PRESIDENT'S COLUMN

# Advise and Consent: Community Consultation in Research and Health Care

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*Should there be community consultation on the conduct of research in emergency care but not on components of health care that should be available to everyone?*

Medicine and its related fields are so protean and so in need of improvement, you never know when you are going to learn something you didn't set out to learn. On our way to do a clinical trial, we got caught in an interagency disagreement about informed consent and were forced to undertake a new approach, which turned out to be the right thing to do—and we learned a lot. These lessons may extend beyond research to health care.

This happened in the performance of the IMMEDIATE Trial (Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency care), an NIH emergency medical service (EMS)-based randomized placebo-controlled effectiveness trial testing whether intravenous glucose, insulin, and potassium ("GIK") can prevent acute myocardial infarction (AMI) in patients with acute coronary syndromes (ACS). (See www.immediatetrial.com.) Because treatment for ACS will have the greatest impact if patients in the community are treated immediately upon arrival of EMS, we faced the challenge of getting informed consent in that setting. Initially we considered a process known as the "Exception from Informed Consent Requirements for Emergency Research," specified in Code of Federal Regulations 21 CFR 50.24. This approach addresses the need for emergency research for severely ill unconscious patients in community settings, where most cardiovascular deaths occur.[1] It requires community consultation, typically through presentations made in public venues and by notices in local newspapers, to explain the research and to allow public comment. This process is meant to address the fact that at the point at which a local citizen becomes a candidate for such a study, providing consent will not be possible; nonetheless, this research is important for advancing emergency care, which will ultimately bring public benefit. Thereby, this process provides "consent" for patient enrollment.

However, candidate patients for the IMMEDIATE Trial are not unconscious; they are awake, and they are experiencing ACS (i.e. either unstable angina pectoris or AMI). We consulted with the FDA, where the 50.24 rule originated, and they determined that since IMMEDIATE Trial patients would be awake, we should use customary informed consent procedures. However, some months later, we were contacted by the NIH Office of Human Research Protection (OHRP); they had concern about the quality of informed consent we would obtain from patients in an emergency setting under the duress of ACS. Conceptually, this posed a surprising question: If valid informed consent cannot be obtained from an individual in the midst of ACS, what does that say about the validity of consent by participants in thousands of clinical trials who have ACS or other acute illnesses? And, outside of research, in usual clinical care, what does this say about the validity of consent obtained from patients being whisked off for emergency procedures, such as cardiac catheterization?

They had a good point. In such a situation, who of us would engage in a dialog sufficient to become fully informed about the consequences of the procedure and then freely consent? Practicing clinicians and researchers know that under such circumstances, "informed consent" is compromised by the patient's mental state, the acute care clinical setting, and the press of time. Moreover, and importantly, care itself may be compromised by the distraction and delay of caregivers obtaining consent. Yet in the midst of initiating invasive procedures for cardiac and other acute or emergency care, having a patient sign to indicate informed consent is routine.

After considering all this, we (and the FDA) agreed with OHRP that it made sense to use the 21 CFR 50.24 approach for enrollment of awake and alert EMS patients into the IMMEDIATE Trial. A key part of this process is community consultation, whereby the community learns about the proposed study and addresses whether patients in their community should be enrolled without consent. (In the case of enrolling patients who are unconscious, such as in a trial of cardio-pulmonary resuscitation in cardiac arrest, no further consent is obtained. For EMS enrollment into the IMMEDIATE Trial of patients who are awake, prior to randomization, paramedics briefly tell them of their option to not participate, and full written informed consent is obtained when they are stable at the hospital. This hybrid approach takes into account patients' impaired attention during initial emergency care and the need to avoid distractions and delays in their emergency care, with a full informed consent process provided as soon as feasible.) In most studies using community consultation, presentations are done by the research team in public venues such as community centers, bingo halls, houses of worship, senior centers, etc., where peo-

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ple can comment on the possibility of the study being done in their community. We found this an inefficient and incomplete method for getting community input, and we worried about biases in presentations done by those invested in the study's conduct. To avoid these problems, we decided to use a standardized phone-based survey conducted by an independent survey company. This was faster, allowed a sample that accurately represented the socio-demographic composition of the community, and provided an opportunity for respondents to understand the study before addressing whether it should be run in their community. The validity of the approach was supported by our finding that the 75% of phone respondents who stated that they would likely participate in the IMMEDIATE Trial closely matched the actual proportions in their communities who ultimately gave informed consent. Thus, although we had not planned for this, we learned that careful community consultation probably better represented the autonomy of individuals and their communities and probably better engaged the public in clinical research—a public good.

Beyond research, might this type of community consultation be applicable to health care? What if we openly asked what health needs are most important to our communities? What if we asked how our health care dollars should be spent? Indeed, what if we then asked what proportions of public resources should be spent on health care, education, bridges, and other shared resources? And how public should such a process be?

We know answers obtained through the public political process might suggest that rather than providing health care for 30 million citizens, we should provide tax cuts for affluent households and businesses. We know if we ask the health care industry to determine how services are paid that high-technology tests and procedures will be more highly valued than primary care visits. We know if we ask health insurance companies whether there should be parity between insurance coverage for mental health care and other care that the answer may be that mental health care deserves less complete coverage. We know if we ask hospitals whether they should acquire new expensive technologies the answer will be yes—even when there is sufficient capacity for that technology in the community. Who best represents the health care interests of individuals in the community? How can we best engage communities in addressing such questions? How best can we have a transparent, fair, and informed consultation with the community?

These health care policy issues all impact individuals' care, but they typically are not under the control of, or even under the influence of, community members. Should there be community consultation on the conduct of research in emergency care but not on components of health care that should be available to everyone? An individual's participation in research is elective and thus subject to choice as to whether and how to participate (although it can be argued that there is an obligation to participate, as research in which others have participated has advanced one's own care). Is this the case for health care in general?

Over a decade ago, widespread community input was sought in Oregon to address choices among care options in the face of limited Medicaid resources to support care. This process, though controversial, is often cited as an example of where public dialog should go in making societal resource allocation decisions about health care. Faced with the costs and benefits of various types of care across populations, if properly informed in an unbiased way, presumably citizens will make good decisions. However, for many reasons, when mixed with the other public and private processes, this doesn't always seem to be the case.

Perhaps the community consultation approach for the Emergency Exception from Informed Consent teaches us important insights. This process builds on the precept that care provided across a community should reflect the values of its members who have had a chance to consider their own and their community's participation. Citizens are told of the specific circumstances, the potential risks and benefits, and then asked whether they would consider participation appropriate. Faced with questions about various kinds of care, individuals may opt for different access to, and allocation of, health care resources than might be obtained using a public health approach emphasizing societal costs and benefits. There is the concern that individuals' choices might include more—and more expensive—care. However, might these answers be more authentic? And therefore, might this process better engage the public in grappling with such decision-making around health care?

Our nation needs individuals' preferences to be better reflected in research and in health care, and our nation needs better quality public engagement and more support for both. It might not be what we intended to learn, but we may learn that community engagement based on representative responses of individuals given full explanations of their potential personal involvement will address these needs better than our current processes. If this could work, and if we could clearly articulate its rationale and process, it might help us address vexing issues that to date have had unsatisfactory solutions.

## Reference

1. Food and Drug Administration. Guidance for institutional review boards, clinical investigators, and sponsor; exception from informed consent requirements for emergency research, draft guidance. Rockville, MD. July 2006.

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