Implementation of Signature Informed Consent for Long-Term Opioid Therapy for Pain

Opioid prescriptions have risen dramatically across the country in the past two decades, including in VA. Rising prescription rates have been accompanied by a rise in drug overdose deaths, with opioid-associated deaths outpacing deaths from other major drug types (see figure below).

Because of the risks associated with opioid use, VA instituted a policy requiring practitioners to obtain signature informed consent from patients prior to initiating long-term opioid therapy, as well as from patients already on long-term opioid therapy. The policy, VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, is intended to ensure that practitioners inform patients about the risks and benefits of opioid medication and alternatives for pain management, and educate patients about how to take opioids safely and keep their drugs secure. May 2015 was the date for full implementation of the directive, including documented signature informed consent for all non-hospice patients receiving long-term opioids for non-cancer related pain. Implementation is strong in a number of facilities, but improvement is needed in many others. Implementation scores range from 92.50 percent to 0.50 percent.

To assist facilities in implementing the required process changes, NCEHC is encouraging facilities to address ethics quality gaps in signature consent for long-term opioid therapy as part of their 2016 IE program metrics, either as a PE cycle or VISN cross-cutting issue. NCEHC is also sharing successful strategies as a way of improving signature informed consent rates around the country. In addition, beginning in Q4 2015, facilities will be able to access the National Center for Patient Safety’s Opioid Therapy Guideline Adherence Report dashboard. The dashboard will help facilities identify gaps in implementation of signature informed consent for opioids and monitor the impact of their improvement efforts.

Promising Practices from the Field
Edith Nourse Rogers Memorial Veterans Hospital in Bedford, MA adopted a strategy that centered on promoting a culture change among providers, and moving toward a multi-modal approach for chronic pain treatment.

(Continued on page 2)
Implementation of Signature Informed Consent
(continued from page 1)

The goal was to lower the number opioid prescriptions. The initiative was broadly focused on collaboration within a team-based model. This occurred through ongoing education with providers at quarterly primary care collaboratives, monthly primary care pain clinical conferences and administrative staff meetings, and biweekly primary care clinical staff meetings. In turn, Bedford primary care clinicians had the support of their teams in obtaining informed consents for chronic opioid therapy while offering alternative treatments. The facility identified a wide variety of opportunities for reaching Veterans and completing consent forms. The main focus was identifying Veterans due for opioid refills before they arrived at their appointments and then ensuring that informed consent was completed and education provided during their visits. In addition, PACT teams regularly reviewed the Opioid Risk Report from the Primary Care Almanac to identify Veterans without informed consents and schedule them to come in for appointments at their upcoming refill. Finally, groups were also available to offer education and complete informed consents for patients who were hard to reach or hard to schedule. When iMedConsent™ signature pads were missing or broken, hard copy versions were obtained and scanned into the chart under the correct note title. Tracking and reporting progress along the entire journey also helped, as did well-timed reminders from the office of the VISN chief medical officer as the deadline neared.

White River Junction VAMC in Vermont chose to intervene at a different place in the treatment cycle. Pharmacy was responsible for checking that informed consent forms were completed before filling opioid prescriptions. If a form was not completed, the Veteran was referred to his or her PACT team. To expedite the process, a PACT RN then provided the Veteran with the consent form and educational materials before a prescriber met with the Veteran to answer questions and sign the iMedConsent™ form.

Overall, VISN 1 was well-positioned to make progress on informed consent for long-term opioid therapy for pain. An existing collaborative, focused on reducing opioid prescriptions and making long-term pain therapy safer, pre-dated the informed consent policy. The VISN had already made tremendous progress in identifying at-risk patients and ensuring they completed pain care agreements. Once the informed consent process was in place, the VISN was able to use existing tracking mechanisms to convert patients from pain care agreements to informed consent and monitor compliance for the awareness of leaders and front line prescribers. Readers can learn more about implementation work in VISN 1 in IE in Action 35, in which we spoke with a team from the Manchester VAMC about their experience.

New Podcast Series Helps Veterans with Tough Health Care Decisions

NCEHC is proud to release a new podcast series, Dialed In: Helping Veterans Take Control of Their Health Care. The podcasts offer a range of topics to help Veterans and their families as they face difficult ethical decisions about health care.

Starting off the series is “What’s An Advance Directive, and Why Should I Complete One?” As VA patients, Veterans have the right to make their own decisions about their health care — but what if they are too ill to decide? Who would they want to make those decisions for them? This podcast discusses advance directives, why it’s a good idea to complete one and who to talk to before doing so.

The second podcast in the series, “Choosing a Health Care Agent,” offers practical information and questions for Veterans to consider when thinking about whom to select as a health care agent in case they become too ill to make their own health care decisions.

All the podcasts feature the voices of Veterans, subject matter experts and experienced VA clinicians. At least two more are slated for production on related topics of importance to Veterans and their loved ones.

Dialed In augments Sound Ethics in Health Care, a series of podcasts created for practitioners and staff on relevant health care ethics issues in VA. Both podcast series directly support the mission of NCEHC through the distribution of accessible ethics educational materials for practitioners, staff, patients and families.

The podcasts can be streamed or downloaded to a computer, smart phone, tablet, media player or other device, and are available at http://vaww.ethics.va.gov/soundethics_podcasts.asp or http://www.ethics.va.gov/soundethics_podcasts.asp.
Medical Librarians Serve as Key Members of an Ethics Consultation Service

Ethics Consultation Committee member and Medical Librarian Barbara Larsen and Library Director Dorothy Sinha of the Minneapolis VA Health Care System shared their experience as librarians participating in ethics consultation during a recent meeting of the Medical Library Association. They presented a poster (below), and were subsequently invited to submit an article on the subject to the Journal of Hospital Librarianship. “During the poster session, I had a steady stream of people stopping by to question me about librarians being on ethics committees,” said Larsen. “Many of them were from major programs like the University of Michigan, University of Virginia, UCLA, Emory University and the National Library of Medicine.”

At Minneapolis, the addition of a medical librarian to the committee has resulted in a significant improvement in the ethics consultation function, and ethics staff have noted the benefits. “Besides serving as a consultant, Barb Larsen does frequent literature searches for us. As a result, we read and discuss more than we otherwise would, and we also have more articles to distribute to those who request ethics consults,” said Ethics Consultation Coordinator (co-lead) and Co-Chair of the Compliance and Ethics Council Dr. Melissa West. In addition, she noted, Larsen keeps local electronic ethics files organized and current.

The poster offers other positive ways that librarians can contribute to an ethics consultation service.

Librarians Embedded In Ethics

Dorothy Sinha, MA, AHIP, Library Director; Barbara Larsen, MA, Medical Librarian; Medical Library; VA Medical Center, Minneapolis, MN

VA INTEGRATED ETHICS MODEL

Ethics Consult:
VA staff face difficult and potentially life altering decisions every day. Responding effectively to ethical questions is essential for both quality patient care and staff morale.

Preventative Ethics:
Examine patterns and trends in requests for ethics consults. Pre-actively identifying prioritizing and addressing concerns about ethics quality at the organizational level.

Ethics Leadership:
Leaders must foster an ethical environment - one that is conducive to ethical practice and that effectively integrates ethics into the overall organizational culture.

Librarians can contribute to their institution’s Ethics Committee by:
- Participating as a member of an Ethics Committee. Most members are usually providers and offer a clinical perspective on ethics issues. Librarians can provide a perspective that bridges a gap between clinical and non-clinical.
- Using interviewing skills that we use daily in reference interviewing to hone in on pertinent issues regarding a specific ethics concern.
- Serving as a master search for literature to provide background for ethics consults, case discussions, or continuing education in bioethics, compliance, and ethics on the job.
- Building a collection of print and/or electronic resources about ethics and compliance in general or in specific practice areas.
- Reviewing, recommending and purchasing DVDs, brochures, or other materials for the annual Ethics Week or Month celebrations at their medical centers or academic institutions.
- Proactively distributing online literature alerts to committee members to keep them current about ethics issues in the news.
- Organizing book clubs or book discussions for multi-disciplinary groups. Books such as Katy Butler’s Knocking on Heaven’s Door or Atul Gawande’s Being Mortal are easily available, accessible and of interest to a wide variety of readers.
- Discovering and promoting relevant databases, social media sites, and podcasts that cover ethics topics.
- Learning and implementing process improvement methods and tools to prevent or minimize future ethics dilemmas in their institution.
- Posting the ANA Codes of Ethics prominently in the Medical Library and promoting awareness of Codes of Ethics for other clinical practice areas.

Content Domains and Range of Ethical Concerns within the VA:
- Shared decision making with patients (how well the facility promotes collaborative decision making between clinicians and patients)
- Ethical practices in end-of-life care (how well the facility addresses ethical aspects of caring for patients near the end of life)
- Patient privacy and confidentiality (how well the facility protects patient privacy and confidentiality)
- Professionalism in patient care (how well the facility fosters behavior appropriate for health care professionals)
- Ethical practices in resource allocation (how well the facility demonstrates fairness in allocating resources across programs, services, and patients). Expensive drugs
- Ethical practices in research (how well the facility ensures that its employees follow ethical standards that apply to research practices)
- Ethical practices in the everyday workplace (how well the facility supports ethical behavior in everyday interactions in the workplace)
- Ethical practices in business and management (how well the facility promotes high ethical standards in its business and management practices)
- Ethical practices in government service (how well the facility fosters behavior appropriate for government employees).

• Posting the MLACodes of Ethics prominently in the Medical Library and promoting awareness of Codes of Ethics for other clinical practice areas.
Protocol for Prioritizing HCV Treatment:
An Ethical Framework

In April 2015, it became clear that VA’s 2015 appropriation for new hepatitis C virus (HCV) drugs would be depleted before the end of the fiscal year. In response, VHA leadership established four workgroups to develop strategies related to providing HCV treatment to VA patients. NCEHC led the workgroup charged with developing a triage protocol for prioritizing HCV treatment based on clinical need. From an ethics perspective, the Protocol for Prioritizing HCV Treatment: An Ethical Framework—which includes an ethical framework and an accompanying prioritization protocol—was necessary. The prioritization protocol was developed to ensure that when there are not enough HCV resources for immediate treatment of all HCV patients, clinical decisions to initiate therapy are based on consistent, fair, and transparent standards that apply across the entire VA system. Prioritization based on which patients are most likely to benefit from treatment, and which patients would be least harmed by waiting for treatment, enables the best and fairest use of limited resources.

NCEHC previously developed guidance on scarce resource allocation for pandemic influenza and an Ebola outbreak. That work informed HCV planning in three areas:

1. Best practices in planning and response are informed by procedural justice principles of transparency, fairness, honesty and accountability, and substantive ethical principles of beneficence, utility, dignity and responsible stewardship.

2. The approach to any scarce resource allocation dilemma depends on the resource and the circumstances that produce the scarcity.

3. Every triage protocol needs to be developed with clinical subject matter experts who establish the clinical criteria that allow the optimal use of resources.

Clinical subject matter experts in VA gastroenterology, HIV, HCV and public health pathogens programs helped to develop this prioritization protocol.

Leadership participation at all levels of the organization is important to this effort. Prioritization decisions should not be made on an ad hoc basis at each patient’s bedside. Rather, consistent triage protocols should be followed systemwide. Triage is a routine and explicit practice in many areas of health care. It is used in emergency departments, on the battlefield and in disaster response, when a unified effort and consistent standards are needed to ensure that scarce clinical resources are allocated efficiently and fairly. A triage protocol is based on knowledge of available resources and the balance of need versus supply. When VHA, VISN and facility leadership implement a triage protocol such as HCV treatment prioritization, they remove the burden of ad hoc allocation from individual clinicians and enable them to fulfill their obligations to care for individual patients within a clear framework. In times of resource scarcity, patient-centered care means informing patients about the shortfall, explaining where they are on the priority list and why, explaining available treatment options, and ensuring consistent implementation of the triage protocol.

“Prioritization decisions should not be made on an ad hoc basis at each patient’s bedside. Rather, to be fair, a consistent triage protocol should be followed systemwide.”

Open and effective communication about HCV treatment protocols is important. The ethical framework for HCV prioritization explicitly calls for VA leadership to be transparent about the resources available for HCV treatment. Good communication helps to maintain trust. Facilities and VISNs can use this memo and other materials to educate staff, Veterans, and their families about prioritization. This can be done through town hall meetings, outreach to VSOs and regular updates to staff and Veterans.

In July 2015, the President signed H.R.3236 - Surface Transportation and Veterans Health Care Choice Improvement Act of 2015, which allows VA to use up to $500 million from the Veterans Choice Fund to cover the costs of HCV care in VA through September 30, 2015. This additional appropriation is still not sufficient to provide immediate HCV treatment to all VA patients. Thus, the continued use of the prioritization protocol is important. Unless FY16 resources are adequate for the immediate treatment of all HCV-infected Veterans, the HCV prioritization plan should continue to be the basis for treatment. The memos Provision of Hepatitis C Treatment – Clarification (issued August 13, 2015) and Initiation of Hepatitis C Virus (HCV) Treatment: Protocol for Prioritization (issued May 21, 2015) are current reference documents for prioritization.
NCEHC Inaugurates Health Care Ethics Consultation Fellowship Program

In September 2015, eight VA ethics consultants will begin the NCEHC Health Care Ethics Consultation Fellowship Program (HCECFP), a three-year fellowship program to enhance consultation skills and broaden ethics knowledge. The goal of HCECFP is to train consultants to provide high quality ethics consultation, act as role models for consultants at their facilities and VISNs, lead ethics consultation services, and improve those services in the future. HCECFP replaces and builds upon the previous VA/University of Chicago ethics consultation fellowship program that NCEHC supported from 2010-2015.

Carol Boggs (Dayton VAMC), Beth Clark (New Mexico Health Care System), Terri Forte (Salt Lake City VAMC), Lori Martin (Lexington VAMC), Sara Miller (Iowa City VA HCS), and NCEHC staff Marilyn Mitchell, Lucy Potter and Basil Rowland each earned a place in the inaugural class of HCECFP fellows, and with it an opportunity to become ethics consultation leaders in VHA.

The fellowship is designed to develop ethics consultation skills and knowledge as described by the American Society of Bioethics and Humanities. The program begins with a year of personal assessment and professional development planning and action, ethics consultation training and coaching, and individual mentoring. Consultants will hone their knowledge of VA’s CASES approach to ethics consultation, review and assess ethics consultations and associated chart notes and records, and participate in teleconferences and online group discussions with other fellows and NCEHC staff.

During the second and third years, fellows are expected to continue to participate in HCECFP ethics consultation coaching sessions, apply what they have learned in practice, and share the skills and knowledge they have gained with other consultants in their facility and VISN. They are also expected to engage in quality improvement activities related to ethics consultation and in building stronger services in their facility or VISN.

“We believe that the new fellowship program is the right mix of structured training by VA experts, education and development activities to build strong ethics consultants into exceptional ones,” said Dr. Ken Berkowitz, acting executive director of NCEHC. “All of VA’s ethics consultation fellows, including those from the prior VA/University of Chicago program, will benefit from the ongoing training and support the National Center for Ethics in Health Care will provide.”

NCEHC expects to open HCECFP to more ethics consultants each year. More information is available at http://vaww.ethics.va.gov/fellowship/ or http://www.ethics.va.gov/activities/consult.asp.

Ethics Consultation Primer 2.0 Released

In August 2015, NCEHC released the second edition of Ethics Consultation: Responding to Ethics Questions in Health Care. This primer establishes VA standards for health care ethics consultation, one of the three core functions of IE. This edition includes new material and refinements, many of which are based on experience and feedback from ethics consultants.

“We developed this edition to be the authoritative reference to guide ethics consultants in using the CASES approach,” said Ken Berkowitz, MD, acting executive director of NCEHC. “We expect all ethics consultants in VHA to become familiar with its updated content, and use it in their work.”

The primer is available at http://www.ethics.va.gov/docs/integratedethics/ec_primer_2nd_ed_080515.pdf or http://vaww.ethics.va.gov/docs/integratedethics/ec_primer_2nd_ed_080515.pdf. For further information, contact Barbara L. Chanko, RN, MBA, at barbara.chanko@va.gov.
Virtual Ethics Quality Improvement Meeting Announced

NCEHC is pleased to recognize the VISNs and facilities selected to participate in the first Ethical Leadership and Preventive Ethics Quality Improvement Meeting. The meeting will be held virtually via Lync meeting on September 21, 11:00 a.m. – 2:00 p.m. EDT. Over 20 posters were received describing EL and PE quality improvement (QI) initiatives based on recent IE program QI activities. For more information, and to see the list of selected participants, go to http://www.ethics.va.gov/integratedethics/EL_and_PE_Virtual_Quality_Improvement_Meeting.asp. On September 21, please visit one or more of the virtual meeting rooms, where poster presenters will discuss their unique QI work and answer questions. You never know what useful practices you might find to support QI activities in your own VISN or facility!

New Ethics Consultation: Beyond the Basics Modules

NCEHC recently modified two modules in the Ethics Consultation: Beyond the Basics (ECBtB) curriculum for delivery online: “Finding the Available Ethics Knowledge Relevant to an Ethics Question” and “Getting Off to the Right Start in a Formal Ethics Consultation Meeting.” The modules will be available via TMS for CEU credit in early FY 2016.

Following the formats established for previous ECBtB online modules, these two modules translate content from the face-to-face trainings into an accessible online format. Each module includes an Independent Learning portion that learners take at their convenience before convening for a faculty-led live Group Activity session, along with Workbooks containing resources ethics consultants can use during the training and in their actual work.

“Finding the Available Ethics Knowledge” shares essential processes for finding the most authoritative ethics knowledge to inform an ethics consultation. It provides a step-by-step approach to searching the Web effectively and efficiently, and opportunities for practicing this approach in a real-time search. All portions of the training can also be taken completely independently.

“Getting Off to the Right Start” provides critical guidance on how to set the right tone and expectations for a formal ethics consultation meeting, and covers key steps for planning, starting, and running the meeting. It also coaches learners on how to develop a suitable “elevator speech” to describe their role as an ethics consultant to patients, family members, clinicians and other staff.

So far, more than 360 learners have successfully completed the virtual modules for “Managing Common Misconceptions” and “Formulating the Ethics Question.” All online trainings in these four modules of the ECBtB curriculum and registration instructions will be announced via the IE listserv. Contact Marilyn Mitchell for further information at marilyn.mitchell@va.gov.