ultimate goal of any ethics consultation process should be to “look upstream,” to identify and improve the systems problem that resulted in an ethics consultation. In this way, they argue, root cause analyses and similar process “result in a general improvement in the quality of care delivered.”

Finally, in the November-December 2009 issue of the *Hastings Center Report*, the Clinical Ethics Credentialing Project takes a comprehensive approach to three areas where the project found little consensus: (1) standards for practice (outside of the Veterans Administration system), (2) valid and reliable measures to rate the quality and effectiveness of the clinical ethics consultation process. This bold project made three important contributions to this discussion: (a) Fundamental Elements of Clinical Ethics Consultation; (b) Standards for Clinical Ethics Consultation; and (c) an eight-step process for assessing the quality of the ethics consultation process. Although there are pockets of good work in these areas occurring within Catholic health care, there is no identified body within the ministry that has taken responsibility for attending to Directive #37. The Catholic health ministry seems best suited to address these issues in clinical ethics consultation for a number of reasons: (a) there is a uniform set of guidelines and principles by which Catholic health care understand ethical decision-making; (b) there is a uniform expectation for what should minimally constitute an ethics consultation service within Catholic health care (Directive #37); and (c) with a long-standing tradition of theological reflection on life, death, suffering and the intersection of these with medicine and the good of health, theologians have been able to enter early debates in bioethics effectively so as to create a wealth of literature relevant to clinical ethics consultation in a Catholic health care ministry. Yet, we have no established standards for what constitutes clinical ethics consultation in Catholic health care, no standards for qualifications of persons responsible for clinical ethics consultation, and no valid or reliable....
measures to rate the quality and effectiveness of clinical ethics consultation in the Catholic health care ministry. Sadly, despite our early and forceful positioning in the bioethics field, we have remained relatively absent from these more recent discussions in the bioethics literature.

An Attempt to Re-engage: The Catholic Health Association Ethics Tracker Beta Group

In 2006, Columbia St. Mary’s (CSM) ethics consultation service began using a Microsoft Access database developed by Harmony Technologies to capture critical elements of ethics consultation. I published on this data from 2003 through 2007 in a past issue of Health Care Ethics USA and will not expand on that here. Of importance for this essay, these data were based on ethics consults where: (a) the initial ethics committee member could identify an ethical dilemma; (b) the consultant(s) could identify the person requesting the consultation; and (c) offer recommendations where appropriate to the reason for the request. Data were abstracted from completed ethics consultation intake forms, written analyses and recommendations, and patient medical records. Additionally, the model for ethics consultation used at CSM was and continues to be based on the American Society for Bioethics and the Humanities’ Core Competencies for Health Care Ethics Consultation. In light of these competencies, CSM’s specific ethics consultation service model would best be characterized as an ethics facilitation approach framed by the mission, vision and values of the health care ministry. This background is important because it represents presumptions around an ethics consultation model that undergirds the data that populate the database. Because the Ethics Tracker database was simply exported to participants of the CHA Beta group, the validity of these presumptions was not tested. Nonetheless, the CHA Beta group does offer a response to points (1) and (3) of the Clinical Ethics Credentialing Project’s critiques of the current state of affairs in clinical ethics consultation.

Standard for Practice

Given the data fields that offer input into Ethics Tracker, an implicit claim is made as to the fundamental elements of clinical ethics consultation (see Table 1). Interestingly, although the CHA Beta group was not involved in the Clinical Ethics Credentialing Project, the data fields align well with the recommendations of the Project’s Fundamental Elements of Clinical Ethics Consultation. This suggests that although there is an often-cited claim that “variations of practice are considerable,” the variations may not be as considerable as previously thought.
Table 1

All data elements required in Table 1 illustrate that: (a) the ethics consultation is tracked for its timeliness between request for and completion of an ethics consultation; (b) a review of the patient medical record must occur; (c) a primary reason for consultation must be discerned with potential for secondary and tertiary reasons noted; (d) one must assess the level of consultation that will best aid determining whether and to what extent a further process with hospital leadership or bioethics committee is necessary; and (e) one needs to note whether and to what extent the ethics consultation was documented in the medical record.
Finally data elements in Table 2 illustrate attention to: (a) clinical diagnoses and (b) discharge disposition in order to establish a basis for continued review and trends related to the major diagnostic category to which the patient’s primary diagnosis is attributed as well as the discharge outcome following ethics consultation.

Valid and Reliable Measures to Rate the Quality and Effectiveness of the Clinical Education Consultation Process

Opel et al. rightly point out that “much of the attention on quality in ethics has focused on improving the internal structures and processes within ethics consultation services… [but] we challenge ethics consultants to look beyond the traditional confines of clinical ethics.”21

In this way, the authors argue that quality improvement efforts in ethics consultation must include both the “quality of practice within ethics consult services, [and] … the quality of health care provided throughout the system.”22 Ethics Tracker attends to these goals through its use of documentation standards for ethics consultation.23

In relationship to standards developed by the Clinical Ethics Credentialing Project, the data elements in Table 3 illustrate attention to: (a) the interdisciplinary nature of the ethics committee in relationship to the expertise relevant to the reason for ethics consultation; (b) the nature of the consultation requested in relationship to policy definitions surrounding what constitutes advisement versus consultation; and (c) standard documentation elements of the ethics consultation in the medical record for later quality improvement.
Table 3

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<thead>
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<th>Patient ID</th>
<th>Biographical</th>
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<th>Data Entry</th>
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</tr>
</tbody>
</table>

Table 4

Level of Consultation
- Consultation
- Medical Record
- Ethics Committee Consultation
- Ethics Adainment
- Retrospective Case Review

Ethics Documentation Elements
- Requested to address concern
- Patient relevant medical information
- Patient and/or surrogate behavior and/or demographic information
- Contextual and institutional situation
- Patient/Surrogate preferences
- Explicit determination or classification of ethically appropriate decision maker
- Clear statement of ethical question
- Summary of ethical analysis
- Recommendations and action plan
- Mention of follow-up plan

Ethics Committee Members in Attendance

Not captured in these Tables is an evaluation tool for requester satisfaction based on timeliness and requestor satisfaction. Table 4 illustrates this tool.

Table 4

<table>
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<th>Number</th>
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<th>Family Medicine</th>
<th>Nursing</th>
<th>Case Management</th>
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<td>0</td>
<td>0</td>
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<tr>
<td>2006</td>
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<td>2007</td>
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<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
<th>Hospital</th>
<th>Internal Medicine</th>
<th>Family Medicine</th>
<th>Nursing</th>
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<td>2007</td>
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</tr>
</tbody>
</table>

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Ethics Tracker automatically issues an email to the requestor of the ethics consultation and secures (locks) the email response to these evaluation questions for integrity of the data.

Collaborative Next Steps

As mentioned earlier, the Beta group did not examine the assumptions about what constitutes an ethics consultation, but rather simply accepted them as part of the goal of standardization in the use of the Ethics Tracker database. Yet, it is these very assumptions that remain untested in the broader ethics literature on clinical ethics consultation.24 Returning to the Clinical Ethics Credentialing Project, one sees that standards for clinical ethics consultation have been established. Those standards include: (1) easy access to clinical ethics consultation (CEC) and a plan for responding to requests for CEC from staff, patients, and family members (or other patient representatives); (2) a clear process for gathering information and making appropriate arrangements to make sure all relevant stakeholders are heard; (3) a formal note in the medical record; (4) a standard format for writing in the chart; (5) recognition of CEC as one of many collaborating services that must be integrated and transparent in its functioning; (6) institutional and peer oversight; (7) methods of ensuring the qualifications and competency of CE consultants; (8) measures for credentialing CE consultants; and (9) a robust quality improvement process.

It is time for the Catholic health ministry to engage the literature concerning the model for ethics consultation along with the standards of what constitutes an ethics consultation. To date, much of the literature contributed from Catholic health care ministries has focused on a model or a set of standards.25 Often cited definitions of what constitutes a clinical ethics consultation serve as illustrative points of departure between the Catholic health care ministry and non-Catholic entities offering an ethics consultation service. For Catholic health care, an essential way to understand the purpose of an ethics consultation service (in existence with other “centers of ethical responsibility”) is as “the systematic effort to discern the imperatives of human dignity.”26 For non-Catholic entities, on the other hand, the purpose of an ethics consultation service “is to improve the process and outcomes of patient care by helping to identify, analyze, and resolve ethical problems.”27 This is not to say that there cannot be convergence between these two visions of what constitutes clinical ethics consultation, but where Catholic health care is explicitly called to establish “appropriate standards for medical ethical consultation” consistent with its understanding of the purpose of an ethics consultation, an obligation exists to discern standards for those who enter the privileged space of the patient physician-relationship to offer ethics consultation.
NOTES


5 For example, the dialogue occurring in the ASBH Affinity Group: Clinical Ethics Consultation Advisory Group (CECAG).


7 Orr and Shelton, p. 83.


9 Opel, et al., p. 223.


14 It should be noted that there is a significant amount of literature discussing the Next Generation model of ethics consultation in Catholic healthcare, but this model does not directly answer the critiques of the Clinical Ethics Credentialing Project nor the question of standards for the Catholic healthcare ministry such as those developed by ASBH. See, Kevin Murphy, “A ‘Next Generation’ Ethics Committee,” Health Progress 87, no 2 (March-April 2006): 26; Gerard Heeley, “A System’s Transition to Next Generation Model of Ethics,” Health Care Ethics USA 15, no. 4 (Fall 2007): 2-4; Philip Boyle, “The Next Generation of Ethics Mechanisms:

15 The author has no conflict of interest in Harmony Technologies, LLC.


18 The ethics facilitation approach is defined in the ASBH *Core Competencies for Health Care Ethics Consultation*, 1998.

19 Dubler et al., p. 23.


21 Opel, et al., p. 221.

22 Opel, et al.

23 These standards were developed in conjunction with Douglas J. Opel at the Treuman Katz Center for Pediatric Bioethics and the Veterans Affairs National Center for Ethics in Health Care *Integrated Ethics Program* and through the use of the Reports Function in *Ethics Tracker* concerning a number of quality tracking fields already highlighted in the Winter 2009 issue of *Health Care Ethics USA*. See, Repenshek, “An Empirically-Driven Ethics Consultation Service,” pp. 10-16.


Responses From Beta Group Participants

Jenny Heyl, Ph.D.    Brigitta Sujdak-Mackiewicz, MA
Director, Ethics    Director, Ethics
St. John’s Mercy Medical Center    OSF Saint Francis Medical Center
St. Louis, MO     Peoria, IL

Alan Sanders, Ph.D.
Director, Center for Ethics
Saint Joseph’s Hospital of Atlanta
Atlanta, GA

**Heyl:** Having participated in ethics consults at a large tertiary-care Catholic medical center for six years, I eagerly anticipated the ethics consultation database that Mark Repenshek had developed in conjunction with Harmony Technologies, and enthusiastically agreed to participate in the Beta group. While understanding that the larger goal was to assist in the development of a tool and processes to use ministry-wide, my personal hopes for the database lay in three areas: 1) to measure work done and demonstrate the value of ethics consultations to my organization; 2) to validate (or correct) the direction in which the ethics committee had been moving in addressing issues upstream; and 3) as a result of the first two, to pave the way for ethics to collaborate with other departments to address quality improvement in systemic issues. Over six years I had collected a good deal of data that had, for the most part, gone unanalyzed. This gave me all the more reason to hope that the Ethics Tracker database could, at the very least, confirm or correct the direction that the ethics committee had pursued over the years. We had already started proactive ethics screening for certain indicators in order to address issues we had seen frequently in ethics consults. Again, the hope was that the analysis would show if we had pinpointed the correct indicators and to what degree the proactive screening was successful.

Mark has made a strong case for the Catholic health care ministry to engage the literature on the model for ethics consultation along with the standards of what constitutes an ethics consult. Upon reflection on my participation in the Beta group, I realize that I let my personal hopes for the database outweigh the larger goal for the Catholic health care ministry. I would like to share some of the challenges I’ve encountered while working with the Ethics Tracker database and end with why I believe this work should continue.
Procedurally, the first challenge was finding the time and/or talent to input the data. The retrospective data did not contain all of the data fields for Ethics Tracker so some reconstruction of the case was necessary. Secondly, the timing of the Beta group activities coincided with the implementation of the electronic medical records (EMR) at my organization. Priorities of the IT department with the EMR rollout precluded any work on interfacing the database with other systems or the EMR itself. Finally, with competing obligations, data input took the lowest priority. The major conceptual challenge was defining what constitutes an ethics consult. Mark comments that it was a given; however, because one of my goals for the database was to illustrate the scope of requests made to the ethics department and the time taken to appropriately address those requests, I expanded the definition beyond the data field parameters. I discovered late in the game that by adding numerous “Discerned Reasons” for consult requests, my results would not fit into the larger goals of the Beta group.

My motivations were directed locally rather than globally, and perhaps I was remiss in not keeping in closer contact with the members of the Beta group to ask what challenges they faced and how they were addressing them. On the local level, I had hoped to have data entry completed on ethics consults for the previous two fiscal years (July 2007-June 2009) with reports generated in time for our January 2010 Ethics Committee Meeting. However, due to the logistical challenges of retrospective data input, as well as the need to correct my expanded definition of what constitutes an ethics consult, I was unable to realize the first two local goals. I expect that this can be completed by March 2010. With regard to the third local goal, ethics has been included in collaborative efforts with other departments addressing quality improvement in systemic issues. However, I’m convinced that with hard data, ethics can have a greater influence in setting the priority of projects to address these issues. I remain convinced that the Ethics Tracker database is a useful tool to achieve these goals. Moreover, I believe that with further work and direction from the Beta group this can expand to other members of the ministry as we work to, as Mark says, “discern standards for those entering the privileged space of the patient-physician relationship to offer ethics consultation.”

Sanders: Mark argues in his article that there is an obligation outlined in the Ethical & Religious Directives for Catholic Health Care Services, Directive #37, for Catholic health care ministries to develop standards for ethics consultation practice, measures for its quality and effectiveness, and qualifications for ethics consultants. Mark parallels his argument with the developing literature addressing standards and quality for ethics consultations outside of Catholic health care. Although Catholic ethics consultations are not exclusive from the quality measures outlined in this literature, Mark suggests...
that it is time for the Catholic health care ministry to address these standards within its own understanding and purpose of an ethics consultation.

There is no doubt in my mind that using a program like Ethics Tracker can make significant contributions to establishing standards for ethics consultation in Catholic health care. Many Catholic institutions already track their ethics consultations, at least on paper. Although my evidence is anecdotal, I suspect that, at minimum, these records include information such as who requested the consult, when the consult was requested, the reason for the request, relevant patient information, ethical analysis and recommendation.

What struck me about Ethics Tracker was the drop down menu for the discerned reason of the request, and how it might appear to a staff member and/or physician who accessed this menu in a Catholic health care setting. The list included options that might be considered routine for ethics consultation in any setting, such as ‘Conflict-code status’, ‘Concern regarding non-beneficial interventions’, and ‘Discerning decision-making capacity’. The list included other options that are unique to a Catholic health care setting, such as ‘Direct/Indirect-ERDs’, and ‘Pre-term mature rupture of membranes-ERDs’. Finally, the list included options that may not be considered unique to Catholic health care, but with a unique lens or perspective, such as ‘mission/care values’, ‘stewardship’, and ‘common good’.

As the pace of health care and demand for quality increases, staff will increasingly rely upon the information they need to enter into a medical chart (most likely electronic) as a measure of their obligations to patients and families. Increasingly, patient and family care may be directed by what information is required and available in an electronic medical record. From this perspective, a program like Ethics Tracker holds great potential to sustain and expand ethical discernment in Catholic health care by making easily identifiable categories of ethical concern available to professionals who frequently change jobs and practice in numerous settings.

In my mind there is both an opportunity and a word of caution here. Mark’s plea is for the Catholic health care ministry to develop standards for ethics consultation within the ministry’s own understanding and purpose of ethics consultation. Much of this understanding and purpose will be outlined to physicians and staff through the ‘reason for request’ categories, such as listed above. I believe it is imperative to be aware that an effort to standardize the practice of ethics will also likely provide the lens through which professionals view ethics in Catholic health care in the future.

If such tools provide and shape the moral lens of the professionals who use them, attention to the breadth, depth and clarity of the categories will be key. In my mind categories such as ‘mission/care values’, and ‘common good’, can help shape and sustain
ethical discernment in Catholic health care, but they may need more development. What does a mission or care value look like in health care? How does an issue of the common good arise in patient care? Such categories may help to educate staff and empower them to address ethical concerns in unique ways in Catholic health care beyond prohibited procedures, provided they are listed in ways in which staff and physicians can easily recognize them in patient care.

Sujdak-Mackiewicz: In a three-year period of ethics consultation data collection at OSF Saint Francis Medical Center (SFMC) and Children’s Hospital of Illinois (CHOI), we observed an average increase in consultations of approximately 75 percent per year. We believe that an important reason for this increase has been the introduction of dedicated ethics personnel at the medical center, who were made available because the staff recognized their importance to the interdisciplinary care team. Thus, when the opportunity to participate in the CHA Ethics Beta project arose, we were eager to investigate benefits of Ethics Tracker, especially given its development as a resource for Catholic health care by its use of the ERDs. The opportunity to participate in the Beta group provided a needed tool for taking the next steps in collecting and analyzing data about ethics consultations.

The benefits of utilizing Ethics Tracker outweigh the challenges. On a practical level, one of the most beneficial aspects of the software is the ability to communicate about ongoing consultations with other ethics consultants who can provide a rationale for their approach to a case that, for various reasons, might not belong in the medical record. If the consultant responsible for the case changes or is working with other consultants, the others can access the record and note progress, next steps, or need for follow-up. The database also allows a consultant to quickly learn whether there has been a consultation on a particular patient during the current or a previous hospitalization.

The Ethics Tracker tool has met our expectations for providing a systematic means to enable standardized data collection of ethics consultations. In addition, by providing a common platform for the collection of standardized data points, the software helps to identify areas for quality improvement. Often a consultation may point to a need for education or for the revision/development of a policy. Such findings underscore the important role of ethics consultation in improving patient care.

The Ethics Tracker also highlights the ERDs. It links the various sections of the ERDs to the reasons for consultation, offering additional benefits. First, this linkage demonstrates an approach to ethics consultation unique to Catholic health care. It integrates not only ethical principles easily recognizable by our colleagues outside of the ministry, but also the ethical principles guiding Catholic health care with an emphasis on the human dignity of the patient and caregiver and the responsibility of
Catholic health care as it relates to ethics consultation per Directive #37. Secondly, it recognizes the role of the ERDs in guiding organizational and clinical practice, giving attention to areas of the ERDs where there may be a need for education, policy development or review, a better understanding of the ERDs themselves, or of the foundational principles underlying Catholic health care.

An unexpected benefit of a formal mechanism for recording ethics consultations has been the opportunity to more carefully define the scope of practice for ethics consultation specifically as it occurs in Catholic health care. By defining the scope of practice within the ministry, ethics will be positioned to demonstrate its unique role in and contribution to the interdisciplinary care team and the organization in general, while simultaneously acknowledging where overlap occurs (e.g., with those working in palliative care). This in turn can provide opportunities for collaboration and sharing of resources. This is particularly important for establishing standards for ethics consultation within Catholic health care and for justifying educational, financial and consultation resources within the ministry.

As the scope of practice in ethics is more clearly defined, those in ethics will be better able to work with interdisciplinary teams both at the bedside and at the organizational level. It will enable them to speak the language understood by the interdisciplinary team -- a language that includes quality improvement -- while highlighting the application of the ERDs to patient care at all levels, integrating them more naturally within the existing quality improvement culture. Ultimately, if a tool such as *Ethics Tracker* is adopted throughout the ministry, it will standardize the scope of practice and establish Clinical Practice Guidelines (CPGs) for various types of consultations. For example, CPGs might be developed for consultations regarding ectopic pregnancy, sexual assault protocols, or cooperation with non-Catholic entities. The development of CPGs may be a logical next step in the professionalization efforts currently being undertaken by those in ethics.

OSF SFMC/CHOI has further expanded the *Ethics Tracker* software with the assistance of Harmony Technologies to track ethics education. This function provides a simple means of correlating consultation data with ethics education. It can track the number of people who participated in an educational event, their field of practice, whether the education was provided because of a consultation or due to the recognition of a particular need (for example, one or more of the ERDs).
Looking Back, Looking Forward: Ethical Challenges for the Ministry

Reflections

Editor’s Note: In reflecting on the end of one year and the beginning of a new decade, we asked four ethicists to share some of the issues that consumed a good deal of their time and energy during 2009 and what they thought might be the focus of their attention in 2010. The four ethicists are:

Fr. Larry Dunklee, M.Div., MA  Carl Middleton, Ph.D.
Director, Mission Integration and Ethics  Vice President, Theology & Ethics
Sacred Heart Hospital  Catholic Health Initiatives
Eau Claire, WI  Denver, CO

Karen Iseminger, Ph.D.  Bridget Carney, Ph.D.
Director, Ethics Integration  System Director, Ethics/Theology
St. Vincent Health  PeaceHealth
Indianapolis, IN  Bellevue, WA

Their responses follow. We think you’ll find their observations interesting and invite you to reflect on your own experience.

1. What were the ethical issues of 2009 that consumed the majority of your time and energy?

Dunklee: Casting a look back at the ethical challenges of the past year, two issues immediately come to mind: (1) the revision of Directive #58 of the Ethical and Religious Directives for Catholic Health Care Services (ERDs) and (2) applying the principles found in Part VI of the ERDs, dealing with partnering with non-Catholic institutions.

In terms of clinical issues, the revision of Directive # 58 that deals with medically assisted nutrition and hydration (MANH), particularly as it applies to patients in a persistent vegetative state, occupied a great deal of my energy and attention. With the revision of the directive, there needs to be ongoing education and dialogue to properly explain and apply the principles of Catholic moral teaching to clinical situations. Participants in these discussions should include clinicians, ethicists, bishops, the lay faithful, and, very
importantly, our clergy. If this educational dialogue does not happen, there is a danger that people will misunderstand the church’s teaching on end-of-life issues, particularly as they apply to the use of MANH.

In looking at organizational ethics challenges confronting our institutions, a good deal of my time was spent pouring over contracts, lease agreements, and partnership arrangements with a view to applying the principles found in Part VI of the ERDs. With regard to the challenges of partnerships and affiliations, there is a risk that we may become afraid to enter into any partnership for fear of being involved in some type of immoral cooperation or creating scandal. Partnerships are an inevitable part of health care, however, and “can be viewed as opportunities for Catholic health care institutions and services to witness to their religious and ethical commitments and so influence the healing profession” (ERD, Part VI, Introduction).

On the other hand, if we become too lax and enter into partnerships without careful scrutiny, we run the risk of compromising our institutional Catholic identity. Early and consistent dialogue between the diocese and the institution is paramount in dealing with these complex arrangements.

Iseminger: As I ponder this last year, I have had the opportunity to facilitate the resolution of a plethora of organizational and clinical ethical concerns in a wide variety of settings, in addition to providing education and preventative ethics programs.

On average, I receive about five to six clinical ethics consults per week. Given this, it is quite understandable that direct clinical ethics consumes significant amounts of my time. These consults so often arise because health care today is steeped in technical and financial challenges that may conflict with principled care for individuals balanced with our obligation to the common good.

Many consults involve exigent decisions regarding end-of-life issues, especially related to disagreement among associates and families regarding cardio-pulmonary resuscitation and other elements of “care at all costs.” Generally speaking, health care needs to be more deliberate about using medical advances as a bridge toward reasonably certain therapeutic goals rather than exploiting extensive technology because of a refusal to acknowledge death. The situation is even more challenging in our neonatal and pediatric intensive care units where we are challenged to decide how much technological support to provide our society’s youngest members who have not had the opportunity to live, cannot speak for themselves, and for whom prognostication is difficult.

Another area of concern has been to provide health care and social support for “marginalized” patients (the mentally ill, developmentally delayed, pregnant substance abusers, undocumented foreign patients, and those with limited health
care literacy and poor preventative care). Many individual ethics consults serve as a stimulus for organizational ethics discernment processes to develop improved practices to prevent future patients from facing similar dilemmas.

**Middleton**: The ethical issues that consumed the majority of our time and energy in 2009 fell under the rubrics of clinical, organizational, and social ethics. The clinical ethics issues related mostly to end-of-life care, including assisting our market-based organizations (MBOs) to develop palliative care programs; artificial nutrition and hydration concerns; pacemakers and implantable cardioverter defibrillators (ICDs) at the end-of-life; and issues around donation after cardiac death.

In the realm of organizational ethics, we were involved in facilitating the “CHI Discernment Process” at MBOs in relation to proposed business transactions and issues of divestiture. We also provided guidance and counseling at both national and MBO levels regarding reduction-in-force decisions.

Under the umbrella of social ethics were several Grand Rounds presentations for medical staffs and senior teams on “Ethical Dilemmas in Healthcare: Economic Crises in Uncompensated Care.”

**Carney**: Since the publication ten years ago of David Blake’s article “Reinventing the Healthcare Ethics Committee” in which he outlines St. Joseph of Orange Health System’s “Model for the Next Generation Healthcare Ethics Committee” (NGHEC), many hospitals and health care systems across the country (e.g., Veterans Administration, Catholic Healthcare East, Catholic Health Initiatives, and Ascension Health) have worked to incorporate aspects of this model into the development of their overall health care ethics programs. PeaceHealth has been on this journey for a number of years and continues to struggle with the challenge of how to successfully build in NGHECs as part of an overall health care ethics program in order for these committees to be proactive agents of systemic change for the improvement of patient care. This has been a major effort over this past year.

A Catholic health care system, PeaceHealth is located in three states (WA, OR, and AK) with bed sizes ranging from 10 to 420, located in remote, rural, and urban settings. In attempting to develop successful NGHECs in each of its facilities, there is no lack of agreement regarding the four principles that undergird these entities and their primary focus. However, successfully incorporating NGHECs into an overall health care ethics program for any health care system cannot be achieved without actively addressing ongoing systemic issues, specifically appropriate and adequate human, financial, and infrastructure support, and stakeholder engagement. These four components are in constant tension.
In order to have effective NGHEC committees, one needs staff that are appropriately trained and adequately resourced. Infrastructure, in the form of administrative, computer, and analytics support is needed to be able to track consults and other work being done so that one can provide concrete documentation of the “added value” of a NGHEC and clinical consult team in improving the quality of patient care. Equally critical to the success of the NGHEC, is stakeholder engagement. Without administrative and clinical leaders and staff supporting the value of a NGHEC and clinical consult team, the work of the NGHEC will continue to be isolated and ineffective. The NGHEC and ethics consult team cannot do the work without the appropriate resources and, in turn, it is then difficult for leaders and staff to see the value of the work, when it is not meeting expectations. These are some of the challenges that we experienced over the past year in one area of our work.

2. **Looking forward to 2010, what ethical issues do you think might rise to the surface? What might be the challenges and opportunities they’ll pose?**

**Dunklee:** In the year ahead, I believe that issues related to organizational integrity will become even more important. Patients and families are expecting a greater integration of services among physicians, clinics and hospitals. But how do we continue to maintain our ethical standards in this ever increasing market-driven society?

Critical to this process will be balancing our many and varied obligations to the poor and marginalized, to the community at large, and to patients, physicians and employees. We also have an obligation to the institutions in which we work to be good and prudent stewards of our resources, enabling us to remain fiscally sound and thereby helping to ensure the growth and development of technologies and services necessary to meet the increasingly complex medical demands of the 21st century.

This balancing of obligations requires a vision which looks beyond what is good only for our own individual department or institution, and focuses on what is in the best interests of the entire Catholic health care ministry of which we are a part. Critical to this will be education of our sponsors, boards, administrators, physicians, and other health care professionals regarding our call to effective and faithful stewardship, while striving for ever more visionary leadership in a manner consistent with Gospel values and the commitments intrinsic to Catholic health care.

While the church has a long and rich tradition of dealing with clinical ethical issues, organizational ethics is presenting us with new questions, challenges and dilemmas. I believe that these challenges will be among the most critical that we face in the decade which lies ahead.
**Iseminger:** My experience as director of ethics integration leads me to champion a three-fold approach to ethics integration for Catholic health care. We need to: maintain our faith-based approach to health care, which embodies compassion for value differences in every scenario; assist our associates in dealing with the moral distress that they experience as a result of balancing mission, technical competence, patient and family advocacy, and economic margins with their personal values; and continue to heighten levels of ethical sensitivity requisite to quality clinical and business practices. Consequently, I believe that one of my primary goals for the next year is to be “present” to associates and families during their times of angst and vulnerability. Human contact and interaction are vital if patients, families and associates are to benefit from the resolution of ethical dilemmas embedded in clinical care.

Other ethics issues I expect to arise or continue in 2010 include our struggle to assist the marginalized regardless of how government ultimately achieves health care reform. Building upon St. Thomas Aquinas’s belief, “action flows from being,” I believe that the best way for us to prepare for these challenges is through education, prayer, and giving associates a voice on issues that concern them. Furthermore, I hope that our associates will view themselves as having abundant ethics and mission resources within themselves, within their clinical milieu, and throughout St. Vincent Health.

**Middleton:** As we explore a number of new business and research opportunities with their increasing complexity, we will be challenged to provide ethical analysis and oversight to ensure that potential partners and their activities comply with our mission and are consistent with the *Ethical and Religious Directives* (ERDs). It will be important for us to teach our senior teams/boards, “just-in-time” organizational and social ethics with a focus on Catholic social teaching, and remind them that mission and ethics need to be at the table in making these business/ministry decisions. As health care undergoes continued change, progressive health care systems are pursuing varied initiatives that will require analysis of potential business transactions (e.g., contracting, partnership) based not only on prudent strategic and business decisions, but also on evaluative criteria that reflect the ethical, religious, and socially responsible and justice commitments of the organization. There is a responsibility to safeguard the “good name” (reputation) of CHI and its position as a health ministry of the church.

**Carney:** The challenge for PeaceHealth and for other health care systems attempting to incorporate a NGHEC is, put simply, to **continue the journey** of striving to build health care ethics programs and NGHECs that are “proactive agents of systemic change” for the improvement of patient care (Blake, 2000:10). We must continue to
find ways to engage key stakeholders so that we can build the human, financial, and infrastructure support needed. This task will continue to be a difficult, but important, commitment in the context of the current budgetary constraints and competing demands on limited resources faced by all of our systems and facilities as we strive to provide compassionate quality care reflective of the mission of Catholic health care.
Mandatory Seasonal Influenza Vaccinations for Hospital Employees

Ethical Considerations

In the midst of all the concern this year about H1N1 influenza (swine flu), an ethically important development is underway in institutional policies regarding seasonal influenza.

- There has been a notable increase in 2009 in the number of health care organizations that have implemented mandatory annual vaccination of employees for seasonal influenza. Those now requiring flu shots include systems (e.g., HCA and Medstar Health) as well as individual medical centers (e.g., Loyola in Chicago).

- Organizationally mandated seasonal influenza vaccination is a major change from past practices in which employees were strongly encouraged, but not required, to get shots. As a major change, it is encountering some resistance.

- **Note:** In the summer of 2009 the New York State Health Department adopted a requirement that all hospital, home care, and hospice workers in the state get seasonal and swine flu vaccinations.

This, the first government-mandated vaccination, has been challenged as a violation of civil rights and, at the time of this writing in late October, enforcement has been halted by a temporary restraining order until a hearing on the cases. This commentary does not address government mandates.

Rationale

Supporters of mandatory seasonal influenza vaccination often reference the following points.

- Vaccination of health care workers has been shown in some studies to lower patient mortality.

- After years of efforts of encouraging healthcare workers to get seasonal flu vaccinations, only about 40 - 50% of them do so across the country.

- Requiring flu vaccination would not be a significantly departure from present healthcare practice. Requirements already exist for mandatory healthcare worker vaccination for such diseases as...
rubella, measles, mumps, hepatitis B, and varicella as well as for annual TB screening.

“Despite considerable evidence that the vaccination of health care workers benefits workers, their patients, their families, and their institutions, few health care professionals take advantage of vaccination programs unless these programs are actively promoted or required as a condition of employment.

“Even when programs are actively promoted, their increases in vaccination rates generally remain below levels required to achieve herd immunity and, therefore, are unlikely to secure the potential benefits from high rates of vaccination.” (Olga Anikeeva et. al. “Requiring Influenza Vaccination for Health Care Workers.” American Journal of Public Health. January, 2009. p. 26.)

Some Clarifications

As noted above, the vaccine that some hospitals are mandating for employees is seasonal flu vaccine, not swine flu vaccine.

• Because seasonal influenza vaccinations are done every year, the appropriateness of a policy mandating vaccination is best analyzed as potential on-going practice, not as an emergency practice.

• There are years of experience relating to the effectiveness and safety of seasonal flu vaccinations (compared to the new H1N1 vaccine) in the assessment of the likely impact of a policy mandating vaccination.

There are different meanings to the word “mandatory” in these policies. For some “mandatory” means that getting vaccinated is a condition of employment, necessary to avoid dismissal. Others allow employees to decline vaccination if they have medical reasons for not getting vaccinated; some allow exemptions for workers with religious objections. Some allow employees to avoid vaccination if they complete a form indicating the reason why they are declining (“informed declination”).

• While permitting informed declination may not seem “mandatory,” it is a significant step away from former practices of leaving the decision up to the individual who need not give an explanation.

The policies mandating vaccination are for health care workers, not the general public and not employees in other kinds of organizations.

• The argument in support of such policies is clearly based on the fact that these workers are involved directly or indirectly in patient care and that this is
relevant in terms of what should be expected or required of them.

The Right to Decline Unwanted Medical Treatment

Many adults choose not to be vaccinated against seasonal influenza even when they are part of the population for whom vaccination is strongly recommended.

Whatever the reason, their decision should ordinarily be accepted. The principle of informed consent means the right to decline routine care just as it means the right to decline more major interventions.

- The word “ordinarily” is a qualifier in the statement above. The qualifier is necessary because our rights are limited by our responsibility to avoid placing others at unnecessary risk of significant harm.

- There is a sound ethical basis for restricting the freedom of individuals to decline health care only when necessary to protect the common good, to protect others from serious harm.

This is the general standard, one which supports a reluctance to endorse mandatory healthcare, except in public health emergencies. Given the important value of protecting patient self-determination, opposition to mandatory vaccination is not surprising.

- The responsibilities of health care workers are, however, somewhat different in this case from those of the general public and the requirements that can be placed upon healthcare workers are also different.

Health Care Workers

While the nature of seasonal influenza does not present the kind of emergency that would justify mandatory vaccination of the public, we need to consider the unique circumstances of hospital workers to determine whether their situation is different.

- At the heart of professional health care ethics is the obligation to avoid harming those in one’s care. At an organizational level, one of the implications of this responsibility is the need to limit hospital-acquired infections as much as possible.

- Another aspect of health care professionalism is the subordination of one’s own interests to the needs of those being cared for. This means that healthcare workers can be expected to stay on the job even when it means risking their own health. On the everyday level, it means an on-going commitment to doing what is needed for patient well-being rather than following one’s own preferences.
Key Ethical Considerations

Good policy recognizes both the general right of individuals to decide freely whether to accept health care interventions for themselves and the responsibility of healthcare workers to protect patients from harm.

Thus, while it is difficult to justify a requirement that is simply designed to protect the employee’s own health, a requirement designed to protect against patient harm is sometimes appropriate.

A strong case can be made for a hospital mandate for annual seasonal influenza vaccination of employees if the following considerations apply:

• There is evidence that patients are in fact put at significant risk and suffer harm when hospital employees have seasonal influenza (even when other infection control methods are used).

• There is convincing evidence that the risks to patients will be significantly reduced by increased vaccination of hospital staff.

• There is good reason to conclude that the level of staff vaccination necessary to protect patients will not be achieved by a voluntary program (even with incentives).

• The categories of employees included in a vaccination requirement are only those necessary to achieve the patient safety goal. (One question is whether employees not involved in patient care activities must be vaccinated.)

• Covered employees for whom influenza vaccination is medically contraindicated are exempted from the requirement.

• Other exemptions for covered employees are limited in order to ensure the effectiveness of the program and fairness in its application.

• Consequences for non-exempted employees who refuse to comply with the requirement are no more severe than necessary to ensure the effectiveness of the program and fairness in its application.

This ethics reflection was submitted by Leonard J. Weber, Ph.D. After many years on the faculty of the University of Detroit Mercy, Dr. Weber is now an Ethics Consultant to health care organizations, and is a member of the Bon Secours Health System Ethics Advisory Group.

Ethics Consultation Redux

In the Fall, 2009 issue of HCEUSA, this section noted the attention given to “ethics consultation and quality” in some of the recent bioethics literature. The current issue of HCEUSA offers a feature article on ethics consultation (“Attempting to Establish Standards in Ethics Consultation for Catholic Health Care: Moving Beyond a Beta Group”) by ethicist Mark Repenshek, along with responses by three Catholic health care ethicists. In his article, Repenshek observes that Catholic health care seems “to be lagging behind the constructive dialogue outside Catholic health care on the matter of ‘standards for medical ethical consultation’ despite the prescriptive language found in Directive #37.” He also notes that, in part, the purpose of the Beta group was to “develop broader consensus on standards for the practice of ethics consultation along with measures for quality and effectiveness, and to spur dialogue on what criteria should constitute qualifications for practitioners within Catholic health care.” In his article, Repenshek underscores the need for greater attention within the ministry to the various dimensions of ethics consultation.

CHA is likely to launch a project to address these issues, but in the meantime Catholic health care systems and facilities might do well to devote time to discussing the proposals of the Clinical Ethics Credentialing Project that appear in the November-December, 2009 issue of The Hastings Center Report (“Charting the Future: Credentialing, Privileging, Quality, and Evaluation in Clinical Ethics Consultation,” pp. 23-33). Among the topics covered in the article are fundamental elements of clinical ethics consultation and standards for clinical ethics consultation. With regard to the former, the working group, drawing upon the bioethics literature and the experience of the members of the working group, proposes that “clinical ethics consultation is an intervention in which a trained clinical ethics professional:

- Responds in a timely fashion to the request for a CEC from any member of the medical care team, patient, or family member;
- Reviews the patient’s medical record;
- Either interviews relevant medical stakeholders or gathers the clinical care team and other consultants to discuss the case;
- Visits the patient and family whenever possible;
- As a preliminary matter, identifies the ethical issues at play and any sources of conflict;
- Involves the patient or family with care providers to promote communication, explore options, and seek consensus, when appropriate;
- Employs expert discussion of bioethical principles, practices, and norms and uses reason,
facilitation, negotiation, or mediation to seek a common judgment regarding a plan of care going forward;

- Attends to the social, psychological, and spiritual issues that are often at play in disagreements about the proper course of care;
- Triggers a further process with hospital medical leaders or a bioethics committee to resolve the situation, if a resolution is not reached;
- Follows up with a patient and family after the initial consultation (although this feature of CEC varies, since in some systems follow-up is a task solely for the medical team);
- Records the process and substance of the consultation, including the consultant’s recommendations and their justification as part of the patient’s medical record;
- Reviews the consultation with others on the CEC service as a basic level of evaluation and peer review; and
- Utilizes a formal and rigorous quality improvement process” (p. 25).

With regard to standards for clinical ethics consultation, the group identifies the following:

- “Easy access to CEC and a plan for responding to requests for CEC from staff, patients, and family members (or other patient representatives);
- A clear process for gathering information and making appropriate arrangements to make sure all relevant stakeholders are heard;
- A formal note in the medical record;
- A standard format for writing in the chart;
- Recognition of CEC as one of many collaborating services that must be integrated and transparent in its functioning;
- Institutional and peer oversight;
- Ensuring the qualifications and competency of CE consultants;
- Measures for credentialing CE consultants;
  - Participation in a formal training program and verification of qualifications,
  - Completion of an apprenticeship;
- A robust quality improvement process” (pp. 26-32).

Each of these receives explication in the article. Also in the article, the authors offer elements of a tool for assessing the quality of ethics consultations (pp. 30-31). Finally, a task force of the American Society for Bioethics and Humanities (ASBH) has revised its “Core Competencies for Health Care Ethics Consultation.” The new draft is available at www.asbh.org for review and comment.
The HCR article and the ASBH competencies provide ample resources for consideration and for efforts at improving the quality of ethics consultation and the preparedness of those who carry it out. While Catholic health care may be “lagging behind” in these discussions and initiatives, there is no excuse for its being “left behind.” The resources are available for achieving greater clarity about various aspects of ethics consultation and for making needed improvements.

R.H.

As we begin our fourth year of the Health Care Ethics USA newsletter, we invite you to take a brief survey to let us know what you think and help us serve you better. The survey will take only five to ten minutes. We value your time and insights and would greatly appreciate responses by February 22, 2010. Thanks in advance for your cooperation.

http://www.surveymonkey.com/s/35SSYB3

If you have any difficulty with the above link, please copy and paste the link into your web browser.
Surgeon Questions Study With “Off-Label” Uses of Medtronic Spinal Product

Dr. Charles Rosen, president of the Association for Medical Ethics and professor of orthopedic surgery at the University of California-Irvine, questioned a 2002 study at Walter Reed Army Medical Center that used Medtronic spine products on soldiers in ways not approved by federal regulators. Rosen expressed concern about the study in a Sept. 29 letter to Army Surgeon General Eric Schoomaker.

In the letter, Rosen questioned if patients knew the products were not approved by the Food and Drug Administration for use in their surgeries and if an independent Institutional Review Board oversaw and approved the “experiments on the men and women of the armed forces.” (Janet Moore, StarTribune.com, Nov. 29, 2009).

Vatican Alerts Doctors to Anti-Life Mindset

Cardinal Tarcisio Bertone, Pope Benedict XVI’s secretary of state, cited an urgent need to educate society about the culture of life at a meeting of Italian physicians at the National Council of Catholic Medical Associations at the Vatican last November.

The cardinal reminded physicians that the activity of the Catholic doctor is revealed useful not only for the purpose of physical health, but also, in a certain sense, for the moral and spiritual health of the patient. (Antonio Gaspari, ZENIT, Nov. 2, 2009).

Weighing Medical Costs of End-of-Life Care

Based on annual data compiled by Dartmouth College, the Ronald Reagan UCLA Medical Center consistently ranks near the top of medical centers that spend the most on end-of-life care but do not have better results than hospitals which spend much less. The medical center has become a target for critics of wasted funds for needless test and futile procedures.

Dr. J. Thomas Rosenthal, chief medical officer of the UCLA Health System, and his colleagues worry that unless the distinction can be clearly drawn between excellence and excess in medical care, efforts to cut wasteful spending could be blunt rationing. “There’s a real risk of doing harm here – real harm,” he said.

Research recently published by UCLA and five other big California medical centers found that for heart failure patients, the hospitals that spend the most seem to save the most lives. Dartmouth researchers maintain that decades of research shows that higher spending does not necessarily buy better patient outcomes. (Reed Abelson, New York Times, Dec. 23, 2009).
OF NOTE

Who Gets Expensive Cancer Drugs? A Tale of Two Nations

Research by the Johns Hopkins Berman Institute for Bioethics into comparisons of access to 11 expensive cancer drugs in the United Kingdom and the U.S. found both countries' systems far from perfect.

Seven of the medications studied are free to all British patients, who pay no out-of-pocket costs. The other four are not covered in the National Health Service because policy-makers determined that costs were not worth the limited benefits provided. U.K. patients who want the drugs have to pay for them on their own.

In the U.S. by comparison, most patients who have health insurance have some coverage for all 11 drugs. However, there is great variation in out of pocket costs based on insurance. Expenses for people on Medicare can range from $1,200 to $24,000. For those with limited or no insurance, costs can exceed $100,000 annually in some cases.

“Policy makers and our society now need to do the hard work of developing a reasoned, evidence-based system of using health care resources wisely, and the first step is to engage in an honest and transparent conversation about the values that should guide those decisions, a conversation that is informed by facts, not politics,” said study lead author, Ruth R. (ScienceDaily, Dec. 14, 2009).

Bending the Rules of Clinical Trials

Ninety percent of 700 clinicians surveyed who are involved in clinical trials consider it acceptable to ignore certain entry criteria if they believe their patient could benefit from the trial, according to a report in the bioethics journal, IRB: Ethics and Human Research. Nearly 60 percent of those surveyed believed researchers should deviate from study rules if research could improve a patient’s care.

“There’s a pervasive idea among clinicians and patients that a new drug or device is going to make things better,” said Dr. Charles W. Lidz, research professor of psychiatry at University of Massachusetts Medical School in Worcester and lead author of the study. Statistically, however, while many experimental treatments are as good as standard therapy, few actually end up being superior, and some are worse.

Dr. Lidz believes it is important for patients to participate in clinical trials if their current treatment isn’t working. Clinical trials are central to determining if a new treatment works. Patients need to realize they are doing this for a larger cause, not necessarily their own interest. (Pauline W. Chen, MD, New York Times, Oct. 29, 2009).
Faith-Based Objections to Vaccines May Threaten Common Good

In light of concerns for a potential swine flu pandemic, some bioethicists say members of religious groups who choose to forgo vaccinations put their neighbors’ health at risk and threaten the common good. “Viruses and other contagious diseases don’t care about our personal beliefs,” said Nancy Berlinger, deputy director of the Hastings Center, a New York-based bioethics research institute.

Berlinger cited a 1944 U.S. Supreme Court decision that said “the right to practice religion freely does not include the liberty to expose the community or the child to communicable disease or the latter to ill health or death.” Another ethical concern when a population refuses to be vaccinated is that public health resources have to be diverted to that population if an outbreak strikes.

“We’re all members of the public, no matter what our personal beliefs are,” Berlinger said, “and there’s a point at which those beliefs start affecting someone else.” (Tim Townsend, beliefnet.news, Dec. 8, 2009).

Fraud and Abuse: Allegran Files Latest Motion in Case Challenging Ban on Off Label Promotion

On October 1, 2009, Allegran, maker of Botox, filed a lawsuit against the government “seeking a declaration that FDA regulations that prohibit companies from engaging in truthful, non-misleading, accurate, and balanced speech about off-label uses of their product are unconstitutional.” Allegran’s concern stems from the plethora of non-label uses of their product Botox. The government responded by filing a motion to dismiss arguing that the claim is not ripe for review as the FDA has never brought claims against Allegran based on off-label promotions before and a motion for summary judgment stating that the FDA’s drug approval system is consistent with the U.S. Constitution. Additionally, the FDA stated, “that it intended to rigorously pursue off-label promotion activities.” On January 15, 2010, Allegran
filed a response to the government’s summary judgment motion. In the complaint, Allegran argued, “that it cannot disseminate any information about off-label uses without fear of prosecution until it knows how the government differentiates between promotional and non-promotional speech.” (BNA Health Care Daily Report, January 21, 2010).

**Johnson & Johnson Accused of Drug Anti-Kickback Scheme**

According to a complaint filed by the United States Attorney in Boston, “Johnson and Johnson paid kickbacks to the nation’s largest nursing home pharmacy to increase the number of elderly patients taking several of its medications” when it paid Omnicare “tens of millions of dollars to buy and recommend Risperidonal, prescription pain relievers Duragesic and Ultram, and the antibiotic Levaquin.” (American Health Lawyers, Health and Life Sciences Daily, January 19, 2010).

**Deals to Restrain Generic Drugs Face a Ban**

A group of House lawmakers and the head of the Federal Trade Commission plan to ask Congress to “block business deals in which the makers of name-brand drugs directly or indirectly pay generic makers to delay competition from cheaper drug alternative.” The group wants Congress to include this in health care legislation. The current House bill includes the prohibition, while the current Senate bill does not. The group claims that Americans could save several billion dollars a year when purchasing prescription drugs and that, “deals between brand names makers and generic makers have delayed the introduction of a range of generics.” (Natasha Singer, The New York Times, January 13, 2010).

**Health Care Fraud Becomes the Newest Multi-Billion Dollar Industry**

In recent months, health care fraud has become the nation’s newest multibillion-dollar industry with scammers making an estimated $100 billion per year as the result of fraud schemes. Health care identity theft topped the list of crimes. According to Louis Saccoccio, executive director of the National Health Care Anti-Fraud Association (NHCAA), this most commonly occurs when someone with legitimate access, such as a hospital administrator or a doctor’s assistant, sells patient information to organized criminal groups. Increasingly, criminal groups are hacking into digital medical records so they can steal money from the $450 billion, 44 million-beneficiary Medicare system -- making the government, by far, the "single biggest victim" of health care fraud, according to Rob Montemorra, chief of the FBI’s Health Care Fraud Unit. One key reason Medicare information is a virtual "goldmine" for fraudsters, according to Montemorra, is the system’s "pay and chase" system. Under the law, Medicare must send out payments within a very short time period.
Using stolen information and Social Security numbers, those engaging in fraud falsely bill Medicare and private insurers for drugs, equipment or treatment that were never prescribed. (CNN January 13, 2010 http://money.cnn.com/2010/01/13/news/economy/health_care_fraud/)

MS Pills Show Promise and Risk, Studies Say

Tests of the first two oral drugs for multiple sclerosis show that both reduce the frequency of relapses and may slow progression of the disease, but have side effects that could pose tough decisions for patients. About 2.5 million people worldwide have MS, a neurological disease that can cause muscle tremors, paralysis and problems with speech, memory and concentration. The studies involve the most common form of the disease, in which people are well for a while and then suffer periodic relapses. Current treatments can reduce the duration and severity of symptoms but require daily injections or infusions. The new studies tested two types of pills. Cladribine, made by Merck Serono and used to treat a rare blood cancer, could be taken by those with MS eight to 10 days a year. The other drug, Fingolimod, is being developed by Novartis for daily use in MS. The research found that patients on the pills were about half as likely to suffer relapses of symptoms as those who took placebos or a commonly prescribed shot for MS. But they also found both drugs significantly lowered immune defenses—in one study, two people died of unchecked herpes infections. The side effects detailed in the new studies are giving some physicians pause. Physicians are mindful of what happened with Tysabri, an MS drug that was approved in November 2004 and pulled from the market the next year after cases of a rare but lethal brain inflammation in some patients. It was reintroduced in 2006, but doctors are still monitoring for side effects. (Mike Stobbe, AP Medical Writer, Jan. 20, 2010 http://news.yahoo.com/s/ap/20100120/ap_on_ne_me/us_med_multiple_sclerosis)

CDC: 1 in 5 Teens Has Cholesterol Problem

One in five teens in the U.S. and more than 40% of obese teens have abnormal cholesterol, according to a new report from the Centers for Disease Control and Prevention (CDC). The findings suggest that the American Academy of Pediatrics’ (AAP) 2008 guidelines—which recommend more aggressive cholesterol testing and intervention in kids, particularly the overweight and obese—make sense, the authors conclude. Overall, one-third of adolescents in the new CDC survey were overweight or obese; 22% of the overweight teens and 43% of the obese teens had at least one blood-fat abnormality (as did 14% of teens who weren’t overweight). Findings were published in the Morbidity and Mortality Weekly Report. “It used to be that family history drove who should be screened. Now the recommendations say to include
weight as a criterion,” says Joyce M. Lee, MD, assistant professor of pediatric endocrinology at the University of Michigan. “With obesity being such a problem in [American] children, conditions that we thought were exclusively adult conditions do seem to be prevalent in a small amount of children.” (CNN January 22, 2010 http://www.cnn.com/2010/HEALTH/01/22/teens.cholesterol/)
Influenza Vaccination for Health Care Workers: A Select Bibliography


*This bibliography was compiled by Lori Ashmore, CHA intern in Mission and Ethics.*
Of Interest

Dignitas Personae


End-of-Life Care


Pandemics


Placebos


Research Ethics

The Clinical and Translational Science Award (CTSA) Consortium has created a searchable online inventory of materials that may be used in education and training in the responsible conduct of research (RCR). These materials are freely accessible to all, and are intended to assist those who provide education and training in RCR within the United States and abroad. Please visit the inventory website at [http://twiki.library.ucsf.edu/do/view/ResearchEthics/WebHome](http://twiki.library.ucsf.edu/do/view/ResearchEthics/WebHome) to review the materials.
Health Care Ethics USA

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