



An Enterprise Risk Management Approach to Critical Patient Decision-Making

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Introduction

Often complex patient care situations do not include a collaborative consultation among key care providers. Moreover, faced with the task of making potentially emotionally charged and life-threatening decisions, many patients may not have the benefit of a truly informed consent process. This article illustrates how using an enterprise risk management framework for inclusive informed decision-making, a care team, the patient, and family members overcame such challenges.

Informed Decision-Making

Consent to treatment is a communication process; not a consent form.¹ Patients and family members loath poor communication and lack of an complete informed decision-making process.

In the health care context, informed choice-making reflects a blend of legal, ethical, and clinical processes.² Rigid rules or laws on consent often clash with the practical realities of time-sensitive decision-making that involves difficult personal and ethical choices. Patients and family members are given options from many different providers without critical information sharing. Without full knowledge, they lack the ability to digest critical information to make a cogent treatment decision. The result is not only a less than well-informed decision-maker; there is real concern about patient dissatisfaction and anger

that may extend to the family or a surrogate decision-maker.³

Various scholars and authoritative sources⁴ have argued that the time has come for a shift in the time-honored approach to consent. Patient-centered care, patient centered-family focused care, and shared decision-making exemplify this shift in thinking. At the core of such calls for change is the need for a practical approach in clinical decision-making, especially when patients face critical, life-threatening or health-altering choices.⁵

Ethics and patient satisfaction aside, there are other serious repercussions in the absence of an effective informed decision-making process. These include the potential for claims of lack of informed consent, assertions of professional misconduct formalized into a complaint before a medical licensing board, regulatory issues that focus on patient grievances or allegations of non-compliance with the Conditions of Participation for Medicare and Medicaid, and complaints to accrediting bodies.⁶ An impressive amount of time and resources can be spent in such circumstances. Adverse publicity can impact market share. As seen in the case scenario, “Peggy’s Case,” it is the type of complex clinical situation that is ripe for an enterprise risk management approach to informed decision-making.

Peggy’s Story

The patient, Peggy (the name used for this article), was admitted to a high-risk Maternal Fetal Medicine unit in a large

academic medical center. Peggy was 31 weeks pregnant and was 39 years old. This was to be her fifth child, as she had three older children from a previous marriage, although this was to be her second child of her current marriage. During the last three months of her pregnancy, she developed what the doctors thought was a “clogged milk duct” in her left breast. Just before she was admitted in to the hospital, she was diagnosed with Stage 3 breast cancer. Peggy and her husband thought her obstetrician was admitting her to the Maternal Fetal Medicine unit to deliver her baby and then start her cancer treatment with chemotherapy. Peggy was very clear that she did not want chemotherapy while she was pregnant as she did not want to take any chances with the health of her baby.

The admitting obstetrician went off duty on Peggy’s second day in the unit and was replaced by his partner. The second obstetrician was against delivering the infant prior to 39 weeks without a valid medical reason. He based his opinion on 2013 guidance from both The American College of Obstetricians and Gynecologists and Society of Maternal-Fetal Medicine recommendation geared to reducing unnecessary deliveries prior to 39 complete weeks.⁷ The second obstetrician argued, however, that it was acceptable to administer chemotherapy during pregnancy. She herself had managed several obstetric patients who had received chemotherapy and delivered healthy infants.

Peggy and her family (including her husband, her adult children, and her father) became very distressed and started making threatening comments to the staff. They also called the local television station about how the patient was promised to be able to deliver her infant so that she could start her cancer treatment, but was now being denied the opportunity to undergo an early delivery. At one point, Peggy’s husband threatened the obstetrician by remarking that “The day you see my wife’s obituary in the paper, is the day I am going to sue you! We were told she could deliver her baby and that is why she was admitted.”

The nursing staff called Risk Management for direction and asked for an ethics consult. While Risk Management and the ethics consult were meeting to decide the best strategy for dealing with this complex situation, the hospital’s Media Department informed them that the local television station would soon arrive to interview the patient and her family. At that point, Risk Management suggested a “*patient-family centered consent process*” in which all the involved parties—the patient, her family, and all potential providers—engage in a shared discussion of the goals of care and treatment preferences.

In a matter of two hours, Risk Management and the ethics consult arranged a shared discussion process involving the obstetrician, the treating oncologist, a neonatologist, a nursery nurse (to be the baby’s advocate), and a patient advocate for the patient. The oncologist attended via telephone conference as she was at a different location. The patient was also encouraged to bring any family, friends, or other support system to be with her in the meeting. Peggy invited her husband, her three adult daughters, and her father to the meeting. The ethics consult was asked to facilitate the meeting.

The facilitator started the meeting with an introduction of all the participants and the reason each individual was asked

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to take part in the discussion. All participants agreed that everyone would have an opportunity to speak and that there would be an open and honest discussion. Other ground rules were discussed, including that if an agreement could not be reached, that at a minimum, tolerance would be accomplished.

As the unborn baby’s advocate, the nursery nurse was asked to pose questions on behalf of the infant. In particular, she was asked to focus on health risk factors involved with an early delivery, impairments from an early delivery, and the potential risk factors from in utero chemotherapy exposure should a decision be made to let the pregnancy proceed to 39 weeks.

Another patient’s advocate also was requested to attend to ensure that the patient and her family were equal participants in the discussion. The patient’s advocate was asked to position herself with the family in the meeting.

The patient was allowed to speak first about her goals for herself and her baby. One of the patient’s adult daughters spoke up by saying, “I am afraid of losing her, just thinking about how it could end up.”

The patient’s obstetrician spoke next and discussed the problems of delivering a 31 week-old infant, the need to abide by the recommendations of no elective delivery prior to 39 weeks, and how she had successfully treated many pregnant patients receiving chemotherapy.

The next person to speak was the oncologist who described the patient’s Stage 3 breast cancer. The specialist explained that Peggy had an aggressive cancer and that chemotherapy needed to be started *immediately* if there was any hope of saving Peggy’s life.

The neonatologist was brought in as an expert to discuss issues with an infant born at 31 weeks and chemotherapy during pregnancy. He explained that there was very little information about the long term effects of chemotherapy on fetuses as they grow into their adolescent and adult years. He was reassuring to the family that taking care of a 31-week infant was something that could be done with the right neonatology team in place. He commented that if the infant was 26 weeks or younger, that there could be some life-long issues for the infant.

All the family members were allowed to ask questions freely—including the patient’s father. Again, the patient and her husband reiterated that she did not want to start chemotherapy while she was pregnant because of the possible effects on her infant—now and in the future. The patient stated, “Right now I am focusing on delivering the baby and bringing him into the world. And, I’ll worry about me later.”

Again the oncologist reiterated her thoughts on Peggy’s health—“Every day that Peggy does not get aggressive chemotherapy, it [the cancer] is actively killing her and shortening her life. What she has left will be greatly shortened.”

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It was noteworthy that the obstetrician was concerned about how the meeting would proceed in light of the previous threats stated by Peggy's husband. However, having listened to the discussion and the options presented the obstetrician stated that she could clearly see that the patient's life was in danger and she would consider inducing the patient today—if the patient would agree.

There was a collective sense of relief. A decision also was made that as soon as the infant was born, scans would be completed to see the extent of the cancer and a Mediport would be implanted so that Peggy could begin her chemotherapy treatments.

A consent document was offered to the patient and her family. It was recommended that the patient ask her family members to sign it along with her to show their support for her decision. The family members signed the consent document as they concurred with the treatment plan as discussed in the conference.

About an hour later, the media showed up and the news story that night was about the patient and the infant to be born and the start of fundraising to help with the medical bills of the family. There was no discussion about the earlier dissatisfaction with the care.

Nursing staff in the Maternal Fetal Medicine unit were relieved about the decision made during the patient-family conference. Most of the nurses identified with Peggy and felt she had been brought to the unit for delivery. The nurses knew that an infant born at 31 weeks could be well taken care of and could develop normally. What they did not know was the long term effects of chemotherapy on a fetus. They were experiencing moral distress.

The baby was born two days later at 4 pounds 8 ounces. Soon after the birth and a short period of recovery, Peggy began her chemotherapy. Peggy lived for about 15 months after her son was born. She was able to take care of him for most of the time. Peggy was 41 years old at the time of her death.

Everyone who was involved with the patient-family conference was affected by the emotion and the critical choices that had to be addressed that day. Most of the professional staff still think and talk about the day of that conference and how it affected their views on shared decision-making, patient preferences, and how a family demonstrated their support for the patient in her wishes for herself and her infant.

Lessons Learned in Peggy's Case

The process used in Peggy's case demonstrates what can be described as inclusive consent decision-making. It is a process that is much broader and flexible than what is often described as "shared decision-making."

As the concept has evolved, shared decision-making focuses on setting a level playing field between care providers and patients. Data is presented to patients, sometimes involving the results of comparative effectiveness research. Decision aids or tools may be used to facilitate the discussion. Patient preferences play a key role in the shared decision-making process.⁸

Shared decision-making has been the subject of criticism.⁹ Some question whether the concept can be well-disseminated in health care. Health care professional training, effective tool design, and the time factors associated with the shared decision-making model have been raised as issues in the literature.¹⁰

Peggy's case involved a much more practical and comprehensive or "inclusive" approach to clinical decision-making. It did not involve the use of comparative effectiveness data. It did not require the use of decision aids. Further, the discourse involved several care providers all at one time and the patient and her family. It was an inclusive approach for exchanging clinical information and personal preferences in a nimble manner, leveraging the services of a communication facilitator.

Taking such an approach meant disseminating in one encounter complete, comprehensive medical information for the benefit of the patient and her family. Information was geared to the patient and family. It was clear, straightforward, and understandable. Assembled together were the medical specialists involved in her complex situation. As such, the care providers had an opportunity to talk in a transparent way among themselves and with the patient and her family. The lesson learned was the benefit of patient-centered, family-focused discussion with a huddle of care providers intimately involved in the needs of the patient and her unborn child.

To a large extent, Peggy's case turned on effective communication and an aligned set of expectations. There were ground rules and a facilitator to keep the discussion on track. Each attendee had the opportunity to speak. The discussion provided a practical, urgent context for discussing relevant clinical guidelines while at the same time addressing the preferences of the patient with input from her family.

The use of an inclusive, informed decision-making process exemplified what is sometimes called patient-family engagement. The traditional "one-on-one" approach for informed decision-making was replaced by a team of care providers, family members, and the patient all with agreed upon goals and objectives. The patient-family engagement did not involve long, tense discussions or multiple meetings. Instead, leveraging the presence of key constituents—care providers, advocates for the patient and the unborn child, the patient, and family—led to a salutary resolution of the situation.

The Benefits of Inclusive Informed Decision-Making

No one can be assured that an inclusive consent decision-making process will work in each situation or that the outcome will result in an agreed upon plan of care. Still, the process has many beneficial attributes focused largely on clear communication, real-time input by attending care providers, and the opportunity to distill down into one discussion what might be the subject of numerous time-consuming conferences. As seen in Peggy's case, critical choices were made in a timely manner, permitting rapid implementation of the care plan for the benefit of the patient and her unborn child.

Going forward, one can envisage implementing such an approach in other complex care circumstances: patients in an intensive care unit, patients with support persons or concerned family members, and patients receiving treatment or consultative services from an array of clinical care specialists. Replacing

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numerous one-on-one conversations with an inclusive discussion can save time, money, and resources while helping to facilitate prompt clinical care.

There are ethical considerations in utilizing an inclusive informed decision-making process. Here, there was a potential for a conflict of interest. Should the needs of the mother prevail over the unborn child? Who should advocate and what should the advocates articulate?

Forethought was given to these issues in Peggy's case. An ethics consult was a participant along with separate advocates for the patient and her unborn child. The ground rules for the discussion incorporated well-recognized principles found in bioethics, including respect for patient autonomy, non-maleficence and justice.

The Mechanics of Inclusive Informed Decision-Making

Designing an inclusive informed decision-making process requires careful thought and input from key stakeholders in the organization. Central to the process are representatives from bioethics, risk management, clinical leadership, legal affairs, and patient safety. At the same time, input should be welcome from pastoral care, social work, patient advocates, and cultural brokers. The goal is to develop a process with guidelines or a framework for discussion that "fits" within the requirements of applicable state law and federal requirements.

The accompanying sample checklist highlights core elements to consider when designing and implementing an inclusive informed decision-making process. The checklist addresses several risk domains familiar to those engaged in enterprise risk management.

Challenges to Consider to Inclusive Informed Decision-Making

Specific items merit close scrutiny and valuable input from legal counsel. For example, how and where should the inclusive encounter be recorded in the patient record? Should each care provider insist on a separate signed consent or is one document sufficient, albeit with a list of named signatories? What process should be followed when one care provider "opts out" or disagrees with the outcome? How should the inclusive encounter be coded and billed? What is necessary in terms of the Conditions of Participation and other applicable federal and state requirements? How will the encounter be billed to private payers? Is there sufficient direction in existing tools on physician payment determinations or will specific guidance be needed for this approach?

Conclusion

Fine tuning the process will require attention to detail. Education is of prime importance for health care professionals involved in inclusive informed decision-making. Debriefing and using "lessons learned" will assist in transforming a novel

concept into a generally accepted practice. The result will be better informed, engaged patients, family members, and providers tasked with making crucial health care decisions. **C**

About the Authors



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Endnotes

- 1 See F.A. Prozovsky, *CONSENT TO TREATMENT: A PRACTICAL GUIDE*, 5TH EDITION (New York: Wolters Kluwer Law and Business, 2015) (with regular supplements).
- 2 *Id.* See also BEAUCHAMP TL, CHILDRESS, JF. *PRINCIPLES OF BIOETHICS*, 7TH EDITION (New York: Oxford University Press, 2013); P.S. APPELBAUM G.W.LIDZ AND A. MEISEL. *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* (New York: Oxford University Press, 1987).
- 3 Azoulay E, Chevret S, Leleu G et al., *Half of families of intensive care unit patients experience inadequate communication with physicians*, *Crit. Care Med.* 28(8):3044-3049 (2000); Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB., *An empirical study of surrogates' preferred level of control over value-laden life support decisions in intensive care units*, *Am. J. RESPIR. CRIT. CARE MED.*, 183:915-921 (2011).
- 4 See, e.g., Institute of Medicine (IOM) Workshop, 2013 at <http://iom.nationalacademies.org/Reports/2013/Partnering-with-Patients-to-Drive-Shared-Decisions-Better-Value-and-Care-Improvement.aspx>. Here, the 2013 IOM Workshop called for strategies and policies to advance patients in partnerships with providers, as leaders and drivers of care delivery improvement through protected use of clinical data, informed, shared decisions, and value improvement. See also Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB, *An empirical study of surrogates' preferred level of control over value-laden life support decisions in intensive care units*, *Am. J. RESPIR. CRIT. CARE MED.*, 183:915-921 (2011); J.N. Weinstein, K. Clay & T.S. Morgan, *Informed Patient Choice: Patient-Centered Valuing of Surgical Risks and Benefits*, *HEALTH AFFAIRS* 26(3):726-30 (May/June 2007); J.S. King & B. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, *Am. J. L. & MED.* 32:429-501 (2006).
- 5 INSTITUTE OF MEDICINE. *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (Washington DC: National Academies Press, 2001). The IOM recommended that "patient-centeredness" be one of the six worthy aims of health care, emphasizing the need to support patient and family through improved communication.
- 6 See *CONSENT TO TREATMENT*, *supra* note 1.
- 7 See www.acog.org/About/ACOG/ACOG-Departments/Deliveries-Before-39-Weeks.
- 8 J.S. King & B. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, *Am. J. L. & MED.* 32:429-501 (2006); Stacey D, Bennett CL, Barry, MJ, Coll NF, Holmes-Rovner D et al., *Decision aids for people facing health treatment or screening decisions*, *COCHRANE DATABASE SYST. REV.* 2014;(1).
- 9 See, e.g., Curtie JR, Tonelli MR., *Shared decision-making in the ICU: value, challenges, and limitations*, *Am. J. RESPIR. CRIT. CARE MED.*, 183:840-841 (2011). See also M. Kuppermann and G.F. Sawaya, *Shared Decision-Making Easy to Evoke, Challenging to Implement*, *JAMA INTERN. MED.*, 175(2):167-168 (2015).
- 10 See *Shared Decision-Making Easy to Evoke, Challenging to Implement*, *supra* note 9.

Sample Tool* Checklist ERM Approach to Critical Patient Decision Making

~~Inclusive Informed Decision Legal Regulatory Considerations~~

- ~~Policy and procedure is consistent with state law consent to treatment requirements.~~
- ~~Policy and procedure is consistent with applicable federal consent to treatment standards under the Medicare and Medicaid Conditions of Participation for Hospitals.~~
- ~~Medical staff bylaws are consistent with applicable federal and state requirements for consent to treatment.~~

~~Inclusive Informed Decision Making Personnel~~

- ~~Policy and procedure identifies those health care professionals who may take part in an inclusive informed decision-making process.~~
- ~~Policy and procedure identifies non-health care professionals who may take part in the inclusive informed decision-making, such as clergy, cultural brokers, and language interpreters.~~

- ~~The policy and procedure identifies those individuals who may serve as communication facilitators in the Inclusive informed decision making process.~~

~~Inclusive Informed Decision Making Training~~

- ~~During the onboarding process, members of the medical staff receive orientation regarding the inclusive informed consent process.~~
- ~~During the onboarding process, for other health care professional and clinical staff there is an orientation with regard to inclusive informed consent.~~
(NOTE: This step is focused on Nurse Practitioners, Doctors of Nursing Practice, Medical Social Workers, clinical psychologists, patient advocate, etc. who may not be members of the medical staff but who go through a credentialing process or an employee onboarding program).
- ~~Inclusive Informed Consent Communication Process training emphasizes~~
 - ~~The use of active listening and when not to use it.~~
 - ~~The use of one person as a note taker.~~
- ~~In academic health care organizations the curriculum includes content on the inclusive informed decision making process.~~

~~Documentation Requirements for Inclusive Informed Consent Decision Making~~

- ~~Policy and procedure describe the process for documenting an inclusive informed consent decision making process~~
 - ~~At a minimum the documentation contains the following details:~~
 - ~~The name(s) and positions attending from the health care organization or provider group attending the patient~~
 - ~~The name(s) of the patient/surrogate and family members~~
 - ~~A detailed summary of the discussion~~
 - ~~An indication that the patient/surrogate was able to make a decision~~
 - ~~An explanation of communication assistance provided to the patient/surrogate~~
 - ~~The names of language interpreters~~
 - ~~The language used in the interpretation~~
 - ~~That each person had an opportunity to speak~~
 - ~~A documented "teach back" used in the process~~
 - ~~A summary any "next steps" at the conclusion of the discussion~~
 - ~~Health care organization policy and procedure outlines who signs and co-signs the treatment consent~~
 - ~~Health care organization policy and procedure outlines who signs and co-signs treatment refusal forms~~
- ### ~~Financial Services and Inclusive Informed Decision Making~~
- ~~Organizational policy and procedure addresses coding and billing for an inclusive informed decision making process.~~
 - ~~The policy and procedure addresses multiple care providers submitting claims for participation in an inclusive informed decision making process.~~
 - ~~The policy and procedure takes into consideration the requirements for coding and billing established by private payers.~~

- The policy and procedure takes into consideration Medicare claims and coding requirements [See, e.g., Medicare Claims Processing Manual (Rev. 3255, 05-08-15); National Coverage Determination; and Local Coverage Determination].
- The policy and procedure takes into consideration Medicaid claims and coding requirements.
- The policy and procedure anticipates claims and coding requirements for other federal programs.

Inclusive Informed Decision Making Case Operational Process Requirements

- A Consent Time Out is completed for the patient or surrogate including:
 - Patient or surrogate communication needs
 - language interpretive services
 - language translation (documents, tools) services
 - Health literacy accommodation
 - Health numeracy accommodation
 - Accommodating and acknowledging pain management impact on cognitive ability
 - Accommodating and acknowledging underlying cognitive and decisional challenges
 - Resources put in place to facilitate consent communication as needed:
 - Language line or interpreter
 - TTY or sign interpreter
 - Cultural broker
 - Videoconferencing for those who cannot participate in person
 - Identify the person who will serve as the facilitator for the discussion
 - An individual who has completed the inclusive informed consent decision making process communication training
 - A person with good communication and listening skills
 - A person who has had experience in facilitating discussions
 - Identify resources to be part of the inclusive consent communication process such as:
 - Bioethics consultant
 - Advocate(s) (more than one if communication involves the interests of multiple patients such as mother and fetus or transplant donors and recipient)
 - Clergy
 - Social Worker
 - Patient Relations/Advocacy
 - Medical professionals
 - Nursing
 - Identify who will attend with or on behalf of the patient and surrogate
 - Identify location for the consent communication discussion taking into consideration:
 - Requirements in terms of confidentiality
 - Requirements in terms of privacy
 - Requirements in terms of security
 - Number of seats required

- The seating arrangement
- Accessibility to audiovisual connection (videoconferencing, language line services, etc.)
- Establishing an agreed upon agenda for the discussion
- Agreeing to a respectful meeting with an opportunity for each participant to speak
- Agreeing to disagree in a respectful manner
- Completing a summary of the meeting including when possible a “teach back” to confirm expectations and any follow up steps
- Prior to the beginning the discussion one person is identified as the “go to” person for follow up communications with and from the patient/surrogate and family
- The inclusive informed decision making process policy and procedure anticipates the need to address the following:
 - Disagreement amount care providers
 - Reconciling and respecting differing health care professional perspectives
 - Managing disruptive friends
 - Managing patient requests to exclude certain individuals
 - Documenting management of challenges
 - Requests to permit medical and health care students observe the inclusive informed decision making process
 - Requests to permit residents and fellows to observe the inclusive informed decision making process
 - Requests to videotape the inclusive informed decision making process

***Sample Tool Checklist ERM Approach to Critical Patient Decision Making**

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