

**National Ethics Teleconference
Informed Consent Practices:
Lessons Learned from Implementing iMedConsent
November 28, 2006**

INTRODUCTION

Dr. Berkowitz:

Good day everyone. This is Ken Berkowitz. I am the Chief of the Ethics Consultation Service at the VHA National Center for Ethics in Health Care and a physician at the VA NY Harbor Healthcare System. I am very pleased to welcome you all to today's National Ethics Teleconference. By sponsoring this series of calls, the Center provides an opportunity for regular education and open discussion of ethical concerns relevant to VHA. Each call features an educational presentation on an interesting ethics topic followed by an open, moderated discussion of that topic. After the discussion, we reserve the last few minutes of each call for our 'from the field section'. This will be your opportunity to speak up and let us know what is on your mind regarding ethics related topics other than the main focus of today's call.

ANNOUNCEMENTS

Some of you may remember that in June this year, we had a teleconference on Ethics Issues in Pandemic Influenza Preparedness. Following that call, the Ethics Center developed materials for facilities to hold their own Staff Discussion Forums to raise awareness and understanding about caregiving obligations, allocation of scarce resources, and other difficult clinical and ethical decisions that will need to be made in the event of a flu pandemic. Those materials include a guide to conducting the forums as well as a PowerPoint presentation: *Tough Decisions: Preparing VA for the Ethical Challenges of Pandemic Influenza*. The materials are available on the Ethics Center's website. We were delighted to learn that several facilities have held forums and we'd like to encourage other facilities to consider planning them as well. Feedback on the forums will help us improve the materials and to learn what issues are of particular concern to you in the field.

PRESENTATION

Dr. Berkowitz:

In today's presentation, we will identify ethical and practical concerns relating to informed consent and the implementation of iMedConsent. We will analyze

several examples where current attempts to implement iMedConsent have revealed ethics quality gaps, and explore strategies to improve practices and close ethics quality gaps in informed consent.

Joining me on today's call are Ray Frazier and Susan Owen.

Ray Frazier, MA – Program Analyst, National Center for Ethics in Health Care; National VA Project Manager for iMedConsent

Susan Owen, PhD – Medical Ethicist, Ethics Consultation Service, National Center for Ethics in Health Care.

Susan, could you begin by providing an overview of the ethical issues related to informed consent?

Dr. Owen:

VHA is very committed to providing a health care environment that promotes shared decision making. Informed consent for treatments and procedures is not optional, but essential to high quality patient care. Not only is informed consent integral to good clinical practice, it is required by ethical standards, VA policy, JCAHO standards, and Federal law.

Dr. Berkowitz:

VHA Handbook 1004.1, "Informed Consent for Clinical Treatments and Procedures," discusses the process as well as the requirement of informed consent, and distinguishes between treatments and procedures that require written signature consent and those that do not. Could you elaborate about what the process of informed consent entails and when signature consent is required?

Dr. Owen:

Informed consent is a process that includes identifying the appropriate decision maker, providing information about a proposed treatment or procedure and its alternatives, supporting voluntary decision making, and documenting the process. For treatments and procedures that pose special risks, informed consent includes an additional step—completing a consent form. VHA Handbook 1004.1 distinguishes between treatments and procedures that do and do not require signature consent, and explains the ethical rationale for this distinction.

Dr. Berkowitz:

Susan, could you elaborate on the ethical standards and principles that support VA policy on informed consent?

Dr. Owen:

The principle of respect for autonomy supports the right of the competent patient to make decisions about his or her own health care. Empowering patients and promoting shared decision making are central values in ethical health care, and informed consent for treatments and procedures is one of the most important ways in which these values are implemented.

The twin principles of beneficence and nonmaleficence also provide an ethical foundation for informed consent policy and practice. Beneficence supports those practices that protect the patient's welfare and nonmaleficence supports those that protect the patient from harm. In the informed consent process, the practitioner is ethically responsible for ensuring that the patient has enough information about risks and benefits of proposed treatments or procedures, alternatives to such treatments or procedures, and risks and benefits of no treatment at all. It is imperative that if the patient chooses to incur risks, he or she must be able to make this choice based on what a "reasonable person" in similar circumstances would want to know in making the treatment decision.

Dr. Berkowitz:

Thank you, Susan, for providing a brief overview of ethical issues related to informed consent policy and practice. In the rest of today's call, we will focus on how these ethical issues relate to the implementation of iMedConsent. Ray, what prompted the Ethics Center to recommend that our system implement this initiative?

Mr. Frazier:

Although empowering patients and promoting shared decision making are central values in ethical health care, it became clear through reports and published studies that there were serious deficiencies in the quality of informed consent in VA and the private sector. Common problems reported included cursory conversations with patients, and incomplete or illegible documentation. Consent forms were sometimes misplaced or lost, resulting in treatment delays or cancellations and legal liability.

To reduce the resulting risk to veterans and the organization, the Ethics Center recommended that VA adopt a comprehensive, national, standardized approach. We refer to this initiative as "Electronic Support for Patient Decisions" or ESPD—to reflect our goal of supporting patient decision-making.

Dr. Berkowitz:

Thank you, Ray. Could you provide some background on how the national iMedConsent deployment actually came about?

Mr. Frazier:

In the Spring of 2004, after extensive review and pilot testing, the Ethics Center recommended that VHA implement iMedConsent, a software application designed to support patient decision making and improve the informed consent process. The phased national rollout was completed in September 2005 and now, every VAMC in the country has access to iMedConsent. There have been and continue to be technical challenges to achieving full implementation, but these are being overcome with the help of the Office of Information and the dedication of the CAC, IRM, and HIM personnel at each facility—especially the designated iMedConsent Points of Contact.

Dr. Berkowitz:

As a background to today's discussion and for those who may not be familiar with how iMedConsent works, could you provide a brief description of how this software application supports the goal of improving the quality of informed consent in VHA?

Mr. Frazier:

Sure, Ken. The iMedConsent program contains a large library of documents, including informed consent templates, drug information, patient instructions, and anatomical diagrams. These materials are tremendously useful, not just to facilitate the informed consent discussion, but for all stages of the patient education process.

For treatments and procedures requiring signature consent, the program walks the practitioner through the various steps required by VA policy. The program automatically populates consent forms with patient information and procedure-specific information (risks, benefits, etc.) and incorporates signatures captured using an electronic signature pad. iMedConsent then stores the completed, signed consent form in the patient record and automatically generates an accompanying progress note in CPRS. Throughout the consent generation process, the program provides help screens, reminders, and policy links to encourage best practices.

Although iMedConsent provides an excellent *tool* for practitioners and patient educators, the quality of informed consent will always rely on skilled providers taking the time to sit down and talk to their patients. Ultimately, there is no substitute for real conversations about treatment goals and health care decisions.

Dr. Berkowitz:

So far, so good. How has the implementation fared? Have practitioners been receptive to the changes that iMedConsent brings about?

Mr. Frazier:

As I mentioned, there have been some technical issues that have impeded iMedConsent implementation at a number of facilities, and the technical and clinical communities are really pulling together to overcome these obstacles. And, as you might imagine, incorporation of informed consent documentation into the electronic medical records process introduces many logistical challenges. By-and-large, technical issues aside, response to iMedConsent implementation has been very positive. VHA clinicians and leadership realize the benefit of standardizing informed consent information across the country. The places we have seen the most problems have been facilities where pre-implementation informed consent practices were not aligned with policy or ethical standards. By walking clinicians through the *process* of informed consent, iMedConsent has highlighted areas where their practices fall short. Such news isn't always the most welcome, but in general, facilities have demonstrated a commitment to improving their health care practices.

Dr. Berkowitz:

We titled today's call, "Informed Consent Practices: Lessons Learned from implementing iMed Consent," and you mentioned that in some cases iMedConsent has highlighted for facilities where their practices fall short. Could you provide examples of such shortfalls and the strategies that a facility might use to remedy them?

Mr. Frazier:

At the outset, I would like to stress that we consider this discussion part of a quality improvement exercise. We have observed informed consent practices in the field and acknowledge the clinical realities that contribute to what we are calling "ethics quality gaps." That being said, I would like to highlight four main informed consent quality gaps that we have observed in the iMedConsent implementation. First is the practice of consenting patients on the gurney when they are about to be wheeled into an operating room or procedure area. Second is the delegation of the informed consent responsibility to personnel who are not authorized to obtain consent. The third is an informal practice of obtaining "witnesses" signatures long after the patient and practitioner have signed the form. And the fourth practice has to do with restrictive local policies that make obtaining consent more onerous than it needs to be.

Dr. Berkowitz:

Let's take the first ethics quality gap, the practice of consenting patients on the gurney. Can you say more about why this is a problem?

Mr. Frazier:

“Gurney consenting” is the routine practice of conducting the informed consent discussion and asking the patient to sign a consent form when the patient is undressed and on a gurney awaiting a surgery or procedure. Gurney consenting in the setting of ambulatory surgery is not acceptable because, first of all, the patient’s ability to freely refuse the treatment is significantly compromised. “The train has already left the station” if you will. Think of it from the patient’s perspective. You’ve come in to the hospital and undressed. You’re lying there in your backless gown with your little hat and booties. Is that a time that you can really make a decision? Will you disappoint your health care team if you tell them that you don’t want to go ahead after learning about the potential risks? After all, they are in their paper hats and booties as well... In waiting so long to obtain the patient’s permission, you have made it very difficult for him or her to say no.

Second, the patient’s ability to fully understand the information being presented by the practitioner and their ability to fully participate in the informed consent discussion is compromised by their circumstances. The United Health Foundation cites studies that indicate that most people suffer 68% hearing loss when naked.¹ It’s an amusing statistic, but I think we all already know this intuitively. We have an obligation to our patients to conduct the informed consent process before they take their clothes off—at a point when they are better able to make a real, informed choice.

For these reasons, consenting patients on a gurney is **ONLY** acceptable when you absolutely cannot obtain consent further upstream from the actual procedure event.

Dr. Berkowitz:

Are there practical as well as ethical issues that have arisen when “gurney consenting” is practiced in the ambulatory surgery setting? How did the implementation of iMedConsent identify this ethics quality gap?

Mr. Frazier:

As it turns out, implementation of iMedConsent in a “gurney consenting” workflow is not only out of compliance with ethical standards for informed consent in VHA. It also raises significant workflow problems when implementing the iMedConsent program. Taking the informed consent discussion to the gurney requires the

¹ United Health Foundation poster available at: http://www.unitedhealthfoundation.org/tips/doc_ad.pdf (Last accessed November 21, 2006).

procurement and maintenance of mobile workstations. This is extremely resource intensive. Generally, we have seen that mobile deployment is best reserved for inpatient settings where you *have to* conduct the consent encounter at the bedside. The majority of these settings also already have the wireless infrastructure in place to support the mobile laptops, carts, and tablet PCs.

Dr. Berkowitz:

In order to close this ethical quality gap and improve efficiency, what strategy do you suggest for a facility with a clinic that practices routine gurney consenting?

Mr. Frazier:

If your clinic practices routine gurney consenting, evaluate ways in which the informed consent discussion can be moved further “upstream” from the procedure event. This will probably entail a significant shift in the clinic workflow and may require additional resources. We recommend that you involve QM and facility leadership in improving the ethical quality of your informed consent workflow and reduce gurney consenting in all clinical settings.

Dr. Berkowitz:

Ray, Could you elaborate on the second ethics quality gap mentioned above related to the delegation of the informed consent process to unauthorized individuals?

Mr. Frazier:

While iMedConsent does not introduce new or revised policy requirements, many facilities have found that use of the program clarifies policy—particularly regarding the clinicians who are authorized to sign consent forms. Several facilities experienced this—for example, a number of facilities had hired physician assistants for the sole purpose of obtaining consent for, say, all procedures performed in urology. While the Ethics Center realizes that these individuals may do a terrific job of educating the patient and answering questions, we are bound to follow federal regulations that, at this time, restrict the authorized practitioner to individuals who have been granted specific clinical privileges to perform the treatment or procedure in question. Facilities need to ensure that that the proper, qualified individuals are obtaining consent according to Handbook 1004.1.² Please remember that VHA informed consent requirements *are the same for paper-based and electronic documentation*. You cannot avoid this requirement by avoiding iMedConsent implementation and sticking to your paper-based consent documentation processes.

Dr. Berkowitz:

² Handbook 1004.1 is available at: http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=404.

Ray, you mentioned a “witnessing” issue as your third ethics quality gap. Can you elaborate on the problematic process?

Mr. Frazier:

At some facilities, the practitioner and patient sign the consent form together, then the “witness” signs at a later time. This completely defeats the purpose of this requirement and essentially forces the individual signing as the “witness” to falsely attest that he or she saw the patient and practitioner sign the form.³ Unless and until the VHA informed consent requirement regarding witnessing is revised, facilities must conform to Handbook 1004.1 as it is currently written. iMedConsent enforces this requirement in that the consent form cannot be saved to the record until all three required individuals (practitioner, patient, and witness) sign the form.

Dr. Berkowitz:

Ray, as a fourth ethics quality gap you mentioned overly restrictive local policies. Could you elaborate on what you mean by this example?

Mr. Frazier:

This last example is an unnecessary procedural hurdle that may have ethical implications for how scarce time and resources are allocated. Some facilities have local policies that are more restrictive than national informed consent requirements. While it is permissible that local requirements be more restrictive (provided that the local requirement does not conflict with the national policy), some requirements place a significant added burden on the ability of practitioners to provide efficient care *and* quality informed consent. These local requirements should be carefully examined by facility leadership and, when needed, Regional Counsel. When the benefits of such requirements do not justify the added burden on practitioners and patients, facilities should strongly consider revision or removal of the restriction(s).

Dr. Berkowitz:

So give me an example of a local policy that is needlessly more restrictive than national policy and may impose unjustified practical burdens on practitioners and patients?

Mr. Frazier:

³ For more information about witnessing requirements, see the Ethics Center publication available at: http://vaww.ethics.va.gov/ETHICS/docs/rx/EthicsRx_20051201_Who_Can_Witness_Signature_Consent.pdf

Going back to the witness requirement in national policy, some facilities have placed specific local restrictions on who may sign as a witness on the consent form. For example, at least one facility mandated that patients' relatives could not witness consent forms. Another mandated that no hospital employee could serve as a witness. National policy allows the witness to be a stranger, family member, friend, volunteer, or employee. Restricting who can witness places an unneeded burden on providers. When iMedConsent is implemented, and forces compliance with the national requirement that the witness actually be a witness to the form's signing, an unneeded restriction on who can sign can bring a clinic to its knees.

There is also a common misperception that witnesses need to be present for the *entire* consent discussion. This is not the case. In signing an informed consent form, the witness is attesting *only* to having actually observed the patient and practitioner sign the form. So where this misperception exists, clarification of the limited role of the witness can significantly free-up the informed consent workflow.

Dr. Berkowitz:

Now that we have discussed some of these ethics quality gaps and barriers to implementation of the iMedConsent program, tell me about the implementation process itself. What steps have facilities taken – or should they taken now – to do a good job with iMedConsent?

Mr. Frazier:

Well, first, the ethics quality gaps need to be addressed. Implementing the program in the midst of noncompliant workflow processes or unnecessarily restrictive policies may be painful. In the initial rollout of the iMedConsent program, the Ethics Center collaborated with Dialog Medical, the vendor of the iMedConsent program, to produce a guidance document for analyzing informed consent workflow processes and for reengineering these processes to be compliant with national policy and iMedConsent implementation. The facilities who did not sufficiently prepare for implementation had problems. For example, consider the “time-out” process. Facilities that implemented iMedConsent without anticipating the changes that an electronic documentation process would introduce often experienced difficulties retrieving the consent form in pre-op or pre-procedure verification of the form.

Dr. Berkowitz:

What strategy or strategies would you suggest to make sure that the consent form is available for surgical site verification in accordance with VHA Directive 2004-028, Ensuring Correct Surgery and Invasive Procedures?⁴

⁴ Available at: http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=1106

Mr. Frazier:

If the workflow in question continues to rely on paper-based verification methods for the “time out,” consider printing the consent form after signatures are obtained, *but before clicking “Save.”* Printing before saving allows you to generate a paper copy of the consent form without having to launch Vista Imaging.

If the facility wants to “go paperless” and wants to use the electronic record in the verification process, clinicians will need a workstation to view the consent image when and where the form is needed for verification in accordance with the correct surgery directive.

The Ethics Center is in the process of rewriting our guidance related to informed consent workflow analysis. We’re incorporating the lessons we have learned in the national implementation to make a more robust tool that can be used *before* implementing the program in a clinical area, and it can be used *after* implementation to identify and correct ethical or procedural concerns that crop up. I hope to have this document ready for release when this transcript is posted to the website.

Dr. Berkowitz:

Thanks Ray. Any more thoughts on what we’ve learned in the implementation of the program?

Mr. Frazier:

To me, one of the most striking results of the iMedConsent implementation process, and the one thing that I think will instigate the most lasting improvements in how we care for our veterans, is the initiation of a real national dialog on informed consent requirements and the ethical considerations that support these practices. We have seen such a groundswell of questions and suggestions from physicians, patient educators, facility and VISN leadership—just about every role and level in the organization. For example:

- Should signature consent be required for thrombolytic therapy?
- May we get a patient’s consent for an HIV test before surgery in the event that there is a needlestick to an employee?
- Can we create a single consent form that combines multiple procedures to be performed on different days?
- Do we have to obtain signature consent for local anesthetic?
- Is there a requirement for signature consent for patients participating in group clinic appointments?

Literally hundreds of informed consent questions have bubbled up. Some we have ready answers for. Others we need to confer as a Center to develop a response. Still others regarding clinical rather than ethical issues, we refer to the appropriate subject matter experts in Patient Care Services. I know that there are some physicians on this call right now, just itching to get to the Q&A section so they can challenge a risk, or question the content of the consent form for procedure x, y, and z. While we won't be able to address specific clinical content issues on this call, this kind of feedback is tremendously encouraging. The quality improvement feedback loop will continue to result in content updates and enhancements that are rolled-out nationwide.

Dr. Berkowitz:

As the Chief of the Ethics Consultation Service, I have certainly seen the increased traffic related to requests for informed consent guidance.

Mr. Frazier:

Yes. And as you know, the result of all of these discussions has been two-sided. On the one side, the Ethics Center has communicated with the field in the form of clarified requirements about informed consent policy and practice. On the other, the feedback from the field has instigated a very thorough self-evaluation of the informed consent handbook. The Ethics Center is in the midst of a major revision of the handbook to clarify and streamline our requirements.

In several instances, we have questioned the legal and ethical underpinnings of specific requirements. As a result of an analysis of our own guidance, we have requested three changes to the Code of Federal Regulations. If approved and implemented, we expect these changes will help facilities construct better informed consent practices.

1. The first change to the federal code that we have proposed would expand the definition of "practitioner" such that more categories of clinicians would be authorized to conduct the informed consent discussion and sign the consent form. This modification is still being discussed and clarified at the national level and, at this time, the Ethics Center cannot disclose the exact ways in which the requirements will be changed.
2. The second change to the regulations will, if approved and implemented, greatly reduce the witnessing requirement such that routine documentation of signature consent will not require a third party signature.
3. The third proposed change would extend the validity of signed consent forms from thirty to sixty days. This would enable workflow to be

constructed such that more informed consent encounters can be moved further upstream so that “gurney consenting” is less of a temptation.

Again, these are just proposals for now and the existing informed consent policy, as provided in the informed consent handbook must be followed.

Dr. Berkowitz:

And I can't stress that enough. We debated about whether or not to include the things that we're thinking about changing in the script and we decided to, in order to reinforce that this really is a two-way dialogue and we take all your suggestions and comments very seriously. But I just need to reemphasize that although Ray talked about the possibility of changing the definition of “practitioner,” of changing the witness requirements, and possibly changing the length of time that a consent is good for in the future, these are all just proposals for now and existing informed consent policy as provided in informed consent Handbook 1004.1 must be followed now.

Dr. Berkowitz:

There are several conclusions that we can draw from this discussion of informed consent and the implementation of iMedConsent.

(1) First, to reiterate, any discussion of iMedConsent begins and ends with the ethical principles that support informed consent policy and practice. As Del Carmen and Joffe note in a 2005 issue of *The Oncologist* entitled “Informed Consent for Medical Treatment and Research: A Review,”

- Bioethicists view informed consent as the practical embodiment of respect for persons and for individual autonomy. . . . This moral framework holds the patient's right and ability to make choices that are consistent with his or her values and preferences to be the main rationale for informed consent. From an ethical perspective, the physician's disclosure obligation is a prerequisite for the exercise of patient autonomy rather than the central focus of informed consent.

Similarly, iMedConsent is not the central focus of informed consent, but rather supports the patient's “right and ability” to choose treatments or procedures that reflect his or her values and preferences.

(2) Second, the iMedConsent initiative is an example of the Ethic's Center's commitment to improving ethics quality at the systems level. An important focus of Ethics Center work is “fostering systems-level responses to the ethical challenges of contemporary health care, an approach we call ‘preventive ethics.’” As part of this approach, the iMedConsent initiative supports patient decisions on a systems level and helps prevent problems before they arise.

(3) Third, in order for this systems-level approach to improving quality to be genuinely effective, the two sided communication between the Ethics Center and local facilities must continue to take place. Improvements for patients in the quality of the informed consent process depends not only on ensuring that facilities are clear about how to comply with informed consent policy and ethics practices when iMedConsent is implemented. Such improvements also depend on continuous feedback from those in the field about challenges and suggestions that arise as a result of the implementation process.

We encourage local ethics resources and clinical applications coordinators responsible for implementing iMedConsent to work together in this process, both to ensure compliance with policy and to clarify challenges and questions for Ethics Center review.

A resource for clarification of “Do’s and Don’ts For Best Practice in Informed Consent” may be found in the August, 2006 issue of InFocus on our website.

(4) Finally, the ongoing challenge – in this as in other areas of health care ethics – is to create and sustain environments in which the ethical principles that we accept can be implemented in practice. In a 2003 article “Consent for Anaesthesia” in the journal *Anaesthesia*, S.M. White and T.J. Baldwin write: “In practice, there remains a considerable gulf between the ethical necessity for consent and the practicalities for obtaining consent.” The goal of iMedConsent is to narrow this gap between theory and practice. At the end of the day, our shared commitment to the needs and welfare of our patients will enable us to meet this goal.

MODERATED DISCUSSION

Dr. Berkowitz:

Well I’d like to thank Dr. Owen and Mr. Frazier for discussing the topic of Informed Consent Practices: Lessons Learned from Implementing iMedConsent. Now that we have had an opportunity to discuss this topic, I would like to hear if our audience has any response or questions.

Caller:

We do a procedure, it’s involves a series of three injections. We typically say at the outset that we are going to be doing a series of three injections, one week apart. And we do the iMed Consent each time the patient comes. My question is: can we use the subsequent informed consent as a progress note since the consent does appear automatically as a progress note?

Dr. Berkowitz:

In response to your question, implementing IMed consent doesn't change policy. Handbook 1004.1 in section (4) on page 3 in the section on "scope" points out that informed consent may be limited to a one time single treatment or procedure, or it may encompass routine care of a particular problem or a series of treatments such as I think that you might be describing. And when that's the case, you don't need to repeat the informed consent discussion each time unless the treatment plan that was in place at the beginning has deviated significantly, or unless there's a change in the patient's condition or diagnosis that you think would reasonably have altered the original informed consent discussion.

So without knowing any details and without wanting to give you a specific answer, it sounds like that if you look through that policy, you might find that your series is covered by the one episode of signature consent and then subsequent parts of the treatment are documented in the progress notes.

Mr. Frazier:

What I would recommend is that as you're explaining the treatment to the patient using iMedConsent, in the treatment description that is on the form, you document how many injections you're going to give over what period of time. Then, the series of treatments planned in the course of care, would be included on the consent form for the patient.

Dr. Berkowitz:

If you have any further questions, you can always send us an e-mail at vhaethics on the Outlook system.

Dr. Williams:

Ken, this is Linda Williams in Little Rock.

I had a question about the rationale behind no longer requiring a witness to a signature on the consent form.

Dr. Berkowitz:

I just want to reinforce, that that proposed change is not something that is in place now. The witness requirements are still in effect. I don't want anyone to get misinformation or to come away with a misimpression. But to discuss the topic, yes. . . .

Dr. Williams:

Could you explain the rationale behind the decision? It seems to me that for a signature to be valid or a consent to be valid you would need to have someone attest that the patient was really coherent, etc.

Dr. Berkowitz:

Well, I haven't been present at many of the discussions about the proposed change. But I can try and give you my understanding of it and then if anyone else in the Center has further insight, then perhaps they can chime in. As I understand it and when you think about it, the practice of having the signature witnessed really hasn't proven to be of any benefit. People thought that by having someone there and signing as a witness that it would provide some legal protection. Oftentimes in practice people have gone back to look for the witness and either they haven't been able to find the witness, or the witness hasn't remembered the event. It hasn't really been a helpful thing, although it has been a procedural burden.

It does seem a little bit odd if we can't trust our practitioners to document the consent process as we do trust them to document everything else in the medical record that they document without a witness

So that reflects some of the thinking that went into the proposal to remove the witness requirement and I guess the bottom line is, it hasn't really provided a practical help to have a witness' signature. It sure has provided a burden for people to get it.

Anyone else in the Center want to add anything?

Ms. Bottrell:

This is Melissa Bottrell, also from the Ethics Center. You brought up a point that's really important, a misperception of what the witness role is. The witness is in fact, under federal law, not attesting that the person was coherent or capable. The witness is only signing to say that the person who is signing is the same person whose name is being written down. So it's a much lower standard than I think is commonly perceived. They are not attesting to that person's coherence, cognitive capacity, the content of the conversation or any other things. All they are saying is that Dr. Jones, whose name is on the form, wrote his name, and Mr. Miller, the patient, is the person whose name is written down on the form.

So it's a much lower standard for the witness which is required of the informed consents policy than witness requirements in other areas.

Dr. Berkowitz:

Thank you. And I must say Linda when I first heard about the discussions, it left me feeling a little bit queasy, I think, just because it's something that I'm so used to. But as I really started to think about whether the witnessing has ever really helped in my experience, I had to say that I thought the answer was probably no.

I don't know whether anyone else wants to comment about the witnessing requirements.

Again, the witnessing requirements in our current policy remain in effect and they have not changed as of now.

Dr. Paul Schneider, Los Angeles:

iMed is such a good driver for quality because it requires people to follow pre-existing policy. I have trouble trying to get people to stick with policy unless they use iMed. What I would love to do, if possible, would be to require the use of it at some point in the future so that we can uphold policy to a level. I wonder what others' thoughts are about that and any timeline that you might have.

Dr. Berkowitz:

Could you tell me a little bit more, Paul, before Ray chimes in about what you mean by increasing that requirement?

Dr. Schneider:

Well, specifically I meant that I would love to set a date and time where we tell people "from now on you may not use paper consent and you must use iMed to do your informed consents" because the paper consents allow people to stretch policy.

Caller:

Aren't we already there already? I thought that was made clear.

Mr. Frazier:

The performance monitors stipulate that every facility is to be fully implemented, using the program in all clinical specialties, within two years of their implementation date. That two-year anniversary will have every facility implemented by September, 2007, since September, 2005, was the last date that the last facility was installed with iMedConsent. And what we've done is draft something that puts that a little more concretely and lays out more clearly the expectations that end users use iMedConsent to document informed consent encounters. That is in concurrence right now. The Deputy Under Secretary for Operations and Management is currently reviewing that draft guidance that the

Ethics Center has put forward. We're hopeful, that within the next couple of weeks that information letter will come out. And then moving forward, early next year we hope to take that and put together a more formal handbook specifically for iMedConsent. All that being said, I want to be clear that it's probably unlikely that everyone will be able to get to a 100% all-the-time use of iMedConsent. There are things at the present time like documentation of consent over the telephone that iMedConsent doesn't really support. And also if the system goes down, a paper back-up system may be necessary. So there are sort of caveats to what we want to tell people as far as how we mandate use of iMed. But we do expect it to be the standard and so essentially it will be for regular, routine consent.

Dr. Berkowitz:

Paul, I doubt that there is any prohibition for one facility to accelerate if they want to – certainly I would think that that would be encouraged. It is very difficult to make such a big change – a culture change – in such a big system in such a short time. So I think it is actually a remarkable timeline -- two-year implementation.

Sherrie Hans:

This is Sherrie Hans, Deputy Director of the Ethics Center. Just to be crystal clear, once a facility has implemented iMedConsent in a program area, it is required that you use it for all consents except for those special occurrences that Ray just outlined. And that will be made very clear in the information coming out from Mr. Feeley. So if it has been implemented in an area, you can tell folks that it is required and they will soon have paper from the Deputy Under Secretary reinforcing that requirement.

James Horning, Sioux Falls, SD:

Should the resident sign these? Should the attending do it, or both?

Dr. Berkowitz:

Well again, the responsibility for documenting the informed consent process is the same as it has been and is outlined in the Handbook. Nothing has changed; if it was something that the resident could or should have signed, they can do it now and same for the attending.

Dr. Horning:

Well, let's say that the residents are in the process of being able to do these on their own, but they are not there yet. I guess the question is: you said that the person doing the procedure should sign. . . .

Dr. Berkowitz:

Well, when you say that they are in the process, but they are not there yet, do you mean that they are in the process of

Dr. Horning:

As an example, they are required, let's say, to put in five central lines or whatever, so . . . they are not certified to do this on their own, regarding staff privileges, etc. but yet they are not just observing these, they are being supervised while they're doing these.

Dr. Berkowitz:

Well again the policy remains the same. And it gives authority to get consent by a practitioner who has been granted specific clinical privileges to perform the treatment or procedure or a medical or dental resident. So, if the medical or dental resident is felt by those people I think who are supervising them to be capable of handling this as part of their graduated level of responsibility in terms of the consent, they would be authorized to get the consent, regardless of whether they have specific clinical privileges to perform the treatment or procedure or not.

And again, that's not a change in policy; that's the way the policy reads and has been read since it has been issued.

Dr. Horning:

Just one comment. This is a generic complaint now amongst practitioners. iMed is in there, we have to use the VistA imaging, then we order all these labs, the x-rays, the medications, etc. Every time you require a provider to go to that computer we are taking time away from that patient and family. And this thing is just getting almost ridiculous here as far as the stuff that we have to do. This is just another clog in here, as far as we have to jump into the computer, pull up VistA imaging and sign in about a hundred times a day or whatever. This is just a general comment, this is nothing personal.

Dr. Berkowitz:

Well, I appreciate that that's your opinion, and as I said we're always glad to hear your concerns. I do think that overall the advances we've made in electronic medical recordkeeping and the iMed system have improved our documentation and improved the quality of care that we deliver. So, although I understand, and I'm attending many weeks of the year and I understand the time commitment that's involved, I do think that on balance, the quality gains that we've achieved far outweigh the burdens. This is probably because, as Dr. Schneider has alluded to before, we took shortcuts before we had the electronic documentation and this level of oversight. I think it's hard to look in the mirror and realize that, but I think it's probably true that we do document and deliver better care now because of the systems changes that we made . . . well, that's my opinion.

Melissa, did you have something to add?

Ms. Bottrell:

I wanted to go back quickly to the signature issue, which is that for those residents' signatures, there is a part in the signature field where a resident can put in their name and they can also name the attending so that you can actually have documentation for residents that meets the student or trainee status of those individuals, and have that extra level of documentation, not just of the person who is doing that procedure, but also of who is observing them.

Caller:

I fully support iMed; I just want to make sure that everyone recognizes what some of the deployment issues are. There are issues of equipment, and that means money and resources that haven't come (obviously) with the mandate to implement iMed; there is a lot of support that's required. Our clinical application coordinators spend a tremendous amount of time as we deploy further and we think that we're about 60-70% deployed throughout our very large institution. They spend a huge amount of time supporting the people who obtain the consent, as well as the equipment. If iMed goes down or the laptops go down, or if, for whatever reason iMed needs to be put back on the laptops, we're constantly having problems. We want iMed to be basically at the hands of the providers wherever they are to avoid some of the problems that the previous physician was bringing up to make it very convenient for people to use it. And I think that has to be recognized as a real issue in implementation of iMed with the additional resources that come in many different sorts of areas that are required to really make it work and work well. It's not a perfect system; once you put it on the computer, it doesn't mean its there forever and that it works perfectly.

Caller:

That is so very true. I will tell you that we are 100% iMedConsent enabled here. The place that does not have iMedConsent in use is on the inpatient units because you cannot in an expedient or quick manner make iMedConsent work on laptops. We specifically have Gateway Pentablets. We have tried several other units, it is so slow, it is an obstruction to physician practice. I'm all for iMedConsent, I am having such a horrible time, I bet we have 10% of our inpatient consents done on IMed, where the doctors would be happy to do 100%, but it doesn't work on Pentab or a laptop.

Mr. Frazier:

There definitely are real technical barriers – I hope that I didn't at all give short shrift to the technical barriers that are out there and we definitely wanted to acknowledge that explicitly in the guidance that we drafted for the Deputy Under Secretary. And what you are talking about with using iMedConsent wirelessly is absolutely the case. Often it's not really – and I don't want at all to shift blame or anything, definitely the problem manifests itself in iMedConsent – but those instances it's the network that really needs to be upgraded. You're right that takes resources and that takes support and that's part of what we conveyed to the Deputy Under Secretary that this really needs to be supported by leadership and be given more resources.

Dr. Berkowitz:

And I think though that it is safe to say that we've made great strides in a short time -- just a year -- and we do hope that that will continue into the future. And again this is a culture change, it's a huge undertaking and each barrier we overcome gets us a little bit closer to our ultimate goal.

We do have a short time left in this call. I do want to say that as usual we didn't expect to conclude this discussion. We will post on our web site a detailed summary of this as we do every National Ethics Teleconference. So you can go visit our web site for summaries of this call and the prior calls. I do want to leave the last few minutes to either continue this discussion or to open it up for comments from the field. If there are other ethics-related topics on your mind, now would be a time to speak up or we have a few minutes left to continue the discussion on informed consent and iMed.

Cincinnati:

Has there been any thought of development of an auditing tool to measure the success of implementation in a particular area once you have implemented?

Dr. Berkowitz:

Ray, do you want to comment about monitors that are in place?

Mr. Frazier:

There is a reporting function. It's an administrator level function that facilities can generate their own reports. They can see whose using it, what specific consents are being completed, how many of them, and that is also rolled up nationally by the iMed servers that do generate just basic usage data and shoot that to Dialog Medical. So we at the national level do get to see even down to the facility level what specialties are generating consents and what aren't. So there are tools at both the facility level and at the national level and we're also going to be working on developing tools at the VISN level, so that VISN will be able to see really who in their facilities are using the program to an acceptable level and who needs improvement.

Cincinnati:

We do use those usage reports in iMed. The question that I had is that they are very good at tracking the numbers of what's being used, but an example, if you have 50 of a certain procedure, you can see that there's 30 of them that are in iMed, obviously the 20 were done on paper. There's no way easily to track that unless you are going back for each procedure that you do and looking at those numbers.

Mr. Frazier:

Some facilities have instituted a tracking mechanism after point of scanning, so that they tally the number of consent forms that are scanned in. Other than that, Melissa, do you want to talk about that briefly?

Ms. Bottrell:

We investigated over a period of two years working with OI a variety of ways to try and connect the actual completed informed consent form of any stripe, so to speak, with completed procedures. And over that period of two years, we realized that there were a number of technical hurdles that were at this point insurmountable, unfortunately. I will tell you that for a small number of procedures (that will be growing slightly), we can track actual completion. As part of the surgical informed consent procedures, there is a surgical informed consent measure which you can find on the executive dashboard. For a small number of procedures we have actual chart reviews matching the numbers of procedures and the numbers of consent forms completed. And so we do have rates and that can be evaluated, but it does not go for every procedures it is a small number of about seven major areas. So that surgical informed consent measure can be

used for a small number of procedures to track actual completion, both using iMed and other forms.

Dr. Berkowitz:

Well, thank you, Melissa, and Ray. I feel its safe to say that as with the tools' evolution, what you call the auditing tools or what I think of as the monitoring functions or the evaluation tools or assessment that we can do of our informed consent will also continue to evolve and hopefully get better and better over time.

CONCLUSION

Dr. Berkowitz:

Well, as usual, we did not expect to conclude this discussion in the time allotted, and unfortunately we are out of time for today's discussion. We will post on our Web site a very detailed summary of each National Ethics Teleconference. So please visit our Web site to review today's discussion. We will be sending a follow up email for this call that will include the links to the appropriate web addresses for the call summary, the CME credits, and the references cited.

We would like to thank everyone who has worked hard on the development, planning, and implementation of this call. It is never a trivial task and I appreciate everyone's efforts, especially, Dr. Owen, Mr. Frazier, and other members of the Ethics Center and EES staff who support these calls.

Let me remind you our next NET call will be on Wednesday, January 31 from 12:00 – 1:00 pm EST. Please look to the Web site at <http://vaww.ethics.va.gov/> and your Outlook e-mail for details and announcements.

- I will be sending out a follow-up e-mail for this call with the summary of this call and the instructions for obtaining CME credits, and the references that I mentioned.
- Please let us know if you or someone you know should be receiving the announcements for these calls and didn't.
- Please let us know if you have suggestions for topics for future calls.
- Again, our e-mail address is: vhaethics@va.gov.

Thank you and have a great day and a great holiday season!

