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SARS: Balancing public safety and individual freedom is a challenge

Laws have lagged behind ideology of modern society

If there was anyone left in doubt, the severe acute respiratory syndrome (SARS) epidemic has put the question to rest. Infectious diseases are back as a major threat to human health, say world public health officials, even among industrialized nations that once believed they were safe from harm.

"The good news, hopefully, is that we will use the SARS experience as a cautionary tale about what we need to do about germs and the public health," says **Howard Markel**, MD, PhD, a professor of pediatrics and communicable diseases and director of the Center for the History of Medicine at the University of Michigan in Ann Arbor, and author of the books *Quarantine!* and the soon-to-be published *When Germs Travel*.

With the advent of vaccines and antibiotics in the middle part of the last century, the conventional wisdom held that the era of infectious diseases as major killers of humankind was over, Markel says.

But the recent emergence of new infectious agents as well as the development of antibiotic resistance in older bacterial pathogens is making it clear that the conventional wisdom was wrong.

"We live in a world of germs," says Markel. "In the last hour, 1,500 people worldwide died of AIDS, tuberculosis, and malaria. And those are diseases we can either prevent or treat. A million children died of measles last year, and we've had a shot for that since 1963 that costs a quarter. I hope the lesson that we learn is that we need to globalize our public health mechanism."

Such a feat is much easier said than done, say public health officials. In the United States alone, a slew of antiquated public health laws, many of which vary widely state by state, are making it difficult for the country to respond to threats of large-scale epidemics such as SARS, anthrax, or smallpox.

"Bioterrorism issues have strengthened the public health response at the federal level," says **Ed Septimus**, MD, medical director of infectious diseases at Memorial Hermann Healthcare System, an 11-hospital system based in Houston. "We have some problems at the local level —

that's a different issue. But when you look at how long it took us to identify the agent that caused AIDS and how look it took to map the genetic fingerprint of the virus, it took years. With SARS, it took days. Our ability, from a public health standpoint, to respond and identify and develop genetic technology is far better than it used to be."

But once the threat has been identified, knowing what to do with cases of infected persons vs. people who have been exposed or possibly exposed will be up to local health officials in individual regions and states.

It is at this level that things begin to get tricky.

At Memorial Hermann, the infectious disease faculty and infection control professionals have worked hard to disseminate information about SARS, emphasize the need for vigilant screening persons presenting to the emergency department and to physicians' offices, and reinforce the message as time goes on, Septimus adds.

When patients come to the hospital ED with symptoms that might match the case definition, they are given a mask and put into respiratory isolation in a negative-pressure room. But in physicians' offices, there are no negative-pressure rooms.

"We've told them that if they have a patient with a suspicious history, they need to put a mask on them and get them back into one of the exam rooms," he says. "We've also had to instruct our clinicians that if you have someone who is not that ill and doesn't require hospitalization, but may potentially have SARS, you need to confine them to a location. That is tricky. It is a sort of voluntary quarantine of sorts. Most responsible people understand that. But what if they don't?"

Use of quarantines

In particular, the possible use of quarantines to confine individuals exposed to the SARS virus has been one of great discussion in public health circles and the media, notes **James Hodge**, JD, LLM, deputy director of the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities.

The problem — and many state public health laws reflect this — is that many people have outdated notions about what the term "quarantine" means, he says.

Images of large numbers of people rounded up and confined for long periods of time in a designated location are out of step with modern public health practices in the United States.

"Quarantine and isolation are not old concepts that we don't use anymore. They are regularly employed," he notes. "The difference is we don't use them on a mass scale."

Isolation of people with particularly contagious conditions, or drug-resistant contagious conditions, is routinely done in hospitals and other health care facilities.

And quarantine, which usually is defined as a limitation placed on the movement of people thought to be exposed to a condition, is done in

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limited circumstances also, Hodge says.

"To be perfectly honest, a quarantine might be useful for the flu in certain circumstances," he says. "If there is an extremely virulent strain of it in a particular area or if you have a particularly vulnerable population that is affected — say a virulent strain that is being transmitted and unable to be controlled in a skilled nursing facility — public health officials may institute a limited quarantine for a specific period of time."

The difference between that kind of quarantine and what has traditionally been known as quarantine is usually that it is voluntary and for a short duration, Hodge explains.

"We are already seeing with SARS very appropriate and responsible uses of quarantine and isolation," he continues. "It has been coming down in the form of a general recommendation from public health authorities that anyone who feels they might have come into contact with a SARS case to refrain from certain types of contact for a short period of time. It is certainly not rounding people up and putting them in a hotel until we are sure they don't have it. It is also not telling them that they have to stay at home constantly. It is basically tailoring a quarantine message in a way that is functional and practical — concentrating on a time period in which a person may be looking for symptoms and the ways in which they might avoid infecting others. We rely on individuals to voluntarily comply with those sorts of suggestions. It would only get more coercive if we see people becoming infected at a greater rate or if we see people who may have been exposed to SARS intentionally or blatantly avoiding these public health recommendations."

State laws out of date

However, although most states seem to be using isolation and quarantine efforts responsibly, the public health laws on the books in many areas do not reflect such modern concepts, says Hodge.

"What many states have is a single-line item quarantine authority in the statute that says something like, 'The secretary of the Department of Health is authorized to use quarantine in any cases involving communicable diseases that may threaten the population,' period," he explains. "That could authorize quarantine for a fantastic amount of things."

Under these public health laws, people with HIV or AIDS, or even influenza could be quarantined involuntarily. Even though states have not attempted to use their powers in this manner, the laws do not reflect the legal standards that should underlie such measures, Hodge says.

"Constitutionally, you need to restrict the measure of the quarantine because it is coercive, it infringes on civil liberties, and it should be restricted to instances involving significant risk to individuals," he explains. "And you should attempt to address a problem with the least-restrictive measures, using involuntary quarantine as a last resort. We should use the least-restrictive ways we can use to bring a halt to a disease spreading."

The U.S. Supreme Court has ruled that it is inappropriate to quarantine individuals who have communicable diseases but do not pose a significant risk of transmission to others, he says.

"For example, tuberculosis is only in its active, communicable state for a brief period; and the rest of the time, a person with TB is completely at no risk to anyone else, and they are out in the population," he says. "No one needs to quarantine or isolate a person under those circumstances. There is no justification — ethically, legally, you just can't do it."

Model statutes provide guidance

Following the terrorist attacks on Sept. 11, and then the subsequent anthrax mailings, the center, at the request of the Bush administration and several state legislators, began work on model legislation that would guide states in ensuring they were prepared to respond to large-scale public emergencies.

"We drafted the State Emergency Health Powers Act, which is a model set of provisions about the sorts of powers we in public health may need to exercise during what we define as a public health emergency. And we have a very high-threshold definition of a public health emergency, a very serious set of circumstances that would justify a governor's declaration of an emergency that would trigger a series of powers," Hodge says.

The model emergency health powers act also is part of a larger project that is working on a model State Public Health Act, which would cover all state public health powers, Hodge adds.

"When you look at existing state laws, you see a lot of fragmentation and inconsistencies, and a lot of antiquation in some ways," he explains. "What we are trying to do is not necessarily provide a solution for all of that but rather to provide a

starting point for states to look at their own internal codes and public health laws to really get a sense of how they might improve. We want to structure these laws to reflect modern scientific principles, modern constitutional principles, modern principles of ethics, and other sorts of issues."

The model legislation is meant to serve as a starting point for discussion, rather than set-in-stone draft legislation to be taken in whole by states across the union.

"These models do not in any way obligate the states. They can use some of the measures or all of them," he adds.

Tailoring public health interventions

A key modern concept the model public health laws support is the tailoring of public health interventions to meet the specific needs of the health emergency, explains Hodge.

"You see different measures with different diseases. With West Nile virus, another infectious disease, the issue of quarantine and isolation never came up," he states. "The reasons are really very simple — you can't spread it person to person. As a result, the public health measures used to combat West Nile are the environmental methods — either eliminating the mosquitoes that spread the virus or eliminating the disease in the animal population."

Quarantine and isolation only would be used with communicable diseases that easily spread via airborne transmission.

"You don't see it used with HIV and AIDS, even though the virus can be communicated easily in epidemiologic terms. But we would use it with conditions like SARS," says Hodge.

Even in those situations, it would be important to move from the least restrictive measures first, to more coercive measures if initial efforts failed to halt spread.

At the other end of the spectrum, you don't want health officials to be too hesitant to initiate a quarantine measure.

"I think that's where China, if they've made mistakes, it is not taking a proper epidemiologic perspective on this particular condition," Hodge says. "For one thing, not doing effective surveillance from the start and then not considering that the disease might be spread through human contact. They were looking at all of the various other ways. Was it through insects? Was there some sort of contamination in the environment? As you explore all of the possibilities, you do have to work under the assumption, for a period of time, that person-to-person transmission is possible."

In the United States, some quarantines were instituted in the initial days of the anthrax exposures even though anthrax is not spread via human contact.

"There was a fear that maybe the spores could survive on the clothes or belongings of those exposed and therefore be spread to others," Hodge notes. "There were some regrettable things done in the first few days of the exposures, in terms of restricting persons with the illness. But it was a safer method of protecting the population, for a period of time."

Due-process issues

Any type of quarantine measure also must be coupled with due-process protections written into the law, adds Hodge. Most of the current state laws do not provide any specific measures of appeal a person subjected to a quarantine order may use.

"When these measures are practiced at the state level, they do provide due process; but our model basically says, 'Let's get all of this scientific and constitutional stuff on the table and make it a statutory requirement so there is no question what authorities need to do during an emergency or otherwise," Hodge says.

Use of quarantines to contain the spread of communicable diseases has always been a tug of war between individual freedoms and the greater good — with the greater good almost always winning, says Markel.

In previous decades, health officials had little to offer patients who contracted a contagious, life-threatening disease — there were often no available treatments or vaccines. So people who got the disease or those known to be exposed were isolated from the rest of society

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and, basically, left to sink or swim.

In the cholera quarantines used in New York in the late 1800s, people were quarantined in large numbers in isolated areas without access to clean food and water or medical care.

"What has changed in the last 100 years is that we tend to be more concerned about the needs and health of the individuals in quarantine," Markel says. "It is becoming as important as the need of the greater good."

(Editor's note: More information about the Center for Law and the Public's Health model public health laws can be found on the center's web site at www.publichealthlaw.net.) ■

Patent fights loom over SARS genes, care options

No one wants to be left out

No sooner had public health officials lauded the international scientific cooperation that led to the discovery of a new Coronavirus as the cause of the highly contagious and deadly severe acute respiratory syndrome (SARS),[1] than scientists from the different communities lined up to ensure they wouldn't be left out in the cold when it comes time to profit from their discoveries.

According to a report in the May 5 *Wall Street Journal*,[2] scientists in Canada, Hong Kong, and the United States all have filed patent applications for all or parts of the new pathogen.

Scientists in Canada who decoded the genetic makeup of the virus have filed a patent application in the United States seeking legal rights to all of the virus' genes. Hong Kong scientists who first viewed the virus under a microscope are seeking to secure a patient on the virus itself. The Atlanta-based Centers for Disease Control and Prevention has also submitted a patent for its specific findings about the SARS virus.

The filings, if granted, could give patent holders exclusive rights to develop certain diagnostic tests, drugs, or vaccines to treat SARS.

In the early days of the AIDS crisis, scientific bickering over credit for key scientific discoveries, including the isolation of the HIV virus itself, delayed development of a diagnostic test.[1]

Now the World Health Organization credits the "unprecedented" international cooperation of scientists, who agreed to openly share information, with the rapid isolation of the SARS virus and the development of early tests used to diagnose the disease.

Scientists now applying for SARS patents say they are merely protecting their right to continue to work on the virus or are responding to the patent filings of others.

University of Hong Kong researcher **Malik Peiris**, MD, whose research team was the first to spot the virus under the microscope, told the *Journal* that he and his colleagues sent samples of the virus to several other researchers without a thought to patent rights. But when others decided to file, he decided they should also.

"Why should we leave the field open to others," he told the newspaper. "If no one else was filing patients, I don't think we would have."

Not all SARS researchers are comfortable with the idea of patenting information they feel should be in the public domain and used for the public good.

Marco Marra, PhD, the head of the Canadian research team working on the virus' gene sequence, told the *Journal* he doesn't want his name on a patent application — and by doing, so he is forgoing any of the 50% of licensing revenues his agency normally allocates to inventors.

Genes should not be subject to patents because they are not true inventions and are now easily sequenced, he said.

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Questioning the search for a Viagra for women

New quest has pros and cons

Following the phenomenal success of the drug sildenafil (Viagra) in treating sexual dysfunction in men, pharmaceutical companies have recently focused intense interest — and research funding — toward finding a comparable drug that will offer the same benefits to women.

But medical knowledge about the causes and characteristics of sexual problems in women lags behind that of men, say researchers who have studied female sexuality. And attempts to find a pharmaceutical remedy may be oversimplifying a complex set of problems.

A recent issue of the *British Medical Journal*[1] contained a report questioning whether pharmaceutical sponsoring of drug research targeted at female sexual dysfunction was inappropriately medicalizing female sexuality.

"To build similar markets for drugs among women, companies first require a clearly defined medical diagnosis with measurable characteristics to facilitate credible clinical trials," journalist **Ray Moynihan** wrote in that article. "Over the past six years, the pharmaceutical industry has funded, and its representatives have in some cases attended, a series of meetings to come up with just such a definition."

Pharmaceutical sponsorship of these meetings has the potential to bias research in favor of narrowing perspectives on female sexuality to those that are normal and abnormal, with the goal of finding a treatment for the abnormal, Moynihan argues.

Used in the right ways — pharmaceutical sponsorship can provide much-needed help to an area of study long overlooked, say others.

Talk about cure premature

The basic physiological processes involved in female sexual functioning are not yet well understood even by researchers, let alone the clinical community, says **Julia Heiman**, PhD, a professor of psychiatry and behavioral sciences and director of the Reproductive and Sexual Medicine Clinic at the University of Washington in Seattle.

So talk of finding a treatment is somewhat premature, she notes.

However, to say that all research aimed at evaluating pharmaceutical approaches are inappropriate at this time is not true either, Heiman says.

"What is probably true is that basic physiological processes, particularly of erection — less so of ejaculation — are more known for men than for women. They have been more researched over the last 20 years," she explains. "But then, men's genital response has been of more interest in terms of various pharmacological treatments even before Viagra, it's just that they were more primitive — injections and prosthetic devices, etc."

The effect is something of a 20-year head start on what is known about the physiology, anatomy, and neurophysiology in men.

"We don't know as much about the anatomy and particularly the physiology and neurophysiology of the genital area in women," she continues. "But to say we don't know anything is not correct. We know a lot about women's psychology and sociopsychology in terms of sexuality."

Even in men, it's important to understand the physical and psychological connection in sexual functioning — and the psychological aspects of male sexuality have often been ignored, Heiman notes.

Viagra doesn't work for all men, she adds. And some men choose to stop taking Viagra after several months, indicating that resolving physical problems does not always resolve the entire problem.

More research about the physical aspects of female sexuality does need to be done, and that is where the current pharmaceutical focus can be helpful.

"Pfizer [the maker of Viagra] is not only funding research into treatments, but they have a lot of resources. They are also funding some basic science research, such as a nationwide questionnaire to women about sexuality," she says. "You can say they are biased in how they ask the questions, but they have involved some researchers with really good reputations. Some of the work that I have done on imaging female genitalia during arousal, Pfizer has funded that. Those are the things I am grateful for, because the NIH [National Institutes of Health] is just not interested in funding work like that."

Defining dysfunction

The concept of sexual dysfunction is a controversial one in the field of research into female sexuality, says **Karen C. Rhines**, PhD, an assistant professor of psychology at Seton Hall University in South Orange, NJ.

"To define 'dysfunctional' or 'abnormal' means you have a clear sense of the opposite — that is, 'functional' and 'normal,'" she explains. "By and large, we don't have a clear sense of that for many of the conditions we treat — including sexuality."

It is clear to many clinicians that their female patients are troubled by the problems they face functioning according to what they feel are accepted social norms.

"We consider something to be dysfunction if it

SOURCES

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is troubling to the client or his or her partners, in the areas of desire, arousal, orgasm, and pain."

The medical community has a long history of medicalizing and pathologizing many areas of female functioning and looking for biological causes to explain "abnormal" symptoms. So concerns about whether medical interventions are appropriate are valid, Rhines says.

"For conditions like sexual pain — vulvar vestibulitis, for example — I think medical intervention has been and will continue to be beneficial," Rines notes. "But for conditions like anorgasmia or, more seriously under study, hypoactive desire disorder, I think medical treatments alone will fail for most women because the root cause of the problem is psychological, not biological."

Search should continue

Like Heiman, Rhines says research into treatments for sexual problems in women should be done, even if a treatment that works for all — or even many — women is not found.

"I think there are concerns with painting female sexual dysfunction with a broad brush," she notes. "On the other hand, to suggest we need to reinvent the wheel with each troubled woman is equally problematic. I think we do need to move to controlled treatment-outcome trials, and, later, to treatment matching."

Although she doesn't believe a panacea for female sexual dysfunction will be found, the search should still continue, she adds.

"As a field, and more broadly, as a culture, we need to re-examine the socialization of women around sexuality and provide some education about both women and men about good and effective sexual practices."

Heiman concurs. "When you look at Viagra, no there is no equivalent in women. Will there be? Who knows?" she says. "In a sense, I am not very interested in that. I am interested in what kinds of different things could help women." ■

Simulated scenarios test, train ethics consultants

Johns Hopkins develops assessment tool

Though some erudite veterans may tell you differently, good ethics consultants are made — not born.

People with the academic and clinical background for service on hospital ethics committees may still have difficulty when it comes to communicating with and dealing with families in crisis.

For example:

• A family member of a patient wants to continue advanced life support measures on a patient who has previously requested such measures not be used.

• Parents of a gravely ill child refuse to consent to necessary procedures to save the child's life.

These are just some of the situations that might require an ethics consult — the convening of an ethics committee or a designated subset of the committee — that meets to resolve a particular conflict.

"It takes time to become a good ethics consultant," notes **Eugene C. Grochowski**, MD, PhD, FACP, associate professor of medicine at Johns Hopkins School of Medicine in Baltimore, and a member of the ethics committees at Johns Hopkins Bayview Medical Center and Franklin Square Medical Center.

While it's a given that ethics consults will vary in quality with the skill and experience of individual consult teams, there is no clearly accepted way to evaluate the quality of ethics consults performed and allow people to improve, he says.

Unlike other medical training situations, it's not practical to let novice ethics committee members observe actual ethics consults and, for similar reasons, it's not practical to allow more experienced consultants to observe newer consultants performing real consults, either.

"The situation is already very stressful. You have some sort of conflict, or there would be no reason for the attending physician to ask for an ethics consult," Grochowski observes. "The presence of another party in that room, would essentially affect and change the consult process. It just doesn't lend itself to that kind of situation."

However, if consult teams are allowed to practice using realistic simulations of consult situations, they might be able to improve their skills without any real-world consequences.

After using carefully designed simulations of clinical scenarios to train physicians in the neonatal and pediatric intensive care units, Grochowski and some Hopkins colleagues began to wonder whether a similar technique could be used to train and evaluate ethics consult teams.

They received a grant from the Niarchos Faculty Innovation Fund at the Johns Hopkins University Berman School of Bioethics to conduct a study of two things: 1) could simulations be developed that realistically approximate an ethics consult; and 2) could an assessment tool be developed to evaluate the quality of the consults.

First, they devised a common ethics consult scenario: the daughter of a woman who has suffered a severe stroke wants her placed on a ventilator. The patient previously had told a physician she did not ever want to be placed on a ventilator should her condition warrant it. The physician wants the ethics consult team to "help" the daughter agree to take her mother off the ventilator.

Next, they recruited experienced volunteer actors to develop the characters involved in the simulation. No script is used, Grochowski emphasizes. The actors must improvise while interacting with an ethics consult team.

The test simulation used three actors — a person playing the patient's daughter, patient's son, and a real physician playing the role of physician.

"We created in-depth characters, maybe 10 or 15 pages of character development," explains Grochowski. "We know who their kids are, what their kids do, where they go to school, etc."

The research team also asked the actors to open certain windows of opportunity for the consult teams — avenues that might lead to a resolution of the conflict or a breakthrough — to see whether the consult team would pick up on them.

In the scenario, the daughter lived in town, while the patient's son lived across the country and traveled to see his mother after her stroke. The patient's husband had died.

The physician had a very strong patient autonomy point-of-view, he adds.

"There were all sorts of different dynamics that we created that were realistic," Grochowski continues. "The patient had been noncompliant with medication for hypertension — she ended up having a stroke. The daughter felt guilty for not coming home immediately when her mother called complaining of a headache. She got there and found her on the floor. She felt the physician was moving too fast, the prognosis wasn't entirely clear, etc. There were some religious references that a family member would make, and there was a question about how well did the consult team follow up on the use of the religious words."

Once the simulation and characters were developed. The simulation was tested by ethics consult teams from Hopkins Hospital in Baltimore.

"We got four separate consult teams — three or four people on each team — to come meet with our 'family,'" Grochowski says.

The only instructions given to the teams were to conduct the consult as they normally would. The actors in the simulation responded, in character, to the actions of the consult team.

"Anything that they needed, we would provide — we had charts for them to look at, consult notes from neurology. The neurologist would be available to talk to the family if they wanted," he notes. "The only difference was that the time frame was compressed. If the family needed to meet with someone, we could have that happen right away, rather than waiting for it to be scheduled."

All of the interactions took place in a conference room that had a camera in the ceiling — the consults were videotaped for later review and evaluation.

When the consult was over, participants were asked to write a brief summary of the experience.

"Our first goal was to demonstrate we could create the real feeling of an ethics consult," says Grochowski. "And the consult team members said they felt that way, and the reviewers looking at the tape saw it that way, too. It appeared to them like the real thing."

As the consult teams sat down to write their summaries in the conference room, Grochowski noticed that they spoke about the simulation as if it were a real ethics consult, as well.

"That happened, literally, with every consult team," he says. "When they were sitting down to write, they had spontaneous post-consult discussions. They talked about it in a way you would talk about a real consult, 'what did they do, what they might have done differently, etc.' They didn't say, 'Gee, those were really great actors. They did a good job.'"

Evaluating the simulations

Just having the videotaped simulation is a good training tool for ethics consult teams and a useful way to help teams improve, Grochowski says.

Because the interactions are videotaped, they are available for both the participating teams and

SOURCE

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others to review later. The tape can be stopped at certain points, allowing for a discussion.

"You can ask the participants, 'What were you thinking here?' Or, 'what were you trying to communicate just then?'" he says. "In that way, you can get a feel for what they were thinking and how they were working through — or not working through — a particular issue."

At the same time, the second part of their study involves developing a standardized, objective assessment tool to evaluate the quality of the consult.

As part of their research, Grochowski and colleagues used the standards for ethics consultation from the American Society for Bioethics and Humanities (ASBH) to develop an assessment tool.

"We tried to create an instrument — and that is still in its formative stages," he explains. "A lot of it is taken from the ASBH standards book — those were the guiding standards. And we included a lot of communications theory background."

The instrument is a series of questions, covering different skills, designed to evaluate the consult.

"We wanted to look at how well the consult team worked together — whether they worked as a team, or whether it was a group-think sort of thing with one person doing the pushing and everyone else just towing the line," he says. "If you believe that multidisciplinary ethics consult teams are an advantage, then they all have to be heard. And you have to create an environment for that to occur."

Experts review tapes, revise tools

The research team has recruited three nationally known bioethicists, with extensive experience performing ethics consults, to review the tapes using the new assessment tool.

"They watched the first tape using the assessment tool, and then made recommendations about improving the tool," Grochowski says. "We did that through one iteration, improving the tool and then having the experts go back and review another tape using the revised tool."

The researchers hope to go through four revisions of the present tool before exhausting their research funding.

To adequately evaluate the assessment tool, it would have to be used to evaluate several different scenarios, using ethics consult teams from a number of different hospitals — something that will take significantly more time, effort, and money, he adds.

"In order to actually validate it, we would need to use different scenarios and different committees. These things are expensive, however, because it takes time to train the actors, because they are not just learning lines, they are creating," Grochowski explains.

But the researchers do feel they have met their first goal and developed a realistic way to simulate ethics consults for learning and evaluation purposes, he adds.

"Because it is not scripted, what each consult team experiences is different depending on how they interact with the family and what they choose to do in what sequence," Grochowski notes. "And the actors react spontaneously to the consult team. There is a lot of emotion involved. They may get angry and storm out of the room. There are all kinds of possibilities." ■

Partial-birth abortion ban expected to pass

Legal challenges expected

In a matter of weeks, the U.S. Congress is expected to enact a federal ban on a pregnancy termination procedure known as partial-birth abortion. President Bush has indicated he will sign the bill into law.

But the end of the political debate on the topic will only be the beginning of the struggle for abortion providers, women's health advocates, and right-to-life organizations. The new law is open to various interpretations and will likely face immediate court challenges, say experts.

"I don't know what the impact will be," says **Warren Hern**, MD, a Boulder, CO, gynecologist and medical director of the Boulder Abortion Clinic, PC. "The legislation is set up so that you could use the language to outlaw any abortion — particularly any second-trimester abortion by any technique. But I think that's the point of the

legislation, anyway."

According to the legislation currently under consideration, a "partial-birth abortion" is a procedure in which the physician performing the abortion:

• deliberately and intentionally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the mother's body, or, in the case of a breech presentation, any part of the fetal trunk past the navel is outside the mother's body; and

• performs the overt act, other than completion of delivery, that kills the partially delivered living fetus.

The bill makes it a federal crime, punishable by up to two years in prison, to perform such a procedure. It also allows the father of the fetus, if married to the mother at the time the procedure is performed, and the maternal grandparents of the fetus, if the woman is younger than 18 years of age, to sue the provider for damages in civil court.

The wording of the legislation is vague and may be construed to cover any number of procedures now in use, says Hern.

"Partial-birth abortion is a propaganda term," he says. "It has never been described in the medical literature and no one has ever seen one. When doctors read this legislation, they can't tell whether they will be prosecuted for doing an abortion, so they just won't do it. They will go do something else."

Confusion over terminology

According to the American College of Obstetricians and Gynecologists (ACOG), the procedure the legislation seeks to ban is clinically known as "intact dilatation and extraction" (intact D&X).

According to a policy statement[1] issued by ACOG in 1997 and revised in 2000, the procedure contains the following four elements:

• deliberate dilatation of the cervix, usually over a sequence of days;

• instrumental conversion of the fetus to a footling breech;

• breech extraction of the body, excepting the head;

• partial evacuation of the intracranial contents of a living fetus to effect vaginal delivery of a dead but otherwise intact fetus.

Because all of these elements are part of established obstetric techniques, the policy statement emphasizes that all four elements must be performed in sequence; otherwise, the procedure is not considered to be an intact D&X.

Although the ACOG's consensus is that there is never any situation where intact D&X would be the only appropriate termination procedure to use, there are situations in which the clinician might determine it to be the most appropriate way, given the specific set of circumstances, to preserve the life and health of the mother.

As examples of situations where the procedure might be used, an ACOG fact sheet on intact D&X lists the following:

• The evacuation of a severely infected pregnancy with maternal sepsis where hysterectomy (incision of the uterus) could lead to peritonitis, shock, and even death.

• The completion of a spontaneous abortion of a living 16-week fetus with known hydrocephalus, presenting with the body delivered and the head entrapped by the woman's cervix. The physician may believe that decompression of the fetal head, to obviate the risk of extensive cervical laceration or a ruptured uterus in the woman.

Although the ACOG statement acknowledges that the procedure is controversial among providers, the organization does not support a ban on the procedure.

"The potential exists that legislation prohibiting specific medical practices, such as intact D&X may outlaw techniques that are critical to the lives and health of American women," the policy statement reads. "The intervention of legislative bodies into medical decision making is inappropriate, ill-advised, and dangerous."

What does the law prohibit?

Another stumbling block for providers, says **Ron Fitzsimmons**, executive director of the National Coalition of Abortion Providers (NCAP) in Alexandria, VA, is that there is still a great deal of confusion about what exactly intact D&X is and what the proposed law prohibits.

The legislation discusses partial delivery of a living fetus, but does not specify a gestational age. Many providers say they perform the procedure intact D&X, but do not do so on a living fetus. The fetus is killed prior to the procedure by administering shot of digoxin into the fetal heart while it still is completely in utero, says Fitzsimmons.

And most providers who say they perform the procedure perform it after the gestational age of 16 weeks, though this is not mentioned in the proposed legislation.

No procedure known as intact D&X has ever been described in the medical literature, in medical

SOURCES

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textbooks, or been the subject of study, adds Hern, who has written textbooks on abortion procedures.

"ACOG has given the definition, but you ask them where they got it and they can't tell you because it's folklore," he says. "There are no case reports. There are no comparative studies. They say that this might be the safest way to do a late abortion in some situations, but how do they know that?"

And no one knows exactly how many of these procedures are performed each year. A report released this year, by the Alan Guttmacher Institute in New York,[2] surveyed abortion providers about the number and types of procedures performed. According to the survey, a procedure known as "intact dilation and extraction" accounted for 0.17% of all abortions in the year 2000 — about 2,200 procedures.

The Guttmacher report used the ACOG definition for intact D&X, but gave the procedure a different name, says Fitzsimmons. And the survey relied on self-reported statistics, which may not be accurate.

"I have only known of one provider who performs the procedure as described in the legislation on a living fetus, and I am not sure that he is still doing so at this point," he adds.

At its annual meeting, NCAP is planning to have legal advisors come in to counsel providers about what the law will and will not permit, Fitzimmons notes.

"We are very concerned. But this is likely to become the law, and then it will be up to the court challenges to decide what will happen," he states.

The proposed legislation is really not so much about outlawing one procedure, as it is a political attempt by anti-abortion lawmakers to intimidate abortion providers, frightening them away from providing any type of procedure, Hern and others allege.

During debate of the legislation in front of the House Judiciary Committee, Rep. **Jerrold Nadler** (D-NY) emphasized that, intact D&X was only one type of procedure used to perform abortions in the second and third trimester, and lawmakers could specifically ban late-pregnancy abortions if they sought to do so.[3]

"We can describe in gruesome terms the actual procedure by which a fetus is aborted, and it sounds terrible, so let's. Because it sounds terrible, let's outlaw it. The fact is, and the opponents of abortion say this constantly too, you can probably describe other abortion procedures and make them sound terrible," Nadler said. "But the fact is that if they're pre-viability, then you can't legislate against them, period. The Supreme Court says so. If they're post-viability you can legislate against them as long as you put in a life and health exception for the mother. So if you want to be honest, you put in a late-term abortion bill that would pass and would pass constitutional muster. If you want to be dishonest and just play to the political galleries but accomplish nothing, then you put in this bill, which is unconstitutional on its face."

Honest disclosure needed

Since the political debate over partial-birth abortions began in 1997, the pro-choice movement and abortion providers have not participated in an honest, public discussion about abortion and the realities of the different procedures used, and that needs to happen, says Fitzsimmons.

"We, as a movement, don't talk about abortion. We have organizations that can't even use the word abortion. But we need to because that's the big elephant sitting in the middle of the room," he states. "We need to talk about abortion — the good and the bad — and we need to talk about it using the terms the women use. Women don't call up our clinics and say, 'I can't have this fetus.' Or, 'I

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want to exercise my constitutional rights today.'"

Providers' reluctance to enter into public discussions about abortion inadvertently leave women hanging. They hear messages from anti-choice advocates about how wrong the procedures are, but there is largely silence and secrecy on the part of the pro-choice movement.

"The message they receive is, 'Hey, it's your 'choice' but after that you're on your own," he says. "What we are left with is all this screaming and yelling and dueling bumper stickers, and women are getting lost in the middle."

References

1. ACOG Statement of Policy. Statement on intact dilatation and extraction. Issued by the ACOG Executive Board. Jan. 12, 1997.
2. Finer LB, Henshaw SK. Abortion incidence and services in the United States in 2000. *Perspect Sex Reprod Health* 2003:35-6-15.
3. Testimony of Rep. Jerrold Nadler before the House Judiciary Committee on Wednesday, March 26, 2003. Accessed on-line at: http://thomas.loc.gov/cgi-bin/cpquery/0?dbname=cp108&maxdocs=100&report=hr058.108&xform_type=3&sel=TOC_168596&. ■

CME Questions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. When your evaluation is received, a certificate will be mailed to you.

21. According to our article, the difference between the terms "quarantine" and "isolation" is:
A. Isolation is used only for one person
B. Quarantine is involuntary, whereas isolation is voluntary
C. Quarantine is used for people exposed to a communicable illness, isolation is used for people who already have it
D. None of the above

22. According to our article, the medical community's knowledge of the physiology of female sexual functioning:
A. Is nonexistent
B. Lags behind similar knowledge about men
C. Is not being studied
D. None of the above

23. The ethics consult simulations researched at Johns Hopkins University School of Medicine:
A. Are completely scripted
B. Are observed by evaluators through two-way mirrors
C. Are videotaped for later evaluation
D. None of the above

24. According to the American College of Obstetricians and Gynecologists, the clinical procedure that the term "partial-birth abortion" most likely refers to is:
A. Intact dilatation and evacuation
B. Intact dilatation and extraction
C. D&E
D. None of the above

Answers: 21-C; 22-B; 23-C; 24-B