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Experts are increasingly recognizing that informed consent can be a valuable tool in advancing patient safety. Preventable medical errors kill and seriously injure thousands of Americans each year, causing personal tragedy and costing the healthcare system billions of dollars. Giving patients more information about their treatments can make them important partners in reducing these mistakes. The Patient Protection and Affordable Care Act ("PPACA"), the new federal health care legislation, provides grants for "integrat[ing] quality improvement and patient safety in the clinical education of health professionals."[1] These grants are a perfect opportunity to educate future healthcare providers on the importance of giving patients the information they need to assist in preventing medical errors. The informed consent process is an ideal vehicle to convey this information because the process is already in place, making it a convenient and inexpensive route to the patient.

More than a decade ago, the Institute of Medicine ("IOM") released its groundbreaking report, *To Err is Human: Building a Safer Health Care System* ("1999 IOM report"), estimating that 44,000 to 98,000 patients die annually in hospitals as a result of preventable medical errors. This large number of mistakes made medical errors the eighth leading cause of death in the United States for that year, exceeding deaths from car accidents, breast cancer, and AIDS. The costs associated with these errors were estimated to be as high as 29 billion dollars in 1999.[2] In response to this report, federal and state governments and private industry instituted various programs to improve patient safety. But those efforts were generally unsuccessful in significantly reducing preventable medical errors.

A 2008 study by the Department of Health and Human Services ("HHS") found that one out of every seven hospitalized Medicare

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1. Patient Protection and Affordable Care Act, Pub.L. 111-148, § 3508 (2011) (codified at 42 U.S.C. §§ 299(b), 3508(a), 294(j)) [hereinafter PPACA].

2. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1, 2 (Linda T. Kohn et al. eds., 1999) [hereinafter TO ERR IS HUMAN].

beneficiaries is measurably harmed as a result of medical mistakes. These adverse events cost taxpayers at least 4.4 billion dollars annually and contribute to the deaths of approximately 180,000 patients each year.[3] An adverse event is defined as a negative consequence resulting from "medical management, rather than the underlying disease."[4] In one month alone, 134,000 Medicare patients experienced at least one adverse event related to their medical treatment. The consequences of these adverse events ranged from "a temporary health setback to death."[5] These large numbers actually underestimate the total amount of adverse events because they do not include harms occurring after discharge from the hospital. And harms after discharge are likely to increase due to pressures in current health care delivery to discharge patients "quicker and sicker."[6]

In a study of ten hospitals in North Carolina, published in 2010 in the New England Journal of Medicine, researchers similarly found little evidence of improvement in overall patient safety. The researchers selected North Carolina as the site for their study because the hospitals in that state "had shown a high level of engagement in efforts to improve patient safety."[7] Yet, the study concluded that "harm resulting from medical care was common" – about 25 harms for every 100 admissions – and that there was no substantial decrease in the rate of errors during the six-year period that the study was conducted.[8]Obviously more must be done.

Federal agencies have recognized the important role patients could play in reducing medical errors. The 1999 IOM report emphasized the need to provide patients with the knowledge and tools necessary to promote patient safety.[9] In 2001, the Agency for Healthcare Research and Quality ("AHRQ") similarly identified improved informed consent as among the top priorities for reducing medical mistakes.[10] These recommendations were based on experience demonstrating that better communication between healthcare providers and patients reduce medical errors and improve outcomes.

The reasons are simple – patients are physically present during every treatment and they and their families are strongly motivated to avoid

3. Duff Wilson, *Mistakes Chronicled on Medicare Patients*, N.Y. TIMES, Nov. 15, 2010, at B3.

4. Alan J. Forster et. al., *The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital*, 138 ANN. INTERN. MED. 161, 162 (2003).

5. *See* Wilson, *supra* note 3.

6. Forster et al., *supra* note 4, at 161.

7. *See* Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 NEW ENG. J. MED. 2124, 2125 (2010).

8. *Id.* at 2130.

9. TO ERR IS HUMAN, *supra* note 2.

10. Michael Burke, *Informed Consent Enters a New Age*, PATIENT SAFETY & QUALITY HEALTHCARE (Nov./Dec. 2005), http:/www.psqh.com/novdec05/techapp.html.

mistakes. Many safety lapses also happen "at the bedside" – for example medication administration errors or lack of hand hygiene – and have a relatively high potential for being observed by patients. In fact, there is evidence that patients already "observe, report and intercept" some of these errors.[11] But to have a significant impact information must be systematically delivered to all patients so they can be more effective in enhancing safety.

Two areas of medical care that especially demonstrate the enormous impact that patients could have in reducing medical errors involve prescription drugs and chemotherapy, both of which have very high error rates. Common chemotherapy errors include improper medication dosages, missing administrations, and wrong administration route. Errors are common in chemotherapy because treatments can vary a great deal based on the particular disease. Patients may also receive many different medications to treat the cancer and to reduce the severity of side effects. Adverse events related to chemotherapy have been estimated to affect between three and sixteen percent of all cancer admissions.[12] These adverse events are particularly troublesome because many chemotherapy drugs are toxic and even small deviations from treatment regimens may have severe consequences.[13]

Cancer patients are particularly good candidates for assisting in safety measures. They often have repetitive procedures and are more likely to have multiple episodes of intense treatment. This gives them a greater opportunity to become familiar with procedures and routines and to learn effective methods of partnering to improve safety.[14]

The most common chemotherapy errors are also easy for patients to observe.[15] Patients have already prevented mistakes by recognizing differences in the administration of their chemotherapy and asking questions about deviations from normal routines. But those incidents are random. There is "[s]cant evidence that patients are being systematically engaged in preventing chemotherapy errors."[16] Hospitals could take greater advantage of the patients' and families' awareness of changes in routine by telling them the doses and scheduling of chemotherapy and asking them to

11. David L. B. Schwappach et al., *Am I Unsafe Here? Chemotherapy Patients' Perspectives Towards Engaging in their Safety*, QUALITY SAFETY IN HEALTH CARE, e9 (Apr. 2010) [hereinafter *Am I Unsafe Here?*].

12. David L. B. Schwappach, et al., *Medication Errors in Chemotherapy, Incidence, Types and Involvement of Patients in Prevention*, 19 EUROPEAN J. OF CANCER CARE 285, 285-87 (2010) [hereinafter *Medication Errors*].

13. *Id.* at 286.

14. *Id.*

15. *Id.* at 291.

16. *Id.*

serve as a second layer of protection against mistakes. Patients could also be encouraged to report symptoms related to drug toxicity. "By being informed and alert to medication regimens, by ensuring medication accuracy on all orders, and by providing all pertinent information to staff, patients can be part of the team effort to reduce errors."[17]

The IOM, the American Hospital Association, and clinical oncology experts all recommend involving cancer patients in preventing medical errors. Ensuring that cancer patients are fully informed of the particulars of their treatment will become even more important as ambulatory infusion units and oral outpatient chemotherapy increase. Some U.S. cancer centers are now providing "patients with a card listing medications, which they can update as they receive treatment at different sites."[18] This is a good first step, but does not do enough to tap the potential of cancer patients to become proactive in protecting their own safety.

Patients can also be proactive in reducing errors related to prescription drugs. "According to one estimate, in any given week, four out of every five U.S. adults will use prescription medicines, over-the-counter drugs, or dietary supplements of some sort and nearly one-third of adults will take five or more different medications."[19] Studies indicate that as many as fifty to sixty percent of patients do not take their prescription drugs properly. Studies also indicate that this deficiency is directly related to the failure to give patients adequate information.[20]

Medication errors are estimated to harm "at least 1.5 million patients every year in hospitals, long-term care facilities and outpatient clinics."[21] The most frequent medication errors occur during prescribing and administration. In a recent adverse drug event prevention study, the rate of adverse drug events ("ADEs") in hospitals was estimated at 6.5 for every 100 hospital admissions.[22] These adverse events often had severe consequences. Other studies have generally confirmed these results.

The ADEs not only cause physical and emotional suffering, but are also costly. According to a 2006 IOM report, each preventable event added

17. Judith H. Hibbard, et al., *Can Patients be Part of the Solution? Views on Their Role in Preventing Medical Errors*, 62 MED. CARE RES. & REV. 601, 602 (2005).

18. *See Medication Errors*, *supra* note 12, at 289.

19. *See* INST. OF MED., PREVENTING MEDICAL ERRORS: QUALITY CHASM SERIES 1,1 (2006) [hereinafter PREVENTING MEDICAL ERRORS].

20. *See e.g.*, Alan R. Styles, *Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts*, 39 CLEV. ST. L. REV. 111 (1991).

21. Dwight D. Kloth, *Guide to the Prevention of Chemotherapy Medication Errors: Causes of Chemotherapy Errors*, CLINICAL ONCOLOGY NEWS 1, 1 (2009) (quoting PREVENTING MEDICAL ERRORS), *available at* http://www.clinicaloncology.com/download/Chemo_mederrors_pt1_WM.pdf.

22. Rainu Kaushal et al., *Medication Errors and Adverse Drug Events in Pediatric Inpatients*, 285 JAMA 2114, 2114 (2001).

approximately $8,750 to the cost of the hospital stay. The result is billions of dollars in unnecessary healthcare spending.[23]

Many of the hospital medication errors involve children and, among children, the most common ADEs involve the youngest and most vulnerable. These errors occur often because administering drugs to children requires calculating doses based on weight. The pharmacy must also dilute the drugs before they can be administered to small children.[24] Families of these children could also be recruited to assist in reducing medical errors.

For patients and families to actively assist in avoiding errors, they should be told the name of the drug, the color, size and shape of the medication, the proper dose, and the frequency of administration.[25] This information will enable patients to detect prescription errors by the pharmacy, double-check hospital administrations of medication, and self-administer medication properly. Medications also require constant monitoring and patients are in the best position to monitor their own symptoms and side-effects. If they are properly instructed, patients can report symptoms that require urgent or emergency care and those that are unusual or unexpected.

Proper instructions regarding medications can also prevent accidents related to taking prescription drugs. For example, if a patient knows that a medication may make him dizzy or faint, he can take the precaution of holding onto furniture when getting up quickly. A patient warned about drowsiness will know not to drive. And, patients informed about dangerous drug, alcohol, or food interactions will be more diligent in avoiding them.

Providing this information need not be overly time-consuming or complex. Educational resources are already being developed to make dissemination of this medical information easier. These resources include printed materials and videos to explain to "patients and families how they can be involved in preventing mishaps."[26] The information can be distributed prior to meetings with healthcare providers giving patients time to digest the information prior to the meeting so they can ask meaningful questions. These tools will also reduce the time the healthcare provider has to spend explaining the medical information to the patient. The information that must be disclosed can also be simple. The IOM recommends, for example, that patients take responsibility for double-checking prescriptions and reporting "unexpected changes in how they feel."[27]

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23. *See* PREVENTING MEDICAL ERRORS, *supra* note 19, at 2.

24. *See* Kaushal, *supra* note 22, at 2115.

25. Neil M. Davis, *Mederrors*, AM. J. NURSING, Feb. 1994, at 16.

26. Patrice L. Spath, *Can you Hear Me Now?* HOSP. & HEALTH NETWORKS 36, 49 (2003), *available at* http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=AHA/PubsNewsArticle/data/0312HHN_FEA_CoverStory&domain=HHNMAG

27. TO ERR IS HUMAN *supra* note 2.

Although improving patient safety is obviously important, health care providers have not been trained to focus on safety in their meetings with patients. Rather, meetings with patients generally center on fulfilling the requirements of informed consent laws designed to ensure that patients receive sufficient information to make informed treatment decisions.

Informed consent statutes and cases generally require that physicians inform patients of the risks and alternatives to medical procedures. Some state statutes go further. For example, Georgia also requires that patients be informed of "the nature and purpose" of the proposed procedure, Maine and North Carolina require a "general understanding of the procedure or treatments," and Washington requires that the patient receive "material facts relating to treatment." [28] But this general language would not require that patients be informed of the required frequency or doses of medication, be apprised of the size, shape, or color of medication, or be given a detailed description of the likely side-effects so the patient can monitor those effects and contact the physician when necessary. Yet this type of information is necessary to enhance the patient's role as a partner in preventing medical mishaps.

This article does not suggest that informed consent laws be changed to require physicians to disclose this information. Including all the provisions that might enhance safety would be too cumbersome. Rather, entities can use the provisions in the PPACA and other methods to develop techniques for folding this additional information into the informed consent process.

The PPACA provides that the Secretary of HHS may award grants to eligible entities to "develop and implement academic curricula that integrates quality improvement and patient safety in the clinical education of health professionals."[29] One effective method of using this grant to enhance patient safety would be to encourage future health professionals to use the informed consent process to make patients players in preventing medical errors.

The PPACA also provides grants for developing effective decision aids that give patients information about treatment options. A decision aid is defined in the Act as "an educational tool that helps patients . . . [t]o decide with their health care provider what treatments are best for them."[30] There is already a foundation for developing decision aids. Computer programs have been developed that use current educational methods to effectively transmit medical information to patients. In some programs, this information includes explanations of preoperative, operative, and

28. *See* GA. CODE ANN. § 32-9-6.1 (West 2011); ME. REV. STAT. ANN. 24 § 2905 (West 2011); N.C. GEN. STAT. § 90-21.13 (West 2011); WASH. REV. CODE § 7.70.050 (West 2011).

29. PPACA, *supra* note 1, at § 3508(a) (codified at 42 U.S.C. § 294(j)).

30. *Id.* § 3506 (codified at 42 U.S.C. 299b-36(b)(1)).

postoperative care and the risks, benefits, and alternatives to treatment. The educational tools include explanatory text, graphics, photographs, animations, and diagrams. These programs already contain some information that will help patients prevent errors, but they could be expanded further to introduce information that would best enable patients to assist in safety efforts. The techniques in these computer systems could also be used to create other programs to educate patients. The mechanisms are already in place to allow easy dissemination of this information.

The patient's willingness to participate in preventing medical errors should also receive attention. Not all patients will be willing or able to participate in protecting their own safety. Patients generally feel better about participating in activities that conform to the traditional patient role. For example, they are usually more comfortable asking about the medical purpose of various procedures than asking if a member of the staff washed his hands or checked the medication dosages before administering them.[31]

Clinical staff can have a significant impact in motivating patients to be more proactive in preventing errors. For example, disclosing information about past medical mistakes has encouraged more patients to become involved in preventing them. Physicians and clinical staff can also instruct patients to take certain actions – such as asking staff about hand-washing – which will encourage them to take steps they might otherwise have avoided. Healthcare professionals must, however, be careful to counterbalance this information with relationships that create trust in the physicians and hospital staff.[32]

At least eight medical schools in the U.S. have recognized the need for better communication between the physician and patient to avoid preventable deaths. These medical schools are screening applicants based, in part, on social skills to ensure that communication between doctors, patients, and nurses improves.[33]

Patients should only be encouraged to actively participate in their care. Those who are unwilling should not be forced to do so. Cancer patients, for example, may be "burdened by severe illness, anxiety, fear, and medication side effects."[34] These techniques for improving safety should not add to their stress, unless they want to become involved. The information given to patients should also be limited so it is manageable. A patient can become involved in preventing medical errors simply by being told what to do, when to do it, and what to watch for. This information should be conveyed

31. *Medication Errors*, *supra* note 12, at 289.

32. *Id.*

33. *See* Gardner Harris, *New for Aspiring Doctors, the People Skills Test*, N.Y. TIMES, Aug. 11, 2011, at A1, A13,.

34. *Medication Errors*, *supra* note 12, at 290.

in the most accessible manner possible.

Disclosing more detailed information about the nature of their medical treatments, the procedures involved, and potential side effects has other benefits besides including patients in preventing errors. This information can improve patient compliance with treatment protocols, result in better patient outcomes, have positive psychological effects, and reduce malpractice claims. All of these benefits can be achieved by adding only a few extra minutes to the meeting between the physician and patient.

Well-informed patients generally comply better with prescribed treatments than those without adequate information.[35] This is only logical. Patients can only comply properly with treatment regimens if they fully understand their roles and instructions. A quicker and healthier recovery is not only better for the patient, but also reduces healthcare spending.

Disclosing adequate information also has positive psychological effects. Greater involvement gives patients a better sense of control, which has been shown to result in decreased anxiety and depression and increased self esteem.[36] Studies also show that patients have superior medical outcomes and recover quicker if they understand the disease process and are more involved in their medical care.[37] For example, in one study, patients informed that they might suffer pain and instructed on pain relief methods needed significantly less pain medication than those who did not receive this information.[38] Similarly, patients who are aware of potential side-effects are generally better able to cope when those side-effects materialize.[39]

Patients are also significantly less likely to bring malpractice actions if they are included in the treatment process and there is effective communication between the physician and patient.[40] Fewer malpractice actions would conserve health care dollars by reducing the risk of adverse judgments and saving physicians time that would otherwise be spent defending lawsuits.

For all of these reasons, physicians should be encouraged to expand the informed consent process to include sufficient information for the patient to

35. Davis, *supra* note 25, at 16; Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 IND. L. REV. 1019, 1036 (1998).

36. Victor Ali, *Consent Forms as Part of the Informed Consent Process: Moving Away from "Medical Miranda,"* 54 HASTINGS L. J. 1575, 1581 (2003).

37. *Id.*, at 1580-81; Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L. J. 899, 943 (1994).

38. Schuck, *supra* note 37, at n.174.

39. *See* Miller, *supra* note 35, at 1037.

40. *See* Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOYOLA U. CHI. L. J. 557, 591 (2000). *See also*, James L. Bernat et al., *Patient-Centered Informed Consent in Surgical Practice*, 141 ARCHIVES OF SURGERY 86, 91 (2006).

become an active partner in his medical care. The minimal extra burden on physicians of disclosing this information will be more than offset by the resulting reduction in preventable medical errors. As added bonuses, providing this information will improve patient health, decrease malpractice claims, and reduce healthcare costs. It is time to stop thinking of patients as passive victims of safety failures and to include them as participants in improving the system. This is a win-win method of reducing medical errors.