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CASE AND COMMENTARY

How Should Risk Managers Respond to Cases for Which No Risk Profile Exists?

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Abstract

Rapid innovation makes some devices available for patient implantation prior to extensive preclinical trials. This article reviews information that risk managers can utilize to help patient-subjects and clinician-researchers make informed decisions about new device implantation in the absence of preclinical trial data. Novel devices should be regarded by risk managers as sources of unknowns with potential for procedural complications and other harms. Risk-benefit analyses during informed consent should include patient-subjects' preferences, experience of the implanting surgical team, disclosure of conflicts of interest, and postprocedure follow-up planning. Checklists can help risk managers facilitate critical conversations and decision making about whether to implant devices with no extant risk profile.

Case

MM is a 60-year-old man with hydrocephalus. His life was saved and his symptoms improved after Dr N implanted a shunt. Like many patients with shunt valves, MM experiences complications at the surgical site, the most pressing of which is the shunt valve's extrusion from the scalp wound. Dr N examines MM's scalp and remarks, "You're one of the patients who happens to have a lot of problems with their shunts. What you really need is a custom-made implant. If I could give you one, it would probably decrease chances of the shunt's failure, help mitigate skin breakdown on your scalp, and prevent the natural contours of your cranium from becoming deformed. I think you'd be a lot happier with a custom-fit shunt, if you agree to have me remove this one and replace it. You'd be the first patient to have a customized cranial implant. If you'd like to talk further about this, we can schedule some time tomorrow to talk about it more. In the meantime, I can present your case to my colleagues and get their ideas, too."

MM agreed to revisit Dr N's clinic the following day. In the morning, before multidisciplinary rounds, Dr N presented MM's case to the team at what team members call their weekly "innovation meeting," to discuss whether, when, and how to integrate new devices, materials, or techniques into practice. The team includes surgeons, surgical nurses, anesthesiologists, nurse anesthetists, case managers, and a risk manager. Dr N clarifies that MM's shunt valve would first be removed and then a

temporary shunt would be placed. MM would take a 14-day course of antibiotics. Then a contralateral craniectomy would accommodate implantation of the shunt valve system that the manufacturer would customize for MM's cranial measurements.

Team members at the meeting exchanged questions and responses. The risk manager took notes to share with colleagues in the hospital's office of general counsel and with other risk managers and left the meeting feeling concerned, as numerous questions about MM's safety remained unanswered—and perhaps unanswerable—until the first-in-human implantation of this device was complete.

Commentary

Growing demand for and explosive growth of technology led to US Food and Drug Administration (FDA) approval of more than 500 000 device models by the late 1990s.[1] Regulatory approval processes for new implantable devices differ from those for new medications and are not as rigorous.[1,2] Devices deemed "substantially equivalent" to existing approved devices can be brought to market without clinical trials prior to first human use if approved through the FDA's 510k exemption process, despite being supported by only a limited amount of data.[1,3] Variability in training and experience of the implanting team, variation in individual patient-subject preferences and risk tolerance,[4] and possible conflicts of interest add additional layers of complexity to balancing patient safety with the need for innovation. Risk managers have critical roles in helping address decisions that patients and care teams must make about whether, when, and how to implant novel, untested devices. This commentary locates introduction of new devices within a framework of ethical principles in health care and introduces a decision matrix for evaluating new device implantation from an ethical perspective.

Clinical Risk-Benefit Analysis

Cerebrospinal fluid (CSF) shunts are lifesaving devices for patients with hydrocephalus caused by tumors, hemorrhage, or normal pressure hydrocephalus. However, morbidity of CSF shunt implantation is significant. Mechanical dysfunction and infection affect at least 17.2% and 6.1% of patients, respectively.[5] The overall shunt revision rate has been estimated at 23.3%, with most revisions occurring within 6 months of the index implantation.[5] Mortality for revision surgery is much higher than for first implantations (11.9 % vs 6.1%, respectively), and need for revision alone increases the incidence of subsequent shunt revision 9-fold.[5,6] A new device, which could possibly decrease the risk of complications and shunt revision, could offer significant potential benefits for this patient.

Shunt customization involves embedding a rigid plastic casing made to fit the contours of a specific patient's skull. Two possible benefits of a low-profile customized shunt implantation are less scalp pressure and fewer dehiscence-related complications and revisions. Similar technology has already been utilized by neurosurgeons for other types of implanted devices, such as deep brain stimulators.[6] These potential benefits appear significant in the case, in large part because the patient has already experienced dehiscence and a need for revision, which, as noted above, could increase this patient's morbidity and mortality risk. Identifying specific subpopulations of patients who could benefit most from implantation of a novel device is a key next step in MM and Dr N's risk-assessment process.[4]

Other risk factors to consider are whether the shunt and casing composition are like those of other devices used in neurosurgery, whether the surgical team is experienced in performing comparable procedures, and how risk of novel shunt placement might compare to risk of traditional shunt placement after a course of antibiotics. Material likeness of new to approved devices for which safe risk profiles have been established and analogous surgical experience are 2 of the most important elements in a risk manager's evaluation of risk in a case like this one.[6]

Ethical Risk-Benefit Analysis

New device implantation requires commitment to executing informed consent processes in ways that express respect for patient-subject autonomy. Patients and their families must be made aware of the rationale for using a new device for which there is little or no extant risk profile, the surgical team's experience with this or similar devices, alternatives such as implanting a device for which a risk profile is known and accepted, and potential conflicts of interest.[3,7] Special consideration must be given to the lack of clinical evidence about a new device, gaps in knowledge about safety, and need for postimplant surveillance. Risk managers can help inform conversations about novel device implantation benefits and risks, identify patients or subgroups of patients that could benefit most from novel device implantation, and provide available information to build a risk-benefit profile for the device.[4]

Patient preferences. Patient perspectives on risk tolerance, for example, can differ from those of other stakeholders (eg, clinicians, manufacturers, regulators) for many reasons. In the case, a patient might choose to proceed with the new shunt in part due to the cosmetic appeal of the lower profile and an expectation of improved quality of life associated with this feature of the new device, whereas practitioners might focus more on technical or procedural considerations. Moreover, different patients are likely to have different attitudes about maximum acceptable risks and minimal acceptable benefits as well as different tolerance levels for uncertainty.[4] Having already experienced failure of a traditional shunt, the patient in the case might be more tolerant of uncertainty and choose the new shunt, especially if the risk-benefit profiles of the new and traditional devices otherwise seem or are expected to be similar. On the other hand, because the new device requires removal of a small portion of skull to allow implantation of the novel embedded customized implant, the patient might not choose to take on additional or unknown risks of serious postoperative complications, such as epidural hematoma.

Perioperative care planning. When patient-subjects have capacity to make decisions, their wishes should be prioritized over advance directives or medical (physician) orders for life-sustaining treatment.[8] Updating advance care planning documents to express patient-subjects' wishes and values is important, since patient-subjects can lose decision-making capacity during a procedure, illness, or hospitalization.[9] Do-not-resuscitate (DNR) orders and policies must be navigated carefully when a patient-subject undergoes implantation of a new device, due to increased risk of cardiac or respiratory arrest.[10] Deliberating about whether and when (especially during anesthetic airway intervention) a DNR order should be perioperatively suspended or continued[10] must include patient or surrogate input. Decision making is easier when potential benefits of the novel device appear likely to—and potential risks appear less likely to—motivate expressed goals of care and when an advance directive fits the situation well.[9] If conflict arises about how to interpret a patient-subject's wishes as represented in advance planning documents, for example, the clinical care team should obtain an ethics consultation.[8]

Anatomic location. Implanting a novel device in or around a patient-subject's brain obliges stakeholders to consider how a patient's identity and well-being can be affected,[11] especially if that device can be accessed or controlled by third parties. For example, shunts might be programmable to prevent over- or underdrainage of cerebrospinal fluid, especially in patients with normal pressure hydrocephalus.[12] Previous studies suggest that gaps between a physician-researcher's understanding and a patient-subject's perception of risks deserve attention and underscore the importance of effective communication.[13] A risk manager can help elicit reflection, clarify concerns, and illuminate perspectives among all involved in decision making.

Commitment to transparency. Conflicts of interest, including financial conflicts and those related to the prestige of innovation, create a need for transparency about the experience and abilities of implanting team members and for disclosures about their personal and professional stakes in novel device implantation. Risk managers can help establish a relational environment in which these concerns can be discussed and in which any relevant data can be illuminated, considered, and addressed. One possible format for these discussions is interprofessional collaborative rounds, wherein clinical care team members, patients, and their families discuss a care plan and establish a shared mental model.[14] Risk managers, clinical teams, patients, and families increasingly have access to databases of outcomes for related procedures and, as a result of the Sunshine Act, access to public databases of payments from device manufacturers to clinicians.[3]

Surveillance and communicating evolving knowledge. In new device implantation, a rich preclinical record of experience and evidence is missing, so a risk-profile is also missing, which creates a gap in knowledge for patient-subjects and clinician-investigators.[3] Even approved devices can later be found to have previously unsuspected or unknown complications. A clinical team and organization have an ethical obligation to discuss providing or arranging for postimplantation surveillance to capture any safety issues that become apparent through patient-subjects' living with the novel device. Postimplantation surveillance thus should be discussed during an informed consent process. All stakeholders, including the patient-subject, should be engaged in surveillance and ongoing disclosures of potential conflicts of interest. Patients, clinicians, and manufacturers should report complications—and certainly adverse events—in the US Food and Drug Administration Manufacturer and User Facility Device Experience database or to the Medical Product Safety Network.[3]

Checklist

The authors have developed a checklist tool (see Table) to set the stage for informed consent or refusal conversations among stakeholders and prompt revelation of factors that can help motivate ethically informed decisions among patient-subjects and the clinical team. Higher scores yielded by use of the tool could be interpreted as supporting a decision to implant a new device for which there is no extant risk-profile. Lower scores would suggest ethical concerns and a need for pause and might prompt a risk manager to recommend an ethics consultation to help address those ethical concerns. This checklist could be applied to the above case.

Table. Checklist Tool for Ethically Implanting New Devices With Limited Clinical Trial Data[a]

Factor	Item No.	Maximum Points	This Patient	Evidence of Greater Favorability	Evidence of Lesser Favorability
Regulatory	1	5	5	FDA approval	Investigational device exemption (eg, emergency)
	2	5	5	IRB approval	
Potential Benefits	3	5	4	Significant potential benefits function and quality of life, reduction in morbidity, and improved survival compared to current available device	Fewer potential benefits of new device compared to current available device
	4	5	3	Benefits long-lasting	Time course unknown
Potential Risks	5	5	3	New device either has similar expected risk or increased risk does not include serious harm compared to current device(s)	New device significantly increases risk of serious complication or death
	6	5	4	Any potential new complications are manageable	New complications introduced are difficult to treat
Device	7	5	0	Non-CNS location	Located near brain
	8	5	5	Functionality similar to devices in use	Novel functionality
	9	5	5	Not accessible	Accessible to third parties
	10	5	3	Implantation procedure similar to other procedures in routine clinical use	Implantation methods differ substantially from those currently in use
Surgeon/ Implanting Team	11	5	5	Has considerable experience implanting similar devices	Less experience with similar devices and implantations
	12	5	5	Has undergone additional training by the vendor with the new device	No or limited additional training with new device
	13	5	4	No conflicts of interest with the vendor and device	Potential conflict of interest (eg, royalties, paid speaker for device manufacturer)
Patient	14	5	5	Belongs to subpopulation of patients with disease most likely to benefit	No subpopulation more likely to benefit known or patient does not belong to the subpopulation likely to benefit the most

				Patient preferences known and include:	Patient preferences unknown or patient uncomfortable with:
	15	5	3	• Acceptance of maximum possible increase in risk	• Maximum possible increase in risk
	16	5	3	• Acceptance of minimal possible increased benefit	• Minimal possible increased benefit
	17	5	3	• Acceptance of degree of uncertainty associated with new device	• Degree of uncertainty associated with new device
Postimplant Surveillance/ Communication Plan	18	5	5	Implanting team or organization has the capacity to provide individual surveillance	Minimal capacity to provide individual surveillance
	19	5	5	Patient able/desires to participate in follow-up	Barriers to follow-up
	20	5	5	Processes in place to monitor implants in other patients and communicate outcomes to this patient	Unable to provide global follow-up and communication
Total Score		100	80		

Abbreviations: CNS, central nervous system; FDA, Food and Drug Administration; IRB, institutional review board.
[a] Users may customize this tool by assigning more or less weight to different items.

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Editor's Note

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Conflict of Interest Disclosure

The author(s) had no conflicts of interest to disclose.

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

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