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Patients' wishes for end-of-life care ignored 60% of the time: Here are some reasons why

Bioethicists can help with policies, rounding, and education

A critically ill patient's known wishes not to be resuscitated or placed on life support following heart failure or stoppage of breathing were ignored 60% of the time, according to a study presented at the Society of Critical Care Medicine's 2014 Annual Meeting.[1] Researchers found that patients' clearly stated wishes not to be resuscitated or placed on life support were not followed in 21 of 35 cases, often because of efforts by patients' families to countermand their known wishes and inability to locate documentation of patients' wishes in a timely manner.

"Patients may forget to provide the documents to key providers, emergency admissions may preclude receiving them, and sometimes families withhold them," says **Tedford J. Taylor**, MDiv, BCCC, FHPC, director of pastoral care and training at Robert Wood Johnson University Hospital Hamilton (NJ).

Without a centralized electronic storage site accessible to clinicians, advance directive documents may never make it into the hands of the health care team. Here are other situations resulting in failure to follow patients' wishes:

EXECUTIVE SUMMARY

Critically ill patients' known wishes not to be resuscitated or placed on life support were ignored 60% of the time, according to a 2014 study — mainly because of efforts by patients' families to countermand their known wishes, and inability to locate documentation of patients' wishes. Bioethicists can:

- Ensure clear policies are in place for how providers will receive, document, communicate, and follow patients' advance directives.
- Be involved in patient rounds to ensure that patients' goals of care are articulated and followed.
- Provide initial training and continuing education to practitioners.

• Patients' wishes were never clearly conveyed.

"Patients did not have a frank and detailed discussion with their physician, or did not fill out an advance directive, or did a living will which doesn't really apply to the clinical situation in which the patient is now finding themselves," says **G. Kevin Donovan**, MD, MA, director of the Pellegrino Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC.

If the patient only left oral instructions regarding preferences, these directions are sometimes too vague for providers to act on. "In such cases, the curative care approach is usually the default. Aggressive, 'full steam ahead,' life-sustaining treatment is the course of care, even if this is not what the patient desired," says Taylor.

• A patient's wishes are ignored by the proxy, despite being well-communicated and documented.

Named health care proxies may disregard their commitment to substituted judgment, as outlined in an instructional directive or living will, and instead, rely on their own ideas of what is in the patient's best interest.

• A practitioner, such as a consulting physician, is out of the communication loop.

By giving a clinically narrow assessment of a patient's condition and prognosis, the provider can spur proxies or family decision-makers to continue treatments that do not match a patient's stated preference.

"It may be hard for loved ones to let go of the hope of recovery," says Taylor. "Clinging to any positive news from a clinician will sometimes cause them to disregard the patient's wishes as they seek one more chance."

• The patient's proxy was not appointed by the patient.

Many jurisdictions have default proxy lists, with a hierarchy of surrogate decision makers named if the patient never identified a surrogate.

"This makes it convenient for the medical team looking for someone to talk to about the patient," says Donovan. "But a legally appropriate proxy isn't necessarily a morally valid proxy who is willing to express the patient's wishes rather than their own preferences."

• The physician knows what the patient wants and would otherwise be willing to follow his or her wishes, but is surrounded by family members who do not agree with the plan, and are threatening to sue the physician.

If a physician would like to follow the patient's wishes but is being blocked by a family member, employing the help of an ethics consultant can often make a difference, says Donovan. "Physicians know that deceased patients can't sue, but living family members can," he adds.

Bioethicists have obligation

Clinical bioethicists have these obligations to help ensure patients' wishes are met, says Taylor:

• To ensure that well-crafted, clearly written policies are in place, spelling out how providers will receive, document, communicate, and follow patients' advance directives.

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EDITORIAL QUESTIONS

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• To be involved in patient rounds, especially on critical care units.

"Ensure that the patients' goals of care are articulated, and followed by all of the clinical team and family decision makers or proxies," says Taylor.

• To engage in the initial training and continuing education of practitioners.

"Use of case studies and other educational formats can increase awareness of the tools available to practitioners, to help ensure patients' goals at the end of life are met," says Taylor.

Georgetown's Pellegrino Center is responsible for ethics education of physicians and medical students, as well as ethics consultation. "Playing that dual role helps reinforce the desirable behaviors of physicians in regard to following patients' wishes, even when they are being opposed by others," says Donovan.

Most jurisdictions provide protection for physicians following patients' preferences, even if others would have them do otherwise. "Physicians need to know and believe that they are more likely to expose themselves to risk by not following the patients' wishes, than they are by following them," says Donovan.

Reluctance to obtain advance directives

Donovan is not seeing increased numbers of advance directives and proxy appointments. "There are some institutions which have done an outstanding job of encouraging patients to fill out advance directives. But across the board, we are not seeing these numbers shift a great deal," he says. "It may be that we have peaked in our ability to encourage and support people in letting their wishes be known in that way."

Some patients are reluctant to have advance directives because they fear providers won't "go the extra mile for them," even when treatments might be beneficial. "This is the exact opposite of a typical scenario at the beginning of the bioethics era," says Donovan. "People were afraid that doctors would put them through all kinds of medical interventions long beyond the time they would be likely to be beneficial."

At that point in time, people wanted advance directives to prevent overtreatment. "Now we are seeing the opposite situation, where treatments are more likely to be demanded by families," says Donovan.

The legality of physician-assisted suicide in Washington, Oregon, and Vermont plays a role in some patients' reluctance to have advance care directives, says Donovan.

"One of the arguments in favor of [physician-assisted suicide], that patients themselves have heard, is that end-of-life care is too expensive," he says. "Some people now fear that the medical establishment does not want to see them treated."

Some patients are aware that both physician-assisted suicide and euthanasia are legal in some European countries. "We are seeing instances of patients being euthanized even against their will, once they are unable to speak for themselves," says Donovan. "Patients are frightened by this prospect and, therefore, are frightened of appropriate discussions on non-beneficial treatments." ■

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Unethical practices uncovered in direct-to-consumer genetic testing

Information often inaccurate or misleading

A patient pays for "direct-to-consumer" genetic screening, and receives results stating she is "high risk" for breast cancer — when in fact, the woman's results indicated a 13% lifetime risk compared with 12% for the general population.

The fact that information is possibly misleading to individuals is the primary ethical concern involving direct-to-consumer genetic testing, says **Cecelia A. Bellcross**, PhD, MS, CGC, director of the Genetic Counseling Training Program in the Department of Human Genetics at Emory University School of Medicine in Atlanta, GA.

As in the above scenario, some test results are overly concerning to people who are really not at

much greater risk than the general population. In other cases, an individual's risk is minimized, such as a report stating someone is at "low risk" for developing diabetes without taking environmental factors or family history into account.

"There has certainly been an evolution in direct-to-consumer genetic testing," says Bellcross. "There were multiple companies that jumped on the genomic risk-profiling bandwagon, but all of those have pretty much gone away at this point."

Guidelines are forthcoming

In 2010, the Food and Drug Administration (FDA) issued letters to direct-to-consumer (DTC) genetic testing companies requesting additional data on the reliability and validity of their tests. "Then in 2013, it issued stronger letters, but did not take specific action against particular companies," says **Katherine Wasson**, PhD, MPH, director of the Honors Program in Bioethics & Professionalism at Neiswanger Institute for Bioethics and assistant professor at Loyola University Chicago. "In response, 23andMe stopped offering its health-related direct-to-consumer genetic testing, and only offers ancestry testing."

On July 31, 2014, the FDA gave Congress notice that it would draft guidelines for the regulation of laboratory-developed tests (LDTs). The guidelines would include any DTC genetic tests that are considered LDTs.

These classifications may provide the consumer with more information on the risk level before ordering such tests, says Wasson, but the full implications are not yet clear.

"These guidelines are likely to take up to a decade to implement," says Wasson. "But the general idea is that the FDA will classify LDTs based on risk — Class I, II, and III — similar to medical devices."

Ultimately, the FDA "clamped down" on allowing companies to provide this service, says Bellcross, in part due to lack of information about the accuracy of the panels being utilized. A patient's results might indicate five markers associated with breast cancer, but these markers may not reflect the patient's risk accurately because they don't take into account the known inheritability of breast cancer. "It's like offering a prediction when you are missing 90% of the information," says Bellcross. "The information may be inaccurate or misleading."

Investigation reveals unethical practices

The Government Accountability Office's investigation revealed that in some cases, direct-to-consumer company representatives were making medical recommendations based solely on the test results.

"The information these companies provided to the clients, both on websites and verbally, was crossing the line of practicing medicine," says Bellcross. "In some situations, a customer service person with a high school education was telling people how often they should have colonoscopies."

Other unethical practices were uncovered, such as representatives instructing people in how to submit an unknowing person's DNA to surprise them with their genetic information. "As time went on, and more studies were done, the clinical utility of this testing was really placed into question," adds Bellcross.

Test results produced increased requests for screening by "worried well" patients, some of which was likely unnecessary. "Obviously, there are issues with over expenditure of health care dollars as it is," Bellcross says. "A patient may have a direct-to-consumer result suggesting a 1% increased risk for prostate cancer at age 30 and insist on a PSA [prostate-specific antigen] test."

As most primary care physicians have little understanding of how to interpret direct-to-consumer genetic test results, they might order requested screening tests to please their patients, says Bellcross. "Whenever you are doing that, you are going to end up with people having biopsies and all sorts of things that are unnecessary," she warns.

Individual's right to know

Individuals have a "right to know" about their own bodies, health, and genetic make-up, says Wasson — the challenge with direct-to-consumer genetic testing is uncertainty surrounding the reliability and accuracy of the different results and how to interpret them.

EXECUTIVE SUMMARY

Direct-to-consumer genetic testing presents multiple ethical concerns, including individuals being given misleading or inaccurate information. In July 2014, the U.S. Food and Drug Administration announced coming draft guidelines for the regulation of laboratory developed tests.

- There are unresolved questions about the accuracy of the testing.
- Some company representatives made medical recommendations based solely on test results.
- "Worried well" patients are requesting unnecessary screening tests.

"Yet some may argue that people should have the freedom to determine if they wish to take a direct-to-consumer genetic test, and what to do in light of such results," says Wasson. In addition, this type of testing may provide some accurate information or motivate people to make positive health changes based on the risk estimates they receive, she acknowledges.

"People have a right to genetic information, but they have a right to accurate genetic information that is usable," says Bellcross. "That's what we need to be offering."

"Time out" until more is known

Any kind of direct-to-consumer testing must be viewed in light of the test's complexity, risks, and patients' varying educational levels, says **Kenneth W. Goodman**, PhD, director of the Bioethics Program at the University of Miami (FL).

"Moreover, even professionals are unsure of the meaning of genetic information," says Goodman. "This is why we have — and ought to use — genetic counselors."

One way to view the latest FDA decision is as a kind of "time out" on direct-to-consumer services until more can be learned about their risks and benefits, according to Goodman. "I'm always worried when patient autonomy and a 'right to know' are invoked as part of a business plan," he says. "Is this really about patient empowerment, or the latest in health care entrepreneurship?"

Much more research on the kinds of risks and harms faced by patients and families of patients who receive uninterpreted genetic data is needed, he urges. "Consumer demand is one component of health policy," Goodman acknowledges. "But it is not the only one, and it should not be dispositive — or we would not need prescriptions, require licensing of doctors and nurses, or regulate drug and device research." ■

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Preclinical detection of brain disorders presents multiple challenges

False-positives may harm patients

There are numerous ethical issues related to preclinical detection of brain disorders or conditions, says **Karen S. Rommelfanger**, PhD, director of the Neuroethics Program and assistant professor in the Departments of Neurology and Psychiatry and Behavioral Sciences at Emory University in Atlanta.

"As our health care system and research move to a model of risk management and disease modifying, we will only see more and more of these unaddressed ethical issues come to the fore," she predicts.

Recently, technologies have been developed that detect signs that precede clinically relevant symptoms. "These preclinical or prodromal assessments are being created for time points at virtually every stage in an individual's life span: autism in infants, schizophrenia in youth, and Alzheimer's in adults," says Rommelfanger.

These preclinical signs generally assess risk for developing the disorder, but do not guarantee the development of these conditions. "Conditions that target the brain not only impact our view of our physical health, but also who we are — and in the case of prodromal assessments, who we may become," Rommelfanger says.

Disclose with "extreme care"

Thomas Cochrane, MD, MBA, senior ethics consultant at Brigham and Women's Center for Bioethics and assistant professor of neurology at Harvard Medical School in Boston, is aware of a

EXECUTIVE SUMMARY

Technology allows for preclinical detection of some brain disorders or conditions, but such testing also presents numerous ethical concerns.
- Patients can benefit with early intervention to slow or prevent these conditions.
- Patients may be harmed by false positives.
- Bioethicists can help develop and promote professional guidelines to ensure tests are used wisely.

case of preclinical testing for Huntington's disease that resulted in the suicide of an asymptomatic patient.

"The disclosure of some diseases needs to be handled with extreme care and forethought," he underscores. "There are a number of worries about preclinical testing. How will patients react to knowing they've got an untreatable neurodegenerative condition?"

Technologies could provide early intervention to slow or prevent these conditions, says Rommelfanger. This would ultimately benefit patients and substantially reduce downstream health care burdens.

However, a false positive — suggesting a high risk for the disorder when really there is no chance that the condition will ever develop — can have serious deleterious consequences for patients and their families, she says.

"False positives could result in unnecessary changes in life course and family decisions, or iatrogenic harm by introducing pharmaceutical interventions, such as those used for schizophrenia, that also introduce a high risk of adverse effects," Rommelfanger says.

Net benefit or net harm?

The main concern about preclinical testing for any disorder is whether the results of the testing will represent a net benefit or a net harm to patients, according to Cochrane.

"The benefits of preclinical testing depend a lot on whether therapy is available for the disease," he says. "If there is preventive therapy available for a disease, then of course preclinical testing would represent a huge benefit."

If there is no preventive therapy, but there is a treatment that works best when initiated early, this also constitutes a benefit, says Cochrane. Knowing about the disease before symptoms begin would allow an individual to be monitored very closely for symptoms.

"If there is no therapy at all, as is currently the case for most neurodegenerative disorders, then the benefits of knowing the diagnosis are mostly psychological," says Cochrane.

Bioethicists can influence

The use of novel preclinical tests outside the research setting is fraught with risk, cautions Cochrane, and should be undertaken deliberately and carefully.

"Those who patent a test naturally want it to be used widely," he says. "Insurers will usually want it used sparingly or not at all — unless there is preventative therapy available."

Patients often want a test in order to know as much as possible, but they may not have thought carefully about the pros and cons of presymptomatic testing.

"Bioethicists can probably have the most influence at the medical society level, in helping develop and promote professional guidelines that are designed to ensure that novel tests are used wisely," says Cochrane.

Ethicists can be involved in designing how and when preclinical assessments occur, suggests Rommelfanger, and determining how results should be communicated to patients.

"Otherwise, the potential of these technologies, as enormous as their potential to substantially reduce human suffering may be, will be undermined by a loss of public trust," she warns. ■

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75% of nephrologists surveyed agree with donor health insurance

Ethical debate still rages over compensation for organ donors

Of 1280 nephrologists surveyed in a 2014 study, a minority indicated they favor rewards for donation, many agree with some compensation, and a considerable majority favor donor health insurance.[1]

According to the study, 75% of nephrologists agree with donor health insurance, 26% favor direct financial compensation, and 31% agree with financial rewards for unrelated donors. Sixty-six percent indicated that they believe the rewards will lead to increased donation.

However, 73% of the nephrologists indicated that rewards will lead to exploitation of the poor, and 37% believe that rewards will negatively impact deceased-donor transplantation.

"In our living donor transplant team, we often refer to the donor process as 'the gift that keeps on taking,'" says **F. Keith Stirewalt**, PA, MBA, MDiv, advance care planning coordinator and Independent Living Donor Advocate at Wake Forest Baptist Medical Center in Winston-Salem, NC.

Despite the apparent benefits to the recipient, economics of time — evaluation, surgery, recuperation, and follow-up — often are underappreciated until experienced by the donor, he explains.

"These 'costs' may present disproportionate burden upon those in lower and middle incomes," adds Stirewalt. For those involved in manual labor, post-surgical physical restrictions disproportionately affect the ability to return to full duty and full pay.

"Transplant surgeons and team members know of the effect on the donor pool," he says. "All too well, they see the significant life change of living with dialysis versus the life change after receiving a kidney."

An unmentioned implication of remuneration centers around kidney paired donation, says Stirewalt. "While some studies indicate that air shipping a paired donation kidney is without difference in short-term graft outcome, most programs prefer donations local to the recipient," says Stirewalt.

In these cases, the economic and time burdens on donors are magnified. "Rewards and compensations may greatly increase the utilization of paired kidney exchanges, ultimately saving the health system significant expense while improving the health of the public," says Stirewalt.

EXECUTIVE SUMMARY

A minority of nephrologists favor rewards for organ donation, many agree with some compensation, and a considerable majority favor donor health insurance, according to a recent survey.

- Time required for evaluation, surgery, recuperation, and follow-up often are underappreciated by donors.
- If money value is put on organs, people in dire financial situations might be induced into giving away one of their organs in return for money.
- Financial coercion would require far more scrutiny by the donation team.

Risk of harm to donors

There are two central ethical concerns involving compensation for organ donors, says **Alberto Giubilini**, PhD, a research associate at the Centre for Applied Philosophy and Public Ethics at the Charles Sturt University-Canberra in Australia. "First, some people simply do not see the human body or its parts as something that can be exchanged in return for money or for some other form of compensation," he says.

Many people see the human body as something sacred and inviolable, he explains, and different from other items of private property that one can decide to buy and sell.

"The second type of ethical concern is, in my view, more compelling, and has to do with the risks of exploitation and of harms to donors," says Giubilini. If money value is put on organs, people in dire financial situations might be induced into giving away one of their organs in return for money.

"This decision might have serious health consequences for [donors], especially if the transaction happens, as is often the case, in a black market where no adequate medical follow-up is guaranteed," says Giubilini.

However, says Giubilini, there isn't necessarily a link between compensation for organs and exploitation. "For example, if the State controls the transaction and offers reasonable compensation to organ donors, then it is unlikely that the transaction will turn out to be exploitative," he says.

More scrutiny required

Rewards for donation must be accompanied by even greater scrutiny by the living donation team, urges Stirewalt. "Active coercion can be difficult to identify. Passive coercion — especially financial coercion — would require far more scrutiny," he says.

Giubilini argues that it would be paternalistic to prohibit compensation for organ donors just because of the risk of exploitation or of harms to vendors. "Compensation for organ donors certainly is one way to increase organ supply," he says. "But there are alternatives that can be nearly as effective."

One such alternative is increasing deceased organ donations through opt-out systems, whereby people are considered to be willing organ donors after their death unless they declare otherwise.

"There is strong evidence showing the effec-

tiveness of opt-out systems," says Giubilini. "For some mysterious reason, however, many countries are unwilling to enforce this type of policy."

This results in a great demand for organs and with many people — especially those from poor countries — willing to sell their organs, says Giubilini. "Because many states are unwilling to legalize organ sales either, black markets in organs will continue to flourish," he says. "And it seems to me this is the worst scenario possible." ■

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Advance directives and health care proxies: Equally effective in influencing doctors' decisions

Advance directives and proxy opinions are equally effective in influencing doctors' decisions, but having both has the strongest effect, says a 2014 study.[1]

"Compared with no information about the patient's preferences, having some indication of their preferences made a really big difference for physicians in their decision about whether to press on versus allowing the patient to die more gently," says **Harold C. Sox**, MD, MACP, professor of medicine emeritus at Geisel School of Medicine at Dartmouth in Hanover, NH.

Sox points to the 1995 SUPPORT study that explored the effectiveness of communication about patients' preferences for end-of-life treatment for intensive care unit patients with a poor prognosis.[2] In that large, multi-site, randomized trial, a comprehensive intervention did not affect physicians' knowledge of seriously ill patients' wishes for end-of-life care, nor the frequency of discussing preferences for cardiopulmonary resuscitation.

"The question is, what happens in real life? Has there been any real progress since the SUPPORT study?" says Sox.

A 2008 review concluded that there was strong-to-moderate evidence to support interventions to improve important aspects of end-of-life care.[3] "Maybe there has been a little progress, but it's probably a pretty good bet that things haven't gotten much better," says Sox. "The question is why — where are the breakdowns?"

EXECUTIVE SUMMARY

Advance directives and proxy opinions are equally effective in influencing doctors' decisions, but having both has the strongest effect, says a 2014 study.
• Advance care planning and regular care planning are starting to merge
• Meaningful use criteria require only an answer to the question of whether the patient has an advance care plan, not the actual plan itself.
• "Big data" have the potential to offer more accurate prognostic estimates.

Merge with regular care planning

Advance care planning and regular care planning are starting to merge, says **Joanne Lynn**, MD, MA, MS, director of the Center for Elder Care and Advanced Illness at Altarum Institute in Washington, DC.

"We are moving into an era where many, many patients have a lot of things going on and they really need a comprehensive care plan," says Lynn, also a former professor of medicine at Dartmouth College and at George Washington University.

"Once you start doing comprehensive care planning, then advance care planning just becomes part of it," says Lynn. In talking about how the patient wants to live as the disabilities or illnesses get worse, it follows that the provider will ask where the patient wants to be when he or she dies, and what kinds of treatments he or she wants.

"It becomes natural to be asking questions about how you want to live your last few months or minutes," says Lynn. "More and more people are dealing with the issue, whether they fill out a formal form or not."

One obstacle is that the "meaningful use" criteria established by the Centers for Medicare & Medicaid Services (CMS) requires only an answer to the question of whether the patient has an advance care plan, not the actual plan itself. "To me, that seems

to be a bad idea. If you know that the person has an advance plan, but you don't know what it says, in some ways you are in worse shape," says Lynn.

Vendors typically don't include this in electronic medical records because it's not required and hospitals aren't requesting it, she explains. "Even a place to scan it in so you have the person's signature would be a good thing," says Lynn. "Summarizing whether the person wants to avoid hospitalization or resuscitation would also be good."

Lynn says that meaningful use criteria need to be updated to include a statement about the patient's prognosis, not just for survival but also for function, as CMS' Continuity Assessment Record and Evaluation (CARE) instrument does.[4] This ensures that the patients and family at least know the general outline of what they face while making decisions, she adds.

"We have a ways to go," says Lynn. "But as it becomes more commonplace for people to die at home or in nursing homes, it will be more common for people to state their preferences."

Big data will offer prognostic estimates

Lynn expects that in the near future, "big data" will offer prognostic estimates that are much more accurate than individual doctors currently offer.

"In an era where Angie's List can give you comments from 100 people about how good a plumber is, surely we will get to the point where a family member of a person who has just had a stroke can say, 'I'd really like to know how people do who have had a similar stroke two years ago,'" says Lynn.

Data will be able to answer such questions as how many of these individuals had to live in a nursing home, details on their functional status, and the best outcomes of a group of 100 people who had a similar stroke, for instance.

"Imagine the difference in advance care planning if you knew that only two out of 20 people did well, 10 died within three months, and all the rest are living with substantial disabilities requiring constant attendance in nursing home or at home," says Lynn. A person could also learn how many of the individuals who had a similar stroke are living independently.

"There's no reason why we can't start answering these questions," says Lynn. "We just haven't set up [systems] to do it yet." ■

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SOURCES

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Informed consent and STEMI research participants controversy

Expectations "likely do not match clinical realities"

An ethical controversy erupted regarding a "delayed-consent" approach used in the recent how effective are antithrombotic therapies in primary PCI (HEAT/PPCI) trial. In the study, researchers compared outcomes in ST-elevation myocardial infarction (STEMI) patients treated with bivalirudin versus heparin.[1]

"The HEAT trial is a really important case for

EXECUTIVE SUMMARY

A "delayed consent" approach to informed consent used by researchers in a recent study comparing outcomes in ST-elevation myocardial infarction patients (STEMI) resulted in ethical concerns being voiced.
- Patients were randomly assigned and treated in the acute phase, with no mention of the trial upfront.
- In almost all prior studies of STEMI, patients have been consented prior to randomization, so they have the chance not to participate.
- A written "short form" can be used describing only the essentials of the study, or a health proxy can make the decision for the patient.

several reasons," says **Neal Dickert Jr.**, MD, PhD, assistant professor of medicine in the Division of Cardiology at Emory University School of Medicine in Atlanta.

Dickert commends the investigators for "addressing head-on" the issue of consent in acute MI trials, and acknowledging that full informed consent is likely not possible in the context of this situation.

"In the modern era, this is the first time that delayed consent has been used in the setting of STEMI," says **R.H. Stables**, MA, DM, BMBCH, the study's lead investigator. Stables is research lead for Interventional Cardiology at Liverpool Heart and Chest Hospital's Institute of Cardiovascular Medicine and Science.

Ideal approach isn't established

The management of STEMI with primary percutaneous coronary intervention (PCI) demands a fast response, Stables notes, as each additional minute of delay before reperfusion is associated with less favorable outcomes.

In the HEAT trial, 50% of patients were randomized within five minutes of hospital arrival. The median time from hospital arrival to the first use of a device in the coronary artery to restore blood flow was just 29 minutes.

During that time period, the diagnosis was made and patients were informed about the diagnosis and the need for emergent catheterization. "Most patients were likely significantly symptomatic, scared, and anxious," says Dickert.

When true informed consent cannot be obtained, available therapies have been approved and proper oversight has been obtained, some trials should be possible without informed consent, argues **Spencer B. King**, MD, a cardiologist at Emory St. Joseph's Hospital in Atlanta and Professor of Medicine Emeritus at Emory University School of Medicine. "I am not sure that 'delayed consent' is a logical concept. But a consent to remain in a trial that the patient has been enrolled in does makes sense," he says

Expectations for full, valid informed consent "likely do not match the clinical reality" of these situations, says Dickert.

Because the risks were low, and because the expectation of full informed consent of a surrogate or patient in this context for a randomized clinical trial is unreasonable, Dickert says the investigators properly pursued alternative strategies.

"The issue of what the best approach is for trials like this — when patients are conscious and not obviously incapacitated, but where barriers to consent like time constraints, stress, and physical symptoms likely limit potential involvement of patients in decisions — has not been worked out," says Dickert.

Right to refuse participation

In almost all prior studies of STEMI, patients have been consented prior to randomization, so they have the chance not to participate, says **Gregg W. Stone**, MD, co-director of The Cardiovascular Research Foundation's Medical Research and Education Division in New York, NY.

"To me, the overriding principle is that the rights of human beings to refuse to participate in an experiment must be preserved," argues Stone.

In the HEAT trial, patients were randomly assigned and treated in the acute phase, with no mention of the trial upfront. They were approached for full informed consent once the acute phase was over.

"Some say that the occasional patient doesn't remember entering into the study," says Stone. "In my experience of running numerous STEMI trials for more than two decades, almost all patients do recall agreeing to participate in the study, and do not feel they were pressured."

Using these processes, when consent in the emergency department is obtained prior to sedation, Stone usually finds that about 60% of STEMI patients decline participation; about 40% join the study.

"Consenting the patient after randomization takes away the patient's right to not participate in an experiment, compromising the rights of the 60%," argues Stone. This is most concerning if the patient dies in the cardiac catheterization lab, he says — after randomization, but before even having the chance to hear about the study.

Stone says that the fact that 99% of patients in the study accepted the randomization after being told about it the day afterward, is in itself proof this type of process doesn't work. "It means that the patients feel helpless, having already been exposed to the experiment," he explains.

Stone acknowledges that this type of trial design results in much faster enrollment a more generalizable study cohort. "To me, these advantages don't nearly make up for the ethical concerns of experimenting on human beings without their knowledge and consent," he says.

Some form of consent might be feasible

There is essentially a universal agreement that one cannot obtain full, informed consent before emergency PCI, according to Stables. The special circumstances of the HEAT trial were also critical, he adds, as the study involved a comparison of two established medications.

Alternative approaches have included the use of an "abbreviated consent" process, usually involving the reading out of some basic information about the study and often verbal assent by the patient.

"We reasoned that it may be unethical to burden a patient with a question of this nature, in this setting, when they have no prospect of reaching an informed and mature conclusion in the time available," says Stables.

Franklin G. Miller, PhD, senior faculty in the Department of Bioethics at National Institutes of Health in Bethesda, MD, acknowledges that standard methods of obtaining informed consent would not have been feasible for patients in the HEAT trial.

"However, it does not follow that no form of advance consent would be feasible," he says.

Patients might have been offered a very simple explanation of the study and asked to agree or refuse participation. "When a simple, informal consent process is used for initial enrollment, patients could be subsequently given a more detailed account of the research, including a written consent document, and asked whether they are willing to provide consent for continuing in the study," Miller suggests.

Conducting the study without prospective consent has the scientific merit of facilitating a representative sample of eligible patients, which is not modified by any selection bias that can come from a proportion of eligible patients refusing to participate, acknowledges Miller.

"However, it is doubtful that overriding the principle of respect for persons justifies waiving advance consent entirely, when prospective subjects are capable of giving some form of meaningful consent," he says. ■

REFERENCE

1. Stables R, Shahzad A. HEAT PPCI: How effective are antithrombotic therapies in PPCI? Program and abstracts of the American College of Cardiology Scientific Session; Washington, DC; March 29-31, 2014.

SOURCES

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CME QUESTIONS

1. Which is true regarding patients' wishes for end-of-life care, according to a 2014 study?
   A. Patients' families rarely ever attempted to countermand the patients' known wishes.
   B. Virtually all providers were able to quickly locate documentation of patients' wishes in a timely manner.
   C. Accessibility of advance care documents played no role in whether patients' wishes were followed.
   D. Patients' known wishes were not followed in the majority of cases.

2. Which is true regarding preclinical detection of brain disorders or conditions, according to **Karen S. Rommelfanger,** PhD?
   A. Harm to patients significantly outweighs any benefits, even if there are early interventions to slow or prevent the condition.
   B. There is significant evidence that benefit to patients outweighs any potential harms.
   C. False positives can have serious deleterious consequences for patients and their families.
   D. Benefits to patients clearly outweigh harms, even if there is no therapy available to prevent or treat the condition.

3. Which is true regarding advance care directives and proxies, according to a 2014 study?
   A. Advance directives were far more effective than proxy opinions in influencing doctors' decisions.
   B. Advance directives and proxy opinions are equally effective in influencing doctors' decisions.
   C. There was no difference in doctors' decision-making when patients had advance directives, compared with when doctors had no information about patient preferences.
   D. Neither advance directives nor proxy opinions influenced doctor's decisions.

4. Which is true regarding nephrologists' attitudes toward compensation for organ donors, according to a 2014 survey?
   A. Few of the respondents agreed with donor health insurance.
   B. Most favored direct financial compensation.
   C. Most of the respondents favored direct financial compensation, even for unrelated donors.
   D. Most of the respondents agreed with donor health insurance.