

Statewide Informed Consent Process

Background and Recommendations for Health Care from the Minnesota Health Literacy Partnership October 2007

This briefing is issued by the members of the Minnesota Health Literacy Partnership, a program of the Minnesota Literacy Council. The Minnesota Health Literacy Partnership is a collaborative group working to promote health by addressing the problem of low health literacy. The Partnership meets monthly and meetings are free and open to the public. For more information, visit the Partnership website at <http://healthlit.themlc.org>.

This briefing is sponsored by the Minnesota Alliance for Patient Safety.

Introduction

Mrs. Cordell-Sieple visited her physician, complaining of gynecological problems. The doctor told her the condition could be “repaired” and scheduled surgery. Upon admission, she was asked to sign a number of papers. Cordell-Sieple recalls that visit: “I didn’t say, ‘Excuse me, I don’t read very well or very fast.’ To me, it was lines and circles over sheets and sheets and sheets.” But she signed them anyway. At Cordell-Sieple’s follow-up visit two weeks later, a nurse asked how she felt after her hysterectomy.

“Inside, my mouth fell open,” she recalls in the American Medical Association (AMA) video *Helping Patients Understand*. “I thought, ‘How could I be so stupid as to allow somebody to take a part of my body, and I didn’t even know it?’ ”¹

Because informed consent often requires patients to sign a pile of forms which use complicated medical terms, Cordell-Sieple’s experience could potentially happen anywhere.

This briefing document outlines how the Minnesota Alliance for Patient Safety (MAPS), and others have helped address issues about informed consent, and outline what can be done to provide true informed consent throughout your health care organization.

The purpose of this briefing is to:

- Explain why the Minnesota Health Literacy Partnership supports universal adoption of the statewide informed consent process;
- Introduce the informed consent process and its benefits;
- Recommend strategies for adoption, promotion and implementation by health care providers; and
- Share cutting-edge resources on health literacy and patient consent.

Why the Minnesota Health Literacy Partnership Advocates Adoption of the Statewide Informed Consent Process

Nearly half of all adults in the United States — 90 million people — cannot understand and use information shared by their health care providers.² A growing and silent epidemic, *low health literacy affects a person’s health status more than any other factor, including education, income, employment or race.*³ Those with low health literacy are a part of all segments of society. For example, even those who speak English well may have low health literacy. In fact, nearly 90 percent of those with low health literacy report that they “read just fine.”⁴ Research shows that all patients, not just those with limited literacy skills, prefer easy-to-read forms and materials.

Health Literacy: *The ability to read, understand and effectively use basic medical instructions and information.*

Evidence shows that a person with low health literacy typically:

- Fails to seek preventive care
- Is less likely to follow treatment plans
- Stays in the hospital longer than someone with higher health literacy
- Has difficulty understanding both oral and written communication
- Is often ashamed to say they don’t understand, or ask for help making health care decisions
- Does not understand what he/she is consenting to for surgery and/or medical procedures.

According to the Minnesota Health Literacy Partnership, the health care system contributes to low health literacy problems by using complicated medical terms when simpler words would work better. Improving interpersonal communication is also a key piece. Partnership Chair Alisha Ellwood noted, “Providers can improve health literacy by listening to patients. On average, providers interrupt patients fewer than 25 seconds after they begin speaking.”⁵

When patients don’t understand the information health care providers are giving them, patient safety is compromised. Patients with low health literacy are unable to speak up about their care, be advocates for themselves, or make informed choices about their health care. A research report in the July 2007 Archives of Internal Medicine found that patients with low health literacy levels were “52 percent more likely to have died than patients with adequate health literacy.”⁶

Besides costs to patients, there are also significant financial costs related to low health literacy, for example:

- Low health literacy increases United States health care costs by \$50–73 billion annually.⁷

- Predicted inpatient spending for a patient with inadequate health literacy was \$993 higher than that of a patient with adequate reading skills.⁸
- Those with low health literacy have an average health care cost of \$13,000 compared to only \$3,000 for those with higher literacy levels.⁹

According to the American Medical Association (AMA), “countless studies in a variety of health care settings have shown that there is a mismatch between patients’ reading skills and the reading skills needed to comprehend the consent forms and handouts they are given.”¹⁰ In addition, an Institute of Medicine (IOM) Report found that the level of complexity and readability often contributes to “information overload, poor understanding and misinformed consent.”¹¹

Informed Consent: *Patients are able to make health decisions in their best interest based on the potential risks and benefits, as well as what is unknown.*

When a patient needs surgery or a medical procedure, he or she needs to understand what will happen to them and why. Written informed consent means that the patient and clinician have signed a document that indicates:

- The patient has been provided information necessary to make an informed decision about the proposed medical treatment or procedure;
- The clinician has talked about the procedure with the patient and answered the patient’s questions; and
- The patient says yes to the procedure.

“Too often informed consent is treated only as a nuisance involving obtaining a signature on a form for the legal protection of physicians and hospitals — and it may not even do that. Even if the form is signed, if the physician did not have a meaningful conversation with the patient about the procedure or treatment, the patient may not be able to make an informed decision about his or her care.”

— Maureen Phillips, J.D., legal counsel, University of Minnesota - Fairview

The National Quality Forum (NQF) has found that the typical informed consent form is unreadable for any level of reader. According the NQF research, 44 percent of patients signing an informed consent form do not know the exact nature of the operation to be performed, and most — 60 to 70 percent — did not read or did not understand the information contained in the form.¹² The American Medical Association has stated that, in most cases, “consent forms involve use of complex descriptions of practice, financial and legal considerations and potential risk-benefit considerations *written at a level well beyond the literacy skills of most patients.*”¹³

BACKGROUND: STATEWIDE INFORMED CONSENT PROJECT

In early 2007, MAPS convened a work group to develop a universal **statewide informed consent process**. The MAPS informed consent form meets the minimum requirements of the Centers for Medicare and Medicaid Services Conditions of Participation guidelines, which took effect in April 2007. These guidelines and the Joint Commission require that a written informed consent process:

- Tell patients about their health status, diagnosis and prognosis;
- Include patients in developing a care plan;
- Allow patients to consent to or refuse specific medical and surgical procedures based on the risks, benefits, and options; and
- Allow patients to participate in planning for care after discharge from the hospital or surgical center.

The MAPS universal form is an affirmation that the conversation has occurred and includes all the elements of a “well-designed informed consent form,” as defined by the Centers for Medicare and Medicaid Services. The consent form is written at a fourth-grade reading level.

Becky Schierman, manager of quality improvement for the Minnesota Medical Association (MMA) explained, “Our goal was to develop a template form that every outpatient and hospital setting could use to facilitate the informed consent process, and would be accepted as comprehensive informed consent documentation.” The universal form can replace a multitude of other consent forms or it can be used in addition to more procedure-specific forms or information. It’s an opportunity to streamline processes.

The form and process were developed and endorsed by the Minnesota Alliance for Patient Safety, which represents about 50 health care organizations, including the Minnesota Hospital Association, the Minnesota Medical Association, and the Minnesota Department of Health. The form has been successfully piloted at several locations, and patients have uniformly found it to easy to read and understand. A statewide rollout of the informed consent form was launched in October 2007 to coincide with National Health Literacy Month.

Top 10 Reasons to Adopt the Statewide Informed Consent Process

1. Simplified form and lower reading level improve patient understanding and meet the health literacy recommendations of the AMA, Joint Commission, Agency for Healthcare Research and Quality, and numerous other governmental, regulatory, and health improvement organizations.
2. Emphasis on informed consent as a process increases patient compliance and satisfaction, both before and after procedures.
3. Use of a single standardized form streamlines processes and reduces unnecessary variation and waste.
4. Improved patient understanding and compliance and the streamlining of clinical processes increase patient safety.

5. The form and process align with the Centers for Medicare and Medicaid Services and Joint Commission regulations and with recent court decisions on informed consent.¹⁴ Since no form can capture all medical risks for every patient, documenting the *process* of informed consent can actually decrease a clinician's or facility's legal risk.
6. Emphasis on process makes it easier to individualize information for differing patient profiles.
7. The form and process have already been created for you – the work is done! All you need to do is use them.
8. Translations of the form into languages other than English will be provided for free.
9. Numbers 1-9 all contribute to lower costs.
10. Endorsement by the Minnesota Alliance for Patient Safety, the Minnesota Health Literacy Partnership, and their member organizations, including Minnesota Medical Association, Minnesota Hospital Association, Minnesota Department of Health, Stratis Health, Midwest Medical Insurance Company, and most major health care providers in Minnesota.

RECOMMENDATIONS FOR ADOPTION AND PROMOTION

Internal adoption and roll-out of the statewide informed consent process will vary across hospitals and surgical centers. The Minnesota Health Literacy Partnership offers these suggestions:

Commitment and Buy-In

- Use this white paper to convey the benefits of adopting, and the risks of not adopting, the informed consent process.
- Secure commitment from key administrators.
- Identify and engage physician champions; meet with clinical leadership groups.
- Involve other key stakeholders in planning and roll-out.
- Ensure that general counsel and risk management officers understand the implications of not adopting the process, e.g. increased medical malpractice; have legal staff help educate medical staff about use of the consent form.
- Use appropriate regulatory agencies as leverage, i.e., Joint Commission, NQF, or agencies that reimburse for care.

Implementation

- Select a point person to coordinate project roll-out; identify a team to implement a concrete plan.
- Include the patient consent process in compliance trainings; ensure that compliance staff understand Centers for Medicare and Medicaid Services guidelines and participate in planning and roll-out.
- Develop separate patient teaching forms to use with consent documents.
- Include health literacy and informed consent in staff training and orientation.
- Disseminate progress reports to key opinion leaders.

- Determine methods to measure impact.

Promotion

- Work with communications staff to internally market the process; design messages for specific audiences.
- Publish feature articles in patient newsletters, provider bulletins, etc.
- Broadcast email factoids to system leadership during Health Literacy Month (October) and/or Patient Safety Week (March).
- Provide CME sessions for providers on the informed consent process and forms.

Resources

- Use attached literacy and consent references to inform internal roll-out.

Sustainability

- Embed the informed consent process within existing organizational policies and procedures.
- Align informed consent goals with strategic initiatives, such as patient safety.
- Publicize organizational best practices.
- Share ongoing measurement and quality results.

BEST PRACTICE

In 2004, HealthEast successfully introduced a new, easier-to-understand patient consent document that was the result of two years of work by employees who had come to see poor health literacy as a patient safety issue. It was stressed that the consent form, no matter how easy it is to read, could not guarantee that the patient's physician has been effective in obtaining informed consent.

HealthEast collected extensive data from staff, patients, and family members, as well as from literature reviews. Research to find other sample tools was fruitless; most consent forms were at the 11-12 grade levels.

Among the lessons learned from the successful implementation of the informed consent form were that proper groundwork is vital and that awareness of the significance of health literacy issues is critical for buy-in.

CONCLUSION

The Minnesota Health Literacy Partnership urges all health care organizations to adopt the uniformed patient consent process and form. Along with MAPS and the many medical organizations who have endorsed this process, the Partnership stands ready to answer your questions and continues to support research and education that explores the critical link between health literacy and informed consent.

A patient attending the Minnesota Alliance for Patient Safety conference in November 2006 commented, “I’ve had multiple surgeries in the past two years and never knew that the consent form was supposed to benefit me. I thought it was just something the hospital needed done.”¹⁵

Ultimately, the uniform consent form will benefit patients, providers and your health care system. Thank you for your commitment.

ENDNOTES

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² National Center for Health Statistics (NCES). Adult Literacy in America: A First Look at the Findings of the National Adult Literacy Survey (NALS). No. 93275; 1993.

³ Institute of Medicine. *Health Literacy: A Prescription to End Confusion*. Washington, DC: National Academy Press; 2004.

⁴ Ibid.

⁵ Roper ASW, LLC. *Health Literacy & the Prescription Drug Experience: The Front Line Perspective from Patients, Physicians and Pharmacists*. Report prepared for Pfizer; September, 2002.

⁶ Baker, DW et al., Health Literacy and Mortality among Elderly Patients, *Archives of Internal Medicine*, 2007; 167 (14):1503-1509.

⁷ American Medical Association Foundation

⁸ Baker DW et al. *Functional health literacy and the risk of hospital admission among Medicare managed care enrollees*. American Journal of Public Health. 2002; 92(8):1278-83.

⁹ Weiss, Barry D, MD. *Health Literacy and Patient Safety: Help Patients Understand Removing Barriers to Better, Safer Care*. Manual for Clinicians, 2nd Ed: AMA Foundation; 2007.

¹⁰ Ibid.

¹¹ Institute of Medicine Committee on Health Literacy.

¹² The Joint Commission. *What Did the Doctor Say?: Improving Health Literacy to Protect Patient Safety*. Oak Terrace, Illinois; 2007.

¹³ Institute of Medicine Committee on Health Literacy.

¹⁴ Weiss, Barry D, MD. *Health Literacy and Patient Safety: Help Patients Understand Removing Barriers to Better, Safer Care*. Manual for Clinicians, 2nd Ed: AMA Foundation; 2007.

¹⁵ Johnson, Bette-Jo. Envision Health Care Education that Patients Can Understand PowerPoint Presentation to Minnesota Health Literacy Partnership; August, 2007.

OTHER RESOURCES

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