The Patient-Centered Medical Home (PCMH) is not a physical structure; rather, it is a model for delivering primary care that promises to improve health outcomes, lower healthcare costs, and improve both patient and provider satisfaction. That is a tall order, but it is being heralded as the savior of primary care at all levels of society. Demonstration projects to implement and evaluate the transformative power of the PCMH are being conducted by the federal government, many state governments, medical societies, private payers, and industry. Not a week goes by it seems without some group offering a seminar or workshop on the PCMH.

The PCMH is an approach to care that promises to deliver the hallmarks of primary care: accessibility, continuity, coordination, and comprehensiveness. Medical practices have different opportunities to achieve accreditation as a PCMH depending on what pilot projects are available in their geographic area and affiliation with sponsoring institutions. The current dominant designation tool used by the National Committee for Quality Assurance (NCQA) measures whether a practice can demonstrate capabilities in the following categories: continuity, clinical information systems, delivery system redesign, patient/family engagement, and coordination. In Michigan, for example, some practices are working with BCBSM to achieve PCMH designation by demonstrating practice transformation in seven areas: extended access, individual care management, chronic disease registry, performance reporting, e-prescribing, patient-provider agreement, and test tracking and follow up.

The high level of PCMH activity is due to the confluence of several conditions: (1) persuasive evidence links a strong primary care system with improved health outcomes; (2) increasing healthcare costs are driven significantly by the rise in incidence and severity of chronic disease, and primary care provides an efficient and effective means of managing complex chronic disease; and (3) the diminishing availability of primary care physicians (PCPs) is nearing crisis proportions (although some say that we have already arrived at crisis). Together, these conditions set up an environment that is receptive to significant primary care reform.

Any successful reform effort will need to address the feared exodus of PCPs from the profession. PCPs are reportedly leaving the profession over dissatisfaction and typically the cause of this dissatisfaction is attributed to PCPs being overworked and underpaid. PCPs earn significantly less than their counterparts in specialty care; they also work very long hours and face workloads that are impossible to complete.

If we need to do something to keep PCPs from leaving the profession and encourage medical students to choose primary care in greater numbers, it might seem that we simply need to increase reimbursement to PCPs and be done with it. You might even argue that increased payment to PCPs engaged in preventive care and coordinated management of chronic disease would in the long run lead to overall cost savings over the current reliance on specialty care to address acute illness.

This increased reimbursement is not going to happen for several reasons. First, insurers are under incredible pressure themselves from businesses to lower costs; increasing payments to one group of physicians in order to achieve long term cost savings won’t yield cost savings in the right timeframe. Second, the current system of physician reimbursement has not acknowledged many of the kinds of activities that comprise a significant part of a PCP’s job. Simply increasing payments for current procedure codes still ignores a significant amount of care that the system does not reimburse. This would turn out to be the wrong fix for a legitimate problem. Third, there is great pressure to modernize the delivery of care so that physicians take advantage of technology to deliver care more safely, more efficiently, and more effectively.

So, enter the PCMH. It promises to slice, dice, and wait, there’s more … but is the PCMH all that? Will it really heal what ails our current primary care system? Maybe it will, maybe it won’t. However, I don’t think we can fully understand the potential of the PCMH, or any other model of delivering primary care, unless we examine a fundamental source of dissatisfaction in primary care, one that goes beyond the usual gripe that PCPs are underpaid and overworked, specifically, the degree to which professional integrity is compromised by our current system for delivering healthcare. The extent to which physicians, PCPs included, are able to carry out their fiduciary responsibility to their patients is importantly intertwined with the system for delivering care;

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however, this is largely an invisible feature of our medical landscape. The connection between professional integrity and models of care delivery might not be immediately evident. Within the bioethics literature on professional integrity, the discussion tends to fall into three categories: conflicts that arise when circumstances make a physician reluctant to execute certain professional duties to the patient, such as preserving confidentiality or truth telling; conflicts that arise when a physician’s professional duty to provide a particular kind of care to a patient conflicts with the physician’s personal morals; and conflicts that arise when financial incentives create a conflict of interest (or the appearance of one) for the physician.

Overlooked in these discussions on professional integrity is a fourth type of conflict—conflicts that are created by the institutional context in which a physician provides care to patients. In the case of primary care, the PCP has a fiduciary responsibility to the patient to deliver competent, compassionate, comprehensive care in a way that makes the PCP accessible to the patient within clinically appropriate timeframes. A PCP can be well trained, knowledgeable, and conscientious—and still certain aspects of delivering the kind of care that a patient deserves will remain outside his/her immediate control. Let me walk you through a series of ways in which a patient’s health encounter can go wrong that negatively affect the physician’s ability to deliver the right kind of care, but lie outside the PCP’s immediate control: the patient calls the office, but is unable to reach a clinically appropriate person to answer his/her questions; the patient reaches the office, but is unable to obtain an appointment within a clinically appropriate timeframe; the patient obtains an appointment, but either the physician is not allotted sufficient time to properly evaluate and manage the patient’s condition or is continually interrupted; the PCP has sufficient time, but clinically relevant information is not accessible when the patient is in the office. And the list goes on, but a picture emerges of the many ways in which the processes that comprise how a practice delivers care converge to influence the degree to which a physician is able to carry out his/her fiduciary responsibility to the patient. Many of the missteps in the list above are the direct result of pressures created by the current system for the delivery of primary care. Why is this the case? Reimbursement in medicine is largely procedure driven, and primary care does not have many procedures. Consequently, PCP income depends heavily on (1) boosting revenue through patient volume; (2) decreasing overhead by the use of less qualified nursing staff; and (3) postponing/rejecting new technologies such as EMR (electronic medical records), electronic practice management, e-prescribing, etc. because they will not yield a sufficient return on investment to warrant their purchase. All of these pressures combine to create a system in which it is difficult for the physician motivated by the fiduciary responsibility to the patient to meet this responsibility well.

Any proposal to improve how primary care is delivered needs to address conditions that make it possible to set up office-based processes that enable PCPs to meet their fiduciary responsibilities to their patients. The PCMH holds promise that reimbursement will change in ways sufficient to alleviate those pressures that impede a physician’s ability to act with integrity: (1) it explicitly motivates investment in technology; (2) it explicitly acknowledges the value of and rewards the kinds of non-physician healthcare workers who can comprise an effective, efficient team; (3) it explicitly rewards access and coordination; (4) it explicitly rewards communication between a patient’s PCP and the various specialists who are contributing to a patient’s care.

So, let’s come back to why we don’t just pay PCPs more for E and M codes. More money alone might be sufficient to reward those physicians whose commitment to professional integrity is so high that they do not need much oversight. But it is probably foolish to develop business practices that rely on the goodwill of individuals alone to be rightly motivated. Any proposal to reform primary care should align the financial motives of physicians with best practices that will yield the best health outcomes and the lowest overall health costs.

In this way, we can come to see that there are two distinct integrity questions: (1) Can a physician motivated by his/her fiduciary responsibilities to his/her patient act within a care delivery model with integrity?

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Recently I had the opportunity to interview Dr. Hilde Lindemann the current president of the American Society for Bioethics and Humanities (ASBH). Our conversation focused on the future of ASBH as well as the topic of her new co-edited book, *Naturalized Bioethics: Toward Responsible Knowing and Practice*.

Dr. Lindemann’s discussion of the future of ASBH revolved around the vigor of the different perspectives that emerge within ASBH, she argued, “I think its existence depends on the strength of the different perspectives that are in it. If the philosophers took it over, or the doctors took it over, or the lawyers or somebody like that, then it would die. What makes it strong and vibrant and active is the interconnection among all of those different perspectives. That is kind of the grandiose or abstract answer, but more immediately and concretely, in the very near future, what we have are two new initiatives.”

The first initiative is a new publication that will highlight and reproduce current literature of interest to ASBH members and the second is the creation of a steering committee for clinical ethics consultants as they work to create a code of ethics. In describing these initiatives, Lindemann explained, “The first of them, which we are very excited about because it looks as if it’s going to happen more immediately, is a reader. The reader will be published in hardcopy and it’s a benefit of membership, so all ASBH members will get it and it’s built like Reader’s Digest. That is, we are reprinting from various journals in the medical humanities and bioethics. We are selecting articles that we find either really important or concentrating on thematic issues. I think it will be three times a year that we will be publishing and in each issue, the plan is about six articles. It will be fabulous, because nobody has time to read everything and this way it will highlight certain articles that the ASBH wants to draw the member’s attention to.”

Regarding the steering committee she explained, “The other large initiative, and this is going to take considerably longer is we are trying to better serve the clinical ethics consultants in ASBH. For a long time they have needed to have a code of ethics for the work that they do, and here again, is one of the things that I love about ASBH. Not everybody in the society needs a code of ethics or wants one; but, clinical ethics consultants do feel the need to have a code, if for no other reason than that they can point to it if the hospital says ‘you have to do such and such,’ and they shouldn’t do such and such. So a piece of what we are doing is getting this code together but we are also looking into how best to think of credentialing clinical ethics consultants. Because you don’t want just anybody who has read a couple of issues of *Medical Humanities Review* to just say ‘I’m a clinical ethicist, I can do this now.’ You do want to have some kind of standard for practicing and guidelines for doing it and some kind of credentials, and probably this will be at least Master’s level or Ph.D. So we have this new steering committee that is looking into coordinating all of these initiatives for the guidelines, the standards, for educational resources, and for the code. Anita Tarzian [Chair, Core Competencies Task Force, ASBH] is the leader for this initiative, and it was just yesterday that the board of directors of ASBH approved Anita’s plan for how to consolidate and move forward in the area of professionalizing the clinical ethics consultations. So you got it hot off the press.”

The next area of discussion with Dr. Lindemann related to her new co-edited book, *Naturalized Bioethics*. She was kind enough to answer the following question: How does ASBH, go about aiding the agenda for a naturalized bioethics (in the words of her chapter) “to change decisively and thoroughly how bioethics is done?” Her response was thoughtful and enlightening, she stated, “That was brave of us don’t you think? We were overly optimistic that we could do that all in one book. We wanted to be bold, because we think it is a bold initiative. How ASBH helps naturalize bioethics is by using the various kinds of knowledge that are available to bioethicists in ASBH including the knowledge from medical sociology, literary studies, religious studies, medical anthropology, law, all of those different kinds of knowledge. I didn’t mention psychology, that’s obviously a big one too. So that, for example, when ethicists make claims that are thoroughly abstract, and removed from any particular social practice, like practicing medicine, then you need to pay careful attention to whether people's actual psychologies can support that type of claim. What we are doing in naturalizing bioethics is to take advantage of all of the kinds of things that very many different kinds of people know and build our bioethics around that. That is if you bring it down to the ground. In that way it is a bottom up approach to ethics but it has normative force, it’s not just well we should do what everybody does, that doesn’t work very well. But you don’t want to miss the important things about what people actually do.”

Dr. Lindemann also elaborated on what the term naturalized bioethics means, she explained, “Naturalized, we borrow from epistemology, which is the study of knowledge, theories of knowledge, that’s what epistemology means, and to talk about a naturalized epistemology is that your theory of knowledge draws from the natural world. The world around you not from ideals about what people should be able to know, so in that way we want to draw on the world around us and not just ethical ideals about what people should do.”

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Perspectives on: Newborn Screening Ethical and Policy Challenges

In the last issue of MHR, Leonard Fleck, Ph.D. wrote about the ethical and policy challenges surrounding newborn blood screening. The contributors to this InkLinks continue this discussion. InkLinks is a regular column in which readers reflect on issues related to the previous lead article. It is meant to tap the rich intellectual resources that this network provides. We welcome your contribution at altimare@msu.edu.

Michigan Addresses Newborn Screening Challenges

In the last issue, Dr. Len Fleck reviewed the history of newborn screening which is widely acknowledged as an important and successful public health program. He also outlined some of the ethical and policy issues that have emerged as a result of recent advances in technology. As of 2009, the Michigan Department of Community Health (MDCH) screens newborns for 49 conditions that may lead to disability or death without early detection and treatment. In addition, Michigan birthing hospitals screen all newborns for hearing loss. State policy decisions to adopt new screening tests are now based largely on recommendations from the federal Department of Health and Human Services (HHS), Health Resources and Services Administration which has sought in recent years to standardize the battery of screening tests offered to newborns regardless of the state in which they are born. The March of Dimes also recommends a list of core disorders that should be included in every state’s screening panel, and the HHS Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children is developing a process to better evaluate available scientific evidence before new disorders are added. Additionally, MDCH relies on guidance from its Newborn Screening Advisory and Quality Assurance Committees. Two hundred Michigan infants were diagnosed through newborn screening in 2007. In addition to laboratory testing, MDCH provides follow-up to assure all babies identified with positive screens receive appropriate confirmatory testing and medical management.

As Dr. Fleck points out, false positive screening tests occur. In the past, poor specificity has been one criticism of population newborn screening but with the recent use of tandem mass spectrometry (TMS) for detection of metabolic diseases, great strides have been made in decreasing the rate of false positive screens while maintaining high sensitivity. The MDCH performance target for false positives is now lower than 0.3% of all infants for the more than 40 metabolic disorders screened by TMS. Therefore, the majority of false positive tests are currently related to the use of immunoassays for detection of congenital hypothyroidism and congenital adrenal hyperplasia. Recent adaptations of TMS for steroid analysis will significantly reduce the false positive rates for these disorders as well. In addition, our state Newborn Screening (NBS) laboratory participates in the Region 4 Genetics Collaborative project to harmonize screening cutoffs. Over 75 states and countries pool de-identified laboratory analytic data to accelerate improvements in the accuracy of detecting rare metabolic conditions. Nevertheless, concerns remain about the potential impact of false positive tests on families as well as on screening programs and health care systems. In order to better understand the parental perspective on this matter, MDCH is participating in a 3-state research study conducted by the Genetic Alliance and University of Maryland that will further explore the issue through parent focus groups and interviews.

Retention, storage and possible use of residual NBS dried blood spot samples for research is another important and timely issue explored in the previous article. Although Michigan samples were previously saved for 21.5 years based on the Attorney General’s opinion in the early 1980s, MDCH recently revised its policy to store samples indefinitely. Some readers might be surprised to learn that, unlike many other states that have only recently begun to address this issue, it was first discussed in Michigan more than ten years ago. In its 1999 report, the Governor’s Commission on Genetic Privacy and Progress recommended that newborn screening samples be retained indefinitely because they represent a vital resource for the study and treatment of disease. In 2000, the Michigan legislature amended the public health code to: “Allow the blood specimens to be used for medical research during the retention period … as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks” (PA 33 of 2000; Senate Bill 0807 of 1999; www.legislature.mi.gov/).

As technology continues to advance and interest in using banked biological specimens for health research increases, MDCH is exploring the feasibility of a population-based biobank for residual NBS samples, tentatively called the “Michigan BioTrust for Health.” Together with key partners, including Michigan State University, we are in the process of addressing many technical and ethical considerations related to such a biobank. Initial feedback from a series of focus groups, presentations, and surveys indicates strong public support for such an initiative, provided proper controls are in place and the public is fully informed.

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Newborn Blood Screening

Dr. Fleck has presented important considerations about both the newborn screening program and use of these bloods for research. I would like to offer some other considerations about the research use of these newborn screening bloods because of my role with the Michigan Department of Community Health IRB. In addition to the dilemmas he mentioned, both newborn screening and research use of leftover newborn screening blood are complicated because the patient/subject has no say, at least until they become an adult. The potential consequences of the patient’s/subject’s lack of say is very different for the two situations. In the case of newborn screening the testing is done specifically for clinical purposes and there is at least a potential direct benefit to the patient. In the case of research use of the leftover newborn screening blood, by definition there is no known benefit to the subject and it is very unlikely there will be any direct benefit. In either case, however, the patient/subject has no say.

The research use of leftover newborn screening blood should be justifiable if the potential benefit of the research outweighs the risk to subjects, including certain groups of people. The potential benefit of research use of leftover newborn screening bloods may be substantial especially because of some unique epidemiological characteristics that are otherwise hard to come by in the United States. Any risk can be minimized, even when the blood is not anonymized and even when it is used for certain research involving the subject’s DNA. This is not to say the risk can be totally eliminated, but there are means to reduce any risk to a reasonably acceptable level.

Assuming there is a potential benefit of using leftover newborn screening bloods for research, and that any risk can be minimized, there is still a need to consider what say the subjects should have. I believe that Dr. Fleck has identified the essential need for public input in the rhetorical question in his conclusion. I also think that say/consent depends on the situation. The plan is to get written permission from the parent/guardian to allow their child’s stored blood to be used for research for bloods prospectively collected. Close to 4 million bloods are already in storage. A judgment was made that getting specific consent was impracticable for these, but efforts should be made to publicize that anyone could ask that their, or their child’s blood, not be used for research.

Specific research would then be individually considered, subject to guidelines set by a community values board and review and approval by a scientific advisory board and our IRB. Research without identifying information could be allowed without further specific consent. This would require judgment that any risk is minimal and that it would be generally acceptable. If those criteria were not met or in question, such research would either require specific informed consent or not be allowed. Once again, this is where the public input is so essential to guide those making these judgments.

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For references:
http://bioethics.msu.edu/
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Grants
• Funded by the MSU Center for Gender in Global Context: Strategic international partnership to explore and develop a residency rotation exchange between the departments of OB/GYN at MSU and the University of Costa Rica and the Caja Costarricense del Seguro Social. The proposal was developed in collaboration with Drs. Richard Leach and Patricia Obando, MSU Department of OB/GYN (May 16-20, 2009)

Presentations
• "Can Evidence-based Medicine 'Teach the World to Sing?'" for the 2009 Global Perspectives Conference, Lansing Community College (March 31, 2009)
• "Childbirth Choices (Not): Why Do We Do What We Do?" for the 2009 Global Perspectives Conference, Lansing Community College (March 31, 2009)

Consultations
• With Thomas Noren, M.D., Marquette General Health System Chief Medical Officer and David Louma, M.D., Assistant Dean for the Upper Peninsula CHM Community Campus and CEO Upper Peninsula Health Education Corporation, on capacity-building in the Marquette General Health System Ethics Committee (March 7-9, 2009)

LEN FLECK

Presentations
• "Health Care Rationing and Priority Setting: How Has Oregon Done?" for Grand Rounds at the University of Michigan Medical Center, Ann Arbor, MI (February 25, 2009)
• "Justice in Health Care Research: How Should the Benefits be Distributed?" for the Mt. Sinai Health Care Research Ethics Conference, New York (March 6, 2009)
• "Health Care Reform: Major Ethical and Political Challenges" for the Michigan State University Undergraduate Bioethics Society, East Lansing, MI (March 27, 2009)

ANN MONGOVEN

Publications
• Just Love: Transforming Civic Virtue, Indiana University Press (June 2009)
News & Announcements

GERALD S. SCHATZ

Publications
• Introductory Note to European Court Of Human Rights (ECHR) (Grand Chamber): Case Of S. & Marper v. United Kingdom (reaffirming qualified genetic privacy rights of persons accused but not subsequently prosecuted or convicted), International Legal Materials, in press

Appointments
• Judge, International Rounds, Philip C. Jessup International Law Moot Court Competition, Washington D.C. (March 22-28, 2009)

MISHA STRAUSS

Presentations
• "Combining Ethics and Fiscal Soundness in a Primary Care Practice" mandatory lecture for Block II CHM students as part of their Career Development Curriculum (April 14, 2009)

Appointments
• Board of Trustees of Chelsea Community Hospital for a 3 year term (Effective January 1, 2009)

TOM TOMLINSON

Presentations
• “End of Life Care—Ongoing Challenges” at MERN Advanced Bioethics Conference: Ethics at the Cutting Edge, Brighton, MI (May 2009)
• “Conscientious Objections: Scope and Limits” at MERN Advanced Bioethics Conference: Ethics at the Cutting Edge, Brighton, MI (May 2009)
• “Protection of Non-Welfare Interests in the Research Uses of Archived Biological Samples” at the New Challenges for Biobanks—Ethics, Law and Governance Conference, Leuven, Belgium (May 2009)