

**1. Implementation need resonates but what about the risks of expedited knowledge to practice (limits of transfer/generalizability)?**

This is a GREAT question. Yes, it is easy for me to oversimplify in giving broad concepts. It would be easy to move to implementation too soon. There need to be people within a system who not only are able to analyze data, but are able to determine what level of evidence should be relevant to change practice. We do this all the time with QI and often with varying levels of rigor, to say the least. Right now, of course, we err on the other side of the spectrum: research is rarely implemented—or is implemented more than a decade after publication—and people repeat studies sometimes 20 times.

**2. How do you propose participation of patients and families, and balancing involvement with no coercion?**

Right now, patients and families participate all the time in quality improvement activities, with generally no transparency that their data are being routinely used in this way to improve care for future patients. Quality improvement, in my view, is a critically important—ethically mandatory—activity for health care institutions to participate in. To me, very low risk research is the same. Often, like with quality improvement, low risk research will be invisible to patients/families—e.g., observational data that examines what patients' outcomes were when various treatments were tried, or that examines what outcomes were when a new strategy was tried such as phoning patients the day after discharge to see if they understand their medication instructions. When research, or a “learning activity” becomes more consequential—where patients might reasonably have important values at stake leading them to want to join or not, or to want to have or refuse certain types of treatments, then always they should be involved in a discussion about whether they want to join. But in low risk endeavors that really look exactly like quality improvement, it's hard to justify not studying patients' records.

Critically, though, an important component of this should be far more transparency than we generally do now with quality improvement. Learning from care that is being delivered is an ethical good, not something to hide. It is something about which institutions should be proud, and should make part of their marketing.

**3. In the absence of an effector arm, is research ethical? (Should absence of implementation prevent research?)**

It depends. In a true learning healthcare system, there can be the commitment internally to implement certain types of findings if they are convincing. To not do so seems hard to justify if, again, the findings are important and convincing. There are absolutely some types of research that begin to build a body of knowledge that are not ready for implementation individually but after a series of studies become convincing. Also, there is still as a norm research funded by entirely different entities than those with the authority to implement findings. E.g., the NIH funds most human research in the USA, but their funds may not be used for patient care. This is far from an ideal situation, and being able to more closely link study questions to implementation both fulfills the promises we made to patients (“Please join so that you can help us improve care in the future”) and it likely helps to make the questions that we study in research far more relevant to the real world.

**4. Your utopia involves: 1) more time for patients, 2) more burdens on providers, 3) with your marked increase in oversight – 1984 type society.**

I had to smile at this one. I'll respond with a definite "maybe" to your assertion. What if I had called the 8 components of our framework "Principles" rather than "obligations"? Let's try that instead. The principles behind a learning health care system should be to respect patients and providers, to provide best care, to be mindful of social justice and those least well off, to implement what we learn, and to participate in learning activities in terms of doing one's part of the common good. To me, this is not really a 1984 scenario.

**5. Regarding #5 – Clarify the distinction between "addressing" health inequalities and "being mindful of" health inequalities.**

The point of this principle in our framework is to consider health inequalities and inequities when selecting which research activities or QI projects or "learning activities" that a system will take on in a given year. Each year, most big health systems embark on a series of particular "learning activities". To help select even a few of these because they represent a problem of inequity—e.g., disadvantaged populations being more likely to be no-shows to appointments; or disadvantaged older patients being less likely to have their shingles or flu vaccines, or finding new treatments for people with sickle cell disease... these are all health and delivery challenges that also, if better addressed, would help to move a tiny needle with regard to health inequality. This principle is saying that this value should drive at least some of the learning that a health system takes on.

**6. What is the plan for implementing what you have learned here about ethics, QI, learning activities, consent, etc. Are they doing this form of governance at Johns Hopkins?**

There are little pockets that are, but mostly across the institution as a whole they are not.

**7. Why should we think, re: obligation 7, that the places that are best at learning are best at implementing? Do those two need to be linked at health system level or for the overall (national) "Health System"?**

They don't need to be, but we would improve the quality of care drastically more quickly if we linked them. This is why QI has been far more successful in changing care than health research has. QI is usually planned, undertaken, and results implemented to change future care by the same team in the same institution. Having that model spread a bit more would likely lead to more changes more quickly. For certain questions, it's only possible with highly trained people running the project and often across many, many institutions. But even so, bringing people in able to say that results will be disseminated internally and possibly with some encouragement to really learn from them in future care delivery would be a pretty significant change in most health care institutions in the USA.

**8. Given that your foundational Hastings piece came out 6 years ago, and the common rule was just revised – doubling down on the research vs clinical care distinction – and likely won't be revised for another three decades... what realistically should the LHS ethics community focus on?**

I'm increasingly thinking that we need to focus more on implementing what we learn. It's the ethical commitment that we make to funders and to patients when we start a project.