NIH Collaboratory

Health Care Systems Research Collaboratory

Stakeholder Advisory Group

Meeting Summary

Engaging Health Care Systems as Partners in Research:
Moving Toward a Sustainable Partnership

May 9th, 2013
World Trade Center Baltimore

CMTP

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Stakeholder Advisory Group Mission

The goal of the Stakeholder Advisory Group (SAG) to the HCS Research Collaboratory is to provide the forum within which people from outside the Collaboratory and health care systems research enterprise can bring their different perspectives, expertise, and responsibilities into the work of identifying, defining and overcoming the barriers to the transformation from a delivery system to a learning health care system. SAG membership will include patients, providers, payers, employers, life sciences representatives, policy makers, and other stakeholders from the public and private sector. The SAG will convene to understand agreements and differences of opinion, and will channel the information learned back to the Collaboratory and to the constituencies represented by SAG members.

Welcome and Overview

Sean Tunis of CMTP, Lead of the Stakeholder Engagement Core (description of Coordinating Center Expert Cores attached), opened the meeting and outlined objectives for the day. Objectives included discussion of two critical issues to the success of the Collaboratory: 1) creating an environment in which participation in learning activities is high among providers, patients/families and administrators, and 2) resolving issues related to regulatory and ethics oversight and consent. In addition, as this was the first face-to-face meeting of the SAG, another important objective was to build relationships among the stakeholders.

Rob Califf of Duke University, Principal Investigator of the Collaboratory Coordinating Center, provided a brief overview of the original charge to the Collaboratory and gave an update on the progress to-date of the Coordinating Center and Demonstration Projects.

Eric Larson of Group Health Research Institute, Lead of the Health Systems Interactions Core, gave an overview of Group Health's vision of a learning health care system and provided examples of projects implemented within their system.

Stakeholder Feedback on Overall Goals of the Collaboratory and Learning Health care Systems

- The notion that learning will lead to better patient care in not in itself sufficient justification for major reductions in research oversight or regulation.
- Sense of group: in the rush to learn more quickly, we must also remain respectful of rights to be fully informed and protected from potential harms.
- SAG feedback provides a reality check on the degree to which reduced oversight may be acceptable.
- Need to further raise public awareness that health care systems are not currently learning systems
- Even those who recognize gaps in knowledge often don't think this is true of their own providers.
- Stakeholder support of learning activities depends heavily on being convinced of commitment to use evidence to change.

Incentives for Health care Systems to Partner in Research

The success of clinical research conducted within health care systems requires the support and willing participation of patients, providers, payers, and administrators. Identifying the appropriate incentives to encourage participation is key to the successes of the Collaboratory demonstration projects, as well as future research efforts. The overarching goal of this session was to stimulate creative thinking about what it will take for health care system stakeholders to be engaged actively as partners in research.

Challenges in collecting PRO data

Patient reported outcomes (PROs) are an important component of learning health care systems; however, there are a number of challenges related to PRO selection and implementation. Amy Abernethy of Duke University Center for Health Research, Co-lead of the PRO Core, gave a short presentation on her work and insights gained from the first 6 months of the Collaboratory. The presentation highlighted challenges to implementing PRO collection in health care settings, including: integration into clinical workflow, ease and accessibility of data collection and reporting technology, resource limitations, and provider and patient incentives.

Stakeholder Feedback Regarding PRO Implementation

- There is a need for an ecosystem surrounding electronic health records (EHRs) that encourages innovation (similar to iOS and Android). This might be accomplished by nudging EHR providers to create an environment for innovation, or supporting personal health record infrastructure consistent with the "meaningful use" or "blue button" initiative.
- From a public payer perspective, PROs are clinically relevant and meaningful for patients as well as providers, particularly for content areas such as pain and fatigue. The complexity is that CMS only has authority to require data collection where it is for quality measurement. Another challenge is that different legacy instruments are used to collect these data and there needs to be unification. There are also concerns regarding who gets the data and how data will be used by payment entities. One suggestion for the Collaboratory PRO work is to align with other areas such as quality reporting requirements to provide a valuable service to physicians.
- Patient-generated data does not need to be limited to PRO instruments. We need to expand beyond the context of PROs to overall collection of data from patients and how we can use this data in health care to inform a variety of issues.
- We need to put equal focus on the integration of PROs into the lifeflow of patients (how patients operate in their daily lives) and families, not just clinician workflow.
- Identifying outcomes that are important to patients requires a deliberative process. Patients need time to absorb and understand the problem, consider possible solutions, and *then* identify outcomes.
- The ONC is interested in collecting information on PROs in a way that can be digitally collected and exchanged just as clinical information. Patient advocates interested in PRO collection are needed at the table for ONC's recently launched *Structured Data Capture Initiative*.
- Physicians are primarily motivated by the desire to improve the quality of care for their patients. If we frame PRO collection in the context of quality improvement, they may likely become more involved.

Engaging patients, providers, and health systems in research

Scott Halpern of the Penn Center for Health Incentives and Behavioral Economics gave a short presentation on incentives for research participants, clinicians and recruitment staff, including financial incentives and other behavioral economic strategies. Key points included the importance of supportive health system leadership and the need for rigorous testing of different approaches to enrollment to examine intended and unintended consequences for patients.

Stakeholder Feedback on Incentivizing Research Participation

- In attempting to increase patient enrollment it is important to understand that, while the motivation for a study or importance of the research makes sense to us, the patient may have many reasons not to get involved. We need to clarify (through continued stakeholder engagement) a number of rationales and reasons for people to participate aside from payment.
- Motivational interviewing by nurses or other health care staff (used extensively by managed care organizations) is one approach to patient enrollment that warrants further exploration.
- Another important incentive for patients is enabling them to learn from others by feeding useful information back to them, allowing them to participate in managing their own health and also to feel less alone in their condition (Patients Like Me has explored this approach).
- There is also interest in the role of "legacy effect" as an incentive for patient participation in research. In the era of Patients Like Me, contributing to the broader community of patients may be an important incentive.
- Narratives, as opposed to incentives alone, are one proposed solution for improving nurse and physician participation. The narrative approach might also be useful for patient enrollment.
- The IRB perspective considers four categories of payment: reimbursing for expenses, compensating for time, tokens of appreciation, and inducement. These distinctions make a big difference in how IRBs deal with payment, but there are no consistent standards. Empirical work in this area is needed.
- An important consideration is how resources should be distributed among patients, practitioners, and health care systems in incentivizing participation. One perspective holds that patients who are approached by their doctor to participate in a study are unlikely to say no, suggesting that resources should be directed toward practitioners. However, it was also noted that doctors are responsive to their patients, and therefore patients and patient groups can become allies in recruitment.

Regulatory and Ethical Oversight of Health Care Systems Research

Issues surrounding ethical oversight and human subject protections in health care systems research have been a significant point of focus both within and outside the Collaboratory during its initial year of funding. There has been a growing recognition within the clinical research and bioethics communities that the current regulatory standards for research involving human subjects may not fit within the changing landscape of a learning health care system, and may impede important learning activities rather than offering the protections they were designed to provide. A recent *Hastings Center Special Report* proposes a new ethics framework for learning health care systems and the Collaboratory provides a valuable opportunity to explore these issues in greater detail.

An Ethics Framework for a Learning Health Care System

Ruth Faden and Nancy Kass of the Johns Hopkins University Berman Institute of Bioethics gave an overview of their work published in the February 2013 *Hastings Center Report* on a new ethics framework for a learning health care system. Their presentation was broken into three parts: 1) practical and moral problems with the current ethical framework, 2) proposal for a new ethical framework, and 3) implications going forward. Briefly, the goals of the proposed ethics framework are twofold: 1) To support the transformation to a learning health care system, and 2) To help ensure that learning activities carried out in such a system are conducted in an ethically acceptable fashion, with rights and interests appropriately protected.

7 Obligations of the New Ethics Framework

1. Respect the rights and dignity of patients and families
2. Respect the judgment of clinicians
3. Provide each patient optimal clinical care
4. Avoid imposing non-clinical risks and burdens
5. Address unjust health inequalities
6. Conduct continuous learning activities (clinicians, health care institutions, payers)
7. Contribute to the common purpose of improving the quality and value of clinical care (patients and families)

Faden RR, Kass NE, et al. An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. Hastings Cent Rep. 2013 Jan-Feb;Spec No:S16-27.

Commentary

Jerry Menikoff of the Office for Human Research Protections, who also authored one of the commentaries in the February 2013 *Hastings Center Report*, gave his (personal) views on the current regulatory challenges and the new ethical framework proposed by Faden and Kass. Dr. Menikoff endorsed the idea of trying to find solutions under current regulations as opposed to rewriting those regulations entirely. He also noted that, in the case of secondary analysis of data, there is little disagreement between the goals of the learning health care system and the current position of the federal government. Enabling low risk activities such as reusing data would allow regulatory bodies to pay more attention to riskier activities.

Challenges outlined by Dr. Menikoff included the automatic application of the Common Rule to any use of "identifiable" information. He noted that research involving data without identifiers is not under the Common Rule, and therefore offers an approach to working under the current system when informed consent is viewed as too much of a burden. Change to the current system will require identifying, out of the universe of research studies, which activities require consent and which do not.

Jeremy Sugarman of Johns Hopkins University noted that the Collaboratory team has struggled with the distinction between the regulatory apparatus we are currently using and the ethical issues we are thinking about. He cautioned the group to keep in mind that our thinking is ahead of the pace of any regulatory change. He also emphasized that in considering the values associated with a learning health care system, we need to think about what other societal values are in the balance. For example, how does the good of health care get balanced with food, security, safety, or well-being?

With regard to the framework, Dr. Sugarman indicated that the first four obligations are consistent with current thinking and not very contentious, however, obligation five (health disparities) and seven (patient obligation) raise more difficult issues. These two obligations are closely linked in that a learning health care system cannot obligate all patients equally to participate without also sharing the benefits of research equally among them. In thinking about specific projects, he encouraged the group to keep in mind that all learning in health care isn't the same and to think about the level of risk, current state of knowledge, moral considerations, and whether all treatments are considered equal. Finally, he noted that much is lumped into the informed consent process – respect for persons, autonomy, liberty, welfare, distribution of benefits, transparency, trust in the system – but that informed consent may not achieve all of these aims. The goal is to figure out alternative models.

Summary of Stakeholder Feedback on the New Ethical Framework

- Emphasizes how much uncertainty exists in clinical care.
- While patients / consumers may recognize this generally, not easily accepted in context of ongoing clinical care.
  - "May apply generally, but my doctor knows what she is doing."
- Patients / consumers also have limited awareness of how much personal data is already collected in health care.
  - Emphasizes need to better educate public that LHS aims to make better use of data, much of which is already being collected.
- Informed consent options are not limited to "fully-loaded" approach vs. no consent.
  - *Explanations* could play a key role: SAG commented on modified approach in which everyone gets *some level* of explanation regardless of the risk involved.
- Distinction drawn between decisions that patients would typically address with their clinician and those they would not:
  - E.g. decisions about hospital staffing don't solicit patient input.

Stakeholder Discussion on a New Ethical Framework for LHS

The difficulty with the notion of shared contribution for a common goal in the context of the learning health care system is that the goal is based on "we don't know what we're doing." It is difficult to explain to people, particularly when they are ill, that there is not as much certainty behind the veil of medical care as they think. In addition, some level of transference to doctors may be a good thing.

Stakeholder Discussion on New Ethical Framework for Learning Health care Systems

- One possible framing for public buy-in to a learning health care system is: *We are doing a lot that is good, but there is still a lot that we don't know. If we can do this together, there is high probability that everyone's care will have the chance to improve.*
- It may be useful to think about the framework, particularly Obligation 7, in public health terms. Many activities authorized in public health to produce knowledge do not require IRB approval.
- Another messaging challenge is to convey the point, without being alarmist, that an extraordinary amount of collection and analysis of personal data is being done already, even in health care. Therefore, we are not moving from a situation where nothing is taking place without consent to one where a ton is being done with patient data without consent. The challenge is to take all of these activities, put them together, and think about which ones require one-on-one conversations vs. broader disclosure, and which ones can move forward without extensive protections vs. needing the full consent and oversight apparatus.
- Several stakeholders pointed out the importance of the terminology used in discussing these issues, and the need to draw connections between common terms, medical and scientific definitions, and definitions that can be used by patients and the public. For example, terms like "clinical research," "clinical trials," and "health research" would benefit from common understanding and usage.
- It was noted that the choice does not need to be full informed consent versus nothing; explanations, along with disclosure and transparency, play a vital role. We need to come up with a model where everyone gets *some level* of explanation regardless of the risk involved. It was also noted that people are very willing to have their data used, but want to be asked.
- In discussing situations that may or may not require consent, a distinction was drawn between decisions that patients would typically work out with their clinician and those they would not. For example, it is commonly accepted that decisions about hospital staffing are made without patient input (e.g., ICU staffing, 5-day radiation schedule).
- A proposed counterpoint to the imperative of consent and IRB oversight is the ethical imperative to test new health technologies. It was noted that the widespread use of expensive technologies that have not been adequately put to the test is a significant reason for the current problem.
- In deciding what information people want and need to have, it is important to provide context related to the decisional dilemma and what is at stake. If you ask people what they want to know about something without providing context, they want to know everything. However, when you explain to people *why* they may or may not want to know certain things, they prefer less information overall.
- Some viewed the phrase "no reason to think patients object or prefer one approach over another" as paternalistic. But, it was emphasized that judgments about patient preferences would be based on extensive and continuous empirical work involving patients and advocates.

Case Studies

Richard Platt of Harvard Pilgrim Health care, Co-Principal Investigator for the Collaboratory, presented a hypothetical example involving the implementation of a new hand hygiene product in three hospitals

(Case Study 1). He asked the SAG to consider 1) whether or not each hospital has conducted human subjects research as defined by the Common Rule and/or HIPPA, and 2) if informed consent would be necessary.

Case Study 1: SoftClean – A New Hand Hygiene Product	
Scenario	Three hospitals (A, B, and C) are adopting a new FDA approved, commercially available hand hygiene product (SoftClean) that is advertised to be easy on the skin AND antimicrobial
Approach	**Hospital A**: A few months after introducing SoftClean, the hospital's infection preventionist surveys personnel about usability and reviews patients' infection experience **Hospital B**: Infection preventionist polls members of her professional association. 50 work in hospitals that have adopted SoftClean and 50 work in hospitals that haven't. They combine their user polls and infection data. **Hospital C**: Infection preventionist polls members of her professional association and 100 hospitals are contemplating adopting SoftClean. They agree that 50 randomly selected hospitals will adopt it immediately and the other 50 will wait a few months. They develop standard survey and reporting forms
Results	**Hospital A:** Personnel report more skin problems, possibly because the product was introduced in winter. A few more patients acquired infections than had done so before. Can't tell if the increase is clinically meaningful since power is limited **Hospital B:** Personnel preferences not comparable because of different survey forms. Patients in SoftClean hospitals had more infections, but these were hospitals with sicker patients **Hospital C:** SoftClean users had fewer skin problems. Patients in SoftClean hospitals acquired fewer infections**.**

Case Study 1: The group spent some time discussing whether scenario C constituted research, with some contending that this situation created more than minimal risk because it involves randomization. It was noted that the only approach that was able to accurately answer the question in this example (Hospital C) presents the biggest obstacle in terms of the need for IRB approval and possible informed consent requirements. Within the current regulatory system, randomization and the intent to generalize findings place the activity in the category of research requiring IRB approval. Although IRBs could reasonably waive individual consent in this situation, the lack of consistency across IRBs means it is possible that individual consent would be required. This case highlights what participants referred to as "perverse incentives" under the current system, where health care systems may avoid answering questions in a rigorous way in order to avoid IRB oversight. It was suggested that as long as "Is the intent to produce generalizable knowledge?" remains the first question on the decision tree, the problem will remain. A better approach in triaging learning efforts might be to first determine if the proposed activity will produce useful information (including the appropriateness of the design), then address the type of approval, consent, and oversight that should be required.

Several meeting participants advocated finding ways to work within the current regulatory system and offered potential approaches. For example, it was noted that much educational research falls under

federal regulations for exempt research. Cluster-randomization is often used in educational research, making it a useful model for consideration. Another suggestion was to work with IRBs to recognize types of research where it is reasonable to waive individual informed consent.

Case Study 2: CER of Medications for Hypertension	
Scenario	A study will compare 2 widely used generic blood pressure drugs in patients for whom either drug would be considered clinically appropriate
Approach	• Clinics will be randomly assigned to always begin treatment with one or the other of these drugs (cluster RCT). • After initial assignment, all further care decisions are made by clinician and patient. • Study outcomes are BP control, stroke, heart attack, and death. • Researchers will collect all outcome data from medical records and death index. No data will be collected from patient or doctor, and nothing else about the patient's care will change.
Case Study 3: CER Study of Ventilator Weaning	
Scenario	A study will compare two methods for weaning patients from a ventilator while recovering from severe pneumonia. One approach will use a written algorithm based on vital signs and oxygen level, and the other will be usual clinical practice.
Approach	• Patients will be randomly assigned to either study arm • Algorithm developed by ICU team based on collective experience • Clinicians are encouraged but not required to follow algorithm fully • Study outcomes are time on ventilator, re-intubation, LOS in ICU • No data will be collected from patient or doctor, and nothing else about the patient's care will change.

After a brief presentation of Case Study 2 and 3 by Dr. Tunis, the SAG divided into four breakout groups to discuss the level of informed consent that should be required in these examples, and more generally, the factors that are relevant to determining which studies should seek individual informed consent. The groups then reconvened as a larger group to share what they learned.

Case Study 2: With regard to the study of hypertension medications, the majority of stakeholders felt that individual-level informed consent should be required, but there was variation in the primary rationale offered for this view. Some emphasized that patients might reasonably be expected to have a preference for one drug versus the other based on different side effect profiles. For others, the primary factor necessitating informed consent was the element of randomization. If a doctor's treatment decisions are being determined by outside forces, some patients would want the opportunity to give consent even if there is no indication that one treatment is better than the other. Additional discussion focused on the quality and efficiency of informed consent. It was proposed that meaningful consent can be acquired at relatively low cost, and that the consent process should be reasonable and not too burdensome. For learning health care systems, another level of consent might be informing patients coming into the system that there are a lot of studies going on to reduce areas of uncertainty, and that the patient is an important partner in this learning. Patients therefore agree up front to be an active

member of a learning health care culture. This approach to consent would be viewed more favorably in cases where the health care system has clearly demonstrated a history of incorporating learning activities to improve patient care.

Case Study 3: Some participants suggested that, because patients would not typically be involved in decisions or discussion about strategies for ventilator weaning, individual consent should not be required in this scenario. However, they noted that under current regulations, such a study would require individual informed consent. Others noted that the emotional response elicited by this case adds an additional level of challenge, in that even if you know that the evidence is not there, integrating that knowledge emotionally may be difficult. Finally, the intention of the study was viewed as important. If the goal is to improve the quality of patient care within a particular organization, as opposed to examining whether a novel approach has an effect on patient outcomes, the perceived need for individual consent is lower even if there is randomization.

Conclusions

The goals of the learning health care system represent a culture shift that needs to be translated to patients, including: the tremendous uncertainty in medicine and the role they have to play in bringing about change, the issue of overprotection and underprotection within the current system, and the need for patients to identify their own values and preferences. If we increase awareness and clarity about the problem and solutions, we can leverage advocacy organizations to press for change. We need to elevate the understanding that all patients share in this problem, regardless of their specific condition. Furthermore, we need to communicate the message that research is a community asset and something to be embraced, not feared. Providing language, methods, and tools to make it easy for primary care physicians and their staff to implement research is important, as well as communicating success stories.

Other insights:

- Thinking through the approach before "opening the floodgates" is vital to avoid unintended consequences from advocacy organizations that do not have the full picture. Providing adequate context and communication is critical.
- The important role that nurses play in the learning health care system should not be overlooked. Nurses are involved in QI/QA initiatives as well as other types of research, and are invested in increasing learning within health care systems.
- We need to find solutions within the current regulatory environment, and also identify situations where change is needed and suggest activities to work toward change. There is a need for some regulatory leeway to experiment with potential solutions.
- There is a critical need for empirical ethics research to arrive at a point of social consensus and create buy-in. One potential strategy is to "crowd source" by developing examples of unanswered research questions that we have the technical ability to answer and soliciting input from a wide audience (including IRBs, advocacy groups, etc.) on the ethical issues they pose.
- An annotated series of already adjudicated decisions that have OHRP's "seal of approval," with an emphasis on examples involving cluster-randomization, would be very helpful for IRBs that are currently in a state of paralysis due to uncertainty over what is acceptable.

Thoughts on the Path Forward For the Collaboratory and the Learning Health care System

- There is a lot of public education needed to build greater support for the necessity of more efficient learning, specifically:
  - Uncertainty and risks in clinical care
  - Potential harms of not learning
  - Risk of overprotection/under-protection with current approach.
- Understanding clinical trials and randomization is really complicated.
  - We need the best materials possibly to explain these concepts using multiple media.
- Progress is possible within current regulatory environment
  - Use cases; adopting best current practices across IRBs
- Modified consent: Greater disclosure/explanation may be viable alternative to standard consent for selected experimental studies
- Acceptance of alternative methods of consent may vary based on the extent to which the provider/system upholds commitments to patients that "learning" will actually translate into improved care.

Longer Term Regulatory Changes

Ultimately, an efficient approach to human subjects oversight in the Collaboratory and more broadly, in a learning health care system, will require some regulatory change. Future discussions on this issue with SAG will explore nature of changes that might gain broad support. SAG members and organizations may be helpful in securing the level of support necessary to motivate reconsideration of current regulations.

Additional Information

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