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Insights on Value and Values from Decision Science for Clinical Ethics

From the Editor

- The Value of Decision Science for Clinical Ethics** 825
Raymond De Vries, PhD

Case and Commentary

- How Should Clinical Ethics Consultants Support Parents' Decision Making?** 831
Katherine J. Feder, MS and Janice I. Firn, PhD, LMSW
- How Should a Physician Respond to a Patient's Pain When New Opioid Prescribing Laws Limit Shared Decision Making?** 838
Alexander J. Hjelmaas, MD and Christian J. Vercler, MD, MA
- How Should We Determine the Value of CAR T-Cell Therapy?** 844
Sara Silbert, MD, Gregory A. Yanik, MD, and Andrew G. Shuman, MD
- How Should Decision Science Inform Scarce Blood Product Allocation?** 852
Eric Kersjes, MD and Lauren B. Smith, MD

State of the Art and Science

- Should Clinicians Leave "Expanded" Carrier Screening Decisions to Patients?** 858
Amanda Fakih, MHSA and Kayte Spector-Bagdady, JD, MBE

Medicine and Society

- How Should Decision Aids Be Used During Counseling to Help Patients Who Are "Genetically at Risk"?** 865
Natalie Evans, PhD, Suzanne Metselaar, PhD, Carla van El, PhD, Nina Hallowell, DPhil, and Guy Widdershoven, PhD
- Which Ethical Considerations Should Inform Hospice Decisions About Caring for Patients With Obesity?** 873
Chithra R. Perumalswami, MD, MSc, Brycin D. Hanslits, and Susan D. Goold, MD, MHSA, MA

Art of Medicine

- What Historical Ideals of Women’s Shapes Teach Us About Women’s Self-Perception and Body Decisions Today** 879
Nealie Tan Ngo
- When Good Women Decide to Do Nothing** 902
Phoebe Cohen
- A Matter of Words** 904
Jessica S. Yang

Viewpoint

- What Clinical Ethics Can Learn From Decision Science** 906
Michele C. Gornick, PhD, MA and Brian J. Zikmund-Fisher, PhD, MA
- How Moral Case Deliberation Supports Good Clinical Decision Making** 913
Giulia Inguaggiato, MPhil, Suzanne Metselaar, PhD, Bert Molewijk, PhD, and Guy Widdershoven, PhD

Letter to the Editor

- Response to “Emerging Roles of Virtual Patients in the Age of AI”** 920
Frederick W. Kron, MD, Timothy C. Guetterman, PhD, and Michael D. Fetters MD, MPH, MA
- Response to “Will We Code for Default ECMO?”: Clarifying the Scope of Do-Not-ECMO Orders** 926
Jacob A. Blythe, MA, Sarah E. Wieten, PhD, and Jason N. Batten, MD, MA

Podcast

- How Can Decision Science Help Navigate Complex Health Decisions?: An Interview With Dr Brian Zikmund-Fisher**

FROM THE EDITOR

The Value of Decision Science for Clinical Ethics

Raymond De Vries, PhD

Bioethics prides itself on its interdisciplinarity. It is a field that invites members of different disciplines to join in the conversation, to bring insights generated by their approach to knowledge to the moral problems of medicine and the life sciences. At first glance, the breadth of bioethical interdisciplinarity—encompassing philosophy, medicine, literature, nursing, social work, religion, social science, and law—is impressive. But, on further reflection, that interdisciplinarity is curiously limited. *Curious* because, despite the disciplinary diversity of bioethics, other disciplines that could improve the quality of bioethics in its clinical and research manifestations have not been invited to the party.

Decision science is one of those fields. And it is a curious omission. Consider this definition from the Center for Health Decision Science at Harvard University: “Decision science is uniquely concerned with making optimal choices based on available information. Decision science seeks to make plain the scientific issues and value judgments underlying these decisions, and to identify tradeoffs that might accompany any particular action or inaction.”¹ In their contribution to this theme issue, Brian Zikmund-Fisher and Michele Gornick offer a slightly different description: “Decision science encourages thoughtful definition of options, clarification of information needs, and acknowledgement of the heterogeneity of people’s experiences and underlying values.”² Reading these 2 definitions, we are forced to ask: Why are we in bioethics not working side by side with decision scientists? Much of our work involves helping people—be they patients, research subjects, caregivers, or researchers—make “optimal choices based on available information” by taking into account their values, experiences, and the trade-offs involved in choosing one option over another.

The University of Michigan Center for Bioethics and Social Sciences in Medicine (CBSSM), of which I am associate director, is fortunate to number decision scientists among its core faculty. I would like to say that their presence is the result of our vision, wisdom, and careful planning, but, in fact—just like the field of bioethics itself—the composition of our center is a consequence of circumstance and happy accident. The field of bioethics arose from the work of a collection of theologians and philosophers who turned their attention to medicine and medical science at a time—the 1960s and 1970s—when the authority of society’s institutions was being questioned and when medical technologies were challenging established boundaries of life, redefining when life begins and ends.^{3,4} It could have been otherwise: the content and concerns of bioethics would look much different had the field emerged in a different historical and social context.⁵ At the CBSSM, it happened that the

people drawn to bioethics included those with expertise in decision science,^{6,7,8} allowing us to combine the concerns of both areas of inquiry. Those who identified with bioethics saw the value in decision science, and those in decision science recognized the importance of bioethics for their work. That history is reflected in the articles collected here.

As you will see, central to the work of both bioethics and decision science is attentiveness to the way values inform choice. Because *value* has multiple, related meanings, when we speak of values, we need to tread carefully. In the context of health care, value often refers to matters economic: the worth of something expressed in monetary value. Indeed, when I first heard of efforts to encourage value-based health care, I thought, *Wow, health care is finally realizing that people's values need to be considered in how care is delivered!* After all, I do work in bioethics, and I assumed that the values in value-based health care referred to those things we find important in life. But I quickly learned that I had the wrong definition of the word. The *NEJM Catalyst* defines value-based health care as “a healthcare delivery model in which providers, including hospitals and physicians, are paid based on patient health outcomes.... Value-based care differs from a fee-for-service or capitated approach, in which providers are paid based on the amount of healthcare services they deliver.”⁹

You, the reader, should keep the differing meanings of value in mind as you consider the theme issue authors' arguments: think about how those 2 meanings are intertwined. Economic value, for example, can be, and often is, something that is “important in life”—a factor to be considered when weighing an ethical question. But the value placed on *costs* is just one among several cultural values—a fact that is confirmed by the uneasiness we would feel if ethicists relied solely on an economic analysis when deciding on the most moral approach to delivering care. True to the goal of decision science—which, in Zikmund-Fisher and Gornick's words, is “to produce choices that are values-congruent”²—the articles included here focus, for the most part, on value as described in the second, important-in-life meaning of the word. Those that do consider costs call attention to the need to weigh the value of economic value.

Concern with the link between value(s) and culture is particularly relevant because this collection is the result of a collaboration between the CBSSM and the Metamedica Department of the Vrije Universiteit Amsterdam led by Guy Widdershoven. This kind of cross-cultural work happens too seldom in the field of bioethics, and its value (yes!) is apparent in the contrast between the differing models of ethical deliberation described by ethicists from the Netherlands and the United States. In explaining the process of *moral case deliberation*,¹⁰ contributors from the Netherlands call attention to the way facts are produced by values and underscore the need to consider both professional and patient values. Their approach to ethical deliberation—which explicitly solicits and applies the values of all parties involved in an ethical dilemma—could prompt American bioethicists to reassess the top-down model of clinical ethics consultation widely used in the United States.¹¹

Using decision science to approach ethical decisions highlights the different ways that values shape the content, process, and outcomes of ethical deliberation. Zikmund-Fisher and Gornick set the stage for the collection in their essay, “What Clinical Ethics Can Learn From Decision Science.” They remind us that those making (or helping others to make) decisions in the context of clinical ethics should consider not only the information that stakeholders must know to make an informed decision but also the “[predictable biases](#)” that influence people’s perceptions and how the task of decision making in conditions of uncertainty is “simultaneously analytical and emotion driven.” Responding to a case in which parents are conflicted about [end-of-life care options](#) for their child, Katherine J. Feder and Janice I. Firn offer an example of how the goal of decision science—to make values-congruent choices—can be realized in practice. They point out the importance of encouraging reflective—instead of reactive—thinking and the need to emphasize that there is no “right” decision, even when ethicists are asked to explain the “right thing to do.”

Economic value—in the form of supply, demand, and affordability—is central to the case study of Sara Silbert, Gregory A. Yanik, and Andrew G. Shuman and that of Eric Kersjes and Lauren B. Smith. Silbert and colleagues discuss the dilemma created when a highly expensive “living drug”—chimeric antigen receptor T (CAR-T) cell therapy—shows promise in treating refractory B-cell malignancies. They consider not only how health care organizations should respond but also whether the [cost of the therapy](#) should be discussed with patients. Similarly, Kersjes and Smith consider the (sometimes) [scarce resource of blood products](#) and how they should be used in end-of-life care—in this case, for a pediatric patient. In both case commentaries, we see the tension created when it is necessary to balance the value of a (costly or scarce) resource for a particular patient with the needs of other patients. The easy way out of this dilemma is what Zussman calls “Hippocratic individualism”¹²—deciding that it is ethical to care for the patient in front of you, ignoring the cost of that decision for others. The authors of these commentaries disagree with that approach and ask us to expand our ethical horizons.

Several articles examine how social values find their way into clinical care and ethics, especially the contribution of Nealie Ngo and of Chithra R. Perumalswami, Brycin D. Hanslits, and Susan D. Goold. In both we see how the way bodies are valued (or devalued) influences care. Perumalswami and colleagues examine the [treatment of patients with obesity](#) by hospice and palliative care practitioners and how stigma and the additional costs associated with the care of these patients compound moral dilemmas in decision making. Ngo uses advertisements, magazines, body satisfaction surveys, and her own struggles with body image to challenge us to consider the ways in which [social valuation of ideal body types](#) can empower and disempower us.

The articles from our colleagues at the Vrije Universiteit focus on the interplay between facts and values. Giulia Inguaggiato, Suzanne Metselaar, Bert Molewijk, and Guy Widdershoven remind us that clinical ethical decision making involves not only the values of patients but also the values brought to the conversation by physicians and nurses. They apply [moral case](#)

[deliberation](#), a method of clinical ethics support, to a case dilemma of how to treat a neonate's pain to illustrate how values influence the interpretation of the facts that are called upon to make morally informed and shared decisions. Natalie Evans, Suzanne Metselaar, Carla van El, Nina Hallowell, and Widdershoven pick up on this theme, warning about the consequences of nondirective counseling and the [use of decision aids](#) in the context of genetic risk. In particular, they argue that decision aids can remove decisions from the source of a patient's values, including family and culture, with no consideration of how the values of the physician and the health system are embedded in these instruments. Their conclusions highlight how clinical culture affects the framing of ethical issues, mirroring research that shows the negative effects on satisfaction and coping of a strong emphasis on respecting the autonomy of patients or parents in medical decision making.^{13,14}

Among the many things that may prevent decisions from reflecting the values of those who are *making* those decisions are social and legal barriers. Alexander J. Hjelmaas and Christian J. Vercler present a [case of opioid prescribing](#) that illustrates this problem and examine how the demands of a busy practice, the constraints of law, and the limits of trust conspire to compromise the patient-physician relationship. They advocate for shared decision making as a solution but admit that adding another task to the work of clinicians—one that is not required or billable—would likely fall by the wayside. In their discussion of the use and interpretation of [expanded carrier screening](#), Amanda Fakhri and Kayte Spector-Bagdady share a similar skepticism about implementing shared decision making. The source of their skepticism is too few genetic counselors, the tension between recommendations made by professional organizations and the more-is-better approach marketed by expanded carrier screening manufacturers, and the challenges facing clinicians who wish to keep up with the ever-evolving range of genetic products. Nevertheless, they insist that this knowledge of these products is essential for helping patients balance the risks and benefits of the individual tests included in the expanded carrier screening panel.

Finally, 2 contributions visually explore dimensions of decision making. In her graphic memoir, Phoebe Cohen shows that taking care of an [incarcerated patient giving birth](#) presents episodes of disagreement—and thus numerous decision points about how to respond to those episodes—among members of a paramedic and emergency response team. And Jessica S. Yang's mixed-media digital illustration of a patient-clinician encounter calls attention to the importance of how clinicians [frame information](#) in their communications with vulnerable patients.

Given the complex decisions confronting patients, health care practitioners, payers, and health policymakers—and given uncertainty about the best choice among care options—it is time to welcome the discipline of decision science to the cross-disciplinarity of bioethics. These articles, examining how patients' and clinicians' personal values color their perceptions of "objective" clinical and economic value, illustrate what we would gain by using the insights of decision science to approach ethically complex cases in health care settings.

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CASE AND COMMENTARY

How Should Clinical Ethics Consultants Support Parents' Decision Making?

Katherine J. Feder, MS and Janice I. Firn, PhD, LMSW

Abstract

Clinical ethics consultants (CECs) frequently provide guidance to parents feeling grief and uncertainty. In response to a case in which a CEC works with parents making end-of-life decisions for their child, we argue that CECs should use insights from decision science to consider how emotional distress, information-processing heuristics, and person-environment relationships can influence decision making. Rather than rely on decision aids, CECs should take a personalized, values-based approach to facilitating decision making that acknowledges context and a plurality of possible "right" answers. By using this approach and insights from decision science to support parental decision making, the consultation itself becomes a decision aid, as consultants and parents engage in shared decision making through facilitated discussion and reflection.

Case

Dr AE, the clinical ethics consultant on call, receives a consultation request from parents of a previously healthy 3-year-old patient admitted to the pediatric intensive care unit. The patient suffered an anoxic brain injury after cardiac arrest during surgery. The damage to his brain is widespread. In the medical team's clinical opinion, he will have lasting neurological deficits, including, but not limited to, problems with cognition, vision, language, and motor function. His parents want to meet with someone from the ethics consultation service to discuss the ethical permissibility of withholding or withdrawing specific interventions from their child. The clinical team would support the parents' decision either to continue aggressive treatment or to transition to comfort care.

When Dr AE enters the consultation room, the parents say, "We're glad you're here. You can tell us the right thing to do."

Dr AE is uncomfortable with the parents' stated expectations about her role as an ethics consultant and about their perception of the role of her expertise in their decision-making process. Before addressing these concerns, Dr AE first seeks to learn more about what the parents view as ethical concerns regarding their son's situation.

The parents explain that they want to make sure they have done “everything” for their son, but they also express that they do not want him to live his life like a “vegetable.” They love their child and want to be good parents to him, but they are struggling with how to do that because they feel both medical paths fail him in some important way that seems to compromise their goals and best wishes for him. Dr AE recognizes the parents’ grief and their experience of conflict about their clinical options.

Commentary

Like many pediatric intensive care ethics consultations involving treatment and quality-of-life decisions for children, Dr AE is called upon to facilitate grieving parents’ decision making when the choices with which they are confronted will result in dramatic and lasting consequences. Given the emotional valence of the consultation, Dr AE will need to draw upon decision science approaches and resources that acknowledge and subsequently mitigate the influence of distress on decision making. Various stakeholders have recommended the use of [patient decision aids](#) (PDA) to promote a shared decision making model.¹ Although such aids are useful for certain choices, such as whether or not to be screened for prostate cancer or how to choose a medication, we argue that each ethics consultation is distinct and requires the ethics consultant to learn more about the individual patient and the patient’s family situation to help decision makers engage in shared decision making based on their values and self-determined best interests. While there is a dearth of PDAs for solving ethical dilemmas, their absence does not preclude the use of decision science, which, as we show, goes beyond aids to encompass the various factors that affect decision-making processes and the science of how human beings make choices.^{1,2,3}

Emotions and Decision Making

Stressful situations and acute emotional states can impair our ability to process complex information and can cause communication to be less effective.⁴ How we make decisions under stress, therefore, is affected by instincts, emotions, and perceptions as much as—if not more so than—by reason, calculation, and logic.³ Even in the best of circumstances, most of us function with less-than-perfect information and cannot analyze all costs and benefits for every possible alternative; cognitive space is limited and our minds concentrate on immediate rather than future needs.³ In addition, a given situation’s relative ambiguity, predictability, uncertainty, and duration also influence how an event is evaluated and which coping mechanisms are used, potentially further impeding decision making.⁵ Under stress, we can overlook salient facts, neglect to involve key stakeholders, or fail to attend sufficiently to long-term consequences.³ *Action bias*, the desire to do something—perhaps anything—to decrease anxiety, could lead to a hasty or poorly considered decision.^{2,3}

In pediatric cases, parents could be viewed as a single unit rather than as individuals. While both parents commonly want to do what is [best for their child](#), it is important to

acknowledge that each parent might process information differently and bring unique perspectives and narratives to the decision-making process, which in turn could influence their experience of grief.^{5,6,7,8}

Roles of an Ethics Consultant

Involving someone less emotionally connected to a situation who is professionally trained to facilitate ethically complex decision making can help reconcile varying perspectives, engender support, and counter a sense of isolation many feel when grieving.^{3,6} Good ethics consultation processes should create a space for decision makers to pause, to assess, and to explore both short- and long-term effects of different choices.^{3,5,6,9} The consultation process also allows for exploration of assumptions held by caregivers or other stakeholders.^{3,6}

To facilitate decision making under the stressful circumstances in the case, Dr AE might use several techniques. One is to reframe the situation in the third person to give the parents some emotional separation from the issue.^{3,6} Dr AE could also emphasize that decision making is not a static process but one that changes over time as new information, experiences, and context emerge and thus that the parents are not bound to a single course of action but can pivot in response to changing circumstances.⁵ Furthermore, Dr AE could help clarify the timing of the choice to be made.

Despite Dr AE's discomfort with the parents' assumption that her role is to make the decision for them ("You can tell us the right thing to do"), it is key that Dr AE establish an alliance with the parents, which could be compromised if she directly confronts their assumptions about her expertise and purpose too aggressively. Ultimately, however, Dr AE must demonstrate her **role as a facilitator** in the parents' decision-making process. By eliciting further information about their goals and values, answering questions as the conversation unfolds, and filling in their knowledge gaps as needed, she can clarify her role over the course of her interactions with these parents. Specifically, Dr AE's behavior and speech should enact her role as a facilitator and delimit its nature and scope; if uncertainty about her role remains as the consultation proceeds, Dr AE will hopefully have established sufficient rapport with the parents to make an explicit verbal statement about the nature and scope of her role.

Furthermore, Dr AE must make it a goal of her time with the parents to unpack what they think the "right thing to do" means. The parents' apparent assumption that the right thing to do is knowable could be based, for example, on misinformation that there is one right answer in such scenarios or that the ethics consultant is the one who knows this answer rather than being the one who could facilitate revelation of options that are ethically defensible. It is not unreasonable for the parents to want to be told the right thing to do in their specific situation; paternalism could offer both respite from their

responsibility and a beacon of clarity amidst uncertainty, grief, and devastation in their family.

Dr AE should emphasize that her role is to facilitate value- and context-based discussion, not to make a decision for the parents. Accordingly, she should strive for deeper understanding of what is motivating their choices or conflict.⁸ She should also articulate, in plain language, a normative ethical framework for facilitating the parents' understanding of how their personal values can be viewed as part of such a framework and thus be used to ground ethically defensible reasons for a decision affecting their child. Articulating such a framework can sometimes help families to discern how their intuitions, values, and preferences can be drawn upon to express—with as much confidence and clarity as can be achieved under conditions of stress and uncertainty—an ethically defensible decision.

Responding to Person-Environment Interaction

Culture, technology, social and individual values, spiritual and religious traditions, and legal and financial struggles are among the many factors that can frame and influence how families approach clinical and ethical decisions.⁶ Each factor plays an important role in determining what is perceived as pertinent for well-being, how meaning is attributed to an event, what coping strategies are used, and how different possible outcomes are assessed.^{6,10} In this case, the parents' lack of confidence in making a decision could be further influenced by a number of factors, including the absence of choices or of specific resources such as health insurance, social support, savings, or information.^{5,6} Part of Dr AE's role is to acknowledge the diverse **context-specific factors** at play and their possible influence on decision making. She might consider employing a more bottom-up approach to talking about ethics—for example, by focusing on the parents' needs and the characteristics of the family—rather than employing what's often characterized as a top-down approach to ethics, such as principlism, deontology, or utilitarianism, when guiding parents through a decision-making process.^{5,11,12}

In the case of this family, the clinical team would support a decision to either continue aggressive treatment or to transition to comfort care. The parents must weigh the child's quality of life under continued aggressive intervention against the irreversibility of their child's death. Their choice will be informed by both the kind of quality of life they value and have envisioned for their child and their family life at home. For example, the decision-making process for these parents could be informed by the needs and best interests of other children or elders in their household whose care could also be influenced by the consequences of this particular decision. Dr AE is obliged to offer (and possibly chart in the patient's health record, depending on the organization) recommendations intended to help a team or family make an ethically complex decision.

At present, the approach described above cannot readily incorporate PDAs. Developing effective decision aids requires understanding patients' and families' decisional needs and finding ways to create materials that can accommodate the differing informational preferences of individuals within a heterogeneous population.² This task is challenging enough for binary decisions ("Do I undergo BRCA testing or not?") when the patient is commonly the decision maker. It becomes even more complicated when the decision is potentially irreversible and those making it might be stakeholders other than the patient. Moreover, the use of PDAs could thwart shared decision making if they feel impersonal to decision makers and insert a dry algorithmic element into an emotionally challenging decisional process.

In any case, clinical ethics consultation and PDAs work towards the same goal: facilitating engagement in shared decision making based on patients' and family members' values.¹³ It is imperative for the consultant to ask patients or families how they want information to be relayed, and it is essential to take their context into account as part of facilitating shared decision making. In taking context into account, the ethics consultation accounts for population differences in real time, functioning as a personalized decision aid.

Conclusion

In summary, clinical and ethical decision making is often influenced by emotions that affect how information is processed. To more effectively support patients and families and to facilitate decision making in line with their values, it is imperative for ethicists to create a safe space for families to transition from reactive to reflective thinking. In this case, by gauging the parents' level of understanding, eliciting their perspectives, clarifying their goals, and engaging in shared decision making, Dr AE can help the parents understand the scope of their choices and how they can draw upon their values to make a choice they can live with. Through such a shared decision-making process, Dr AE can demonstrate her role as a facilitator (rather than as a decision maker), and, by emphasizing the importance of a defensible decision over a "right" one, she can help the parents make a decision that makes sense for them. In effect, Dr AE serves as a decision aid for the family by providing techniques and resources from the broader field of decision science to fit their personal context.

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Editor's Note

The case to which this commentary is a response was developed by the editorial staff. Background image by Samantha Welker.

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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.

CASE AND COMMENTARY

How Should a Physician Respond to a Patient's Pain When New Opioid Prescribing Laws Limit Shared Decision Making?

Alexander J. Hjelmaas, MD and Christian J. Vercler, MD, MA

Abstract

This commentary responds to a case and examines pragmatic concerns about operating a busy outpatient practice in compliance with new laws that regulate opioid prescribing. Specifically, the article considers how regulating opioid prescribing can influence the therapeutic alliance in patient-physician relationships and how innovations in decision science can facilitate shared decision making given time constraints.

Case

LJ is a 64-year-old woman with a history of hypertension, osteoporosis, and major depressive disorder who fractured her left tibia and fibula and had an open reduction and internal fixation 12 weeks ago. Since the operation, she has been taking oxycodone for pain, and though she has reduced the number of pills she takes from 2 every 6 hours to 1 every 8 hours, she still feels it's helpful to take 2 pills before bedtime each night to sleep. At her follow-up visit, her radiographs do not definitively show complete healing. Since it is difficult to determine whether there has been adequate healing of the bone, a decision is made to have her continue physical therapy and follow up in one month with more radiographs. She is running low on oxycodone and requests more to get through the next 4 weeks.

Her surgeon, Dr M, is concerned that LJ still requires 2 pills at night and worries that LJ is developing opioid dependence. Dr M is running over an hour behind clinic schedule, and new state opioid prescribing laws now require more paperwork and counseling with a patient before prescribing more oxycodone this long after an operation.

Dr M feels conflicted: LJ might not be fully healed from her injury and could be experiencing ongoing pain from an unhealed fracture, or LJ could be developing opioid dependence. Ordinarily, Dr M would prescribe more oxycodone, but new laws have made normal practice less expedient. It has also been Dr M's typical practice to engage in shared decision making with patients when prescribing narcotic pain medications. Now, however, she is unsure how to balance her obligation to follow new legal requirements with her obligation to take a patient's claim of pain seriously. Dr M considers how to respond.

Commentary

When helping LJ, Dr M should be conscious of potentially conflicting ethical principles. For example, Dr M should consider that providing a refill would likely express respect for LJ's autonomy and do good by offering pain relief and enabling continuation of LJ's physical therapy. Dr M would likely weigh these autonomy and beneficence concerns against nonmaleficence: by not prescribing opioids, Dr M could help LJ avoid suffering opioid dependence and substance use disorder. Additionally, Dr M could consider the principle of justice and whether prescribing more opioids for this particular patient at this particular time could constitute overprescription that exacerbates an [ongoing crisis](#). The situation faced by LJ and Dr M is a common one in outpatient practice in the United States and presents several conflicts for both physician and patient.

More Options

It seems reasonable for Dr M to prescribe more opioid medication for LJ in hopes that it would support this patient's continued healing and physical therapy. Adequate pain control in the short term can lead to long-term, opioid-free pain relief. The indication, after all, was for an acute bone fracture and LJ's pain seems to be secondary to inadequate healing of the fracture.

However, in opioid-naïve patients, recovery from surgical pain frequently leads to long-term opioid use¹ and dependence. Prescription of opioids for nonchronic pain has increased in recent years in the United States,¹ which now faces a crisis of widespread opioid misuse. According to the Centers for Disease Control and Prevention, there were 47 600 deaths related to opioid misuse in 2017, representing an astonishing 67.8% of all drug overdose deaths.² In the same year, more than 191 million opioid prescriptions were filled in the United States.³ These facts, surely known to Dr M, would give her good reasons to recommend alternatives to continued opioid therapy.

Dr M could recommend an opioid taper and non-opioid pain medications, such as acetaminophen or nonsteroidal anti-inflammatory drugs, assuming LJ has no contraindications for such therapies. While an opioid taper could be helpful, particularly given Dr M's concern that LJ is developing dependence, several considerations suggest that continuing opioid therapy could also be appropriate. It will be important for Dr M to gather more information about LJ's opioid use and, ideally, engage LJ in a process of shared decision making to arrive at a treatment plan.

Shared decision making (SDM), a component of patient-centered care, has been defined by Elwyn et al as "an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences."⁴ By upholding the principles of respect for autonomy and beneficence, SDM facilitates more meaningful

and appropriate informed consent.⁵ Several studies have demonstrated SDM's benefits in the context of opioid prescribing. SDM can reduce opioid use⁶ and increase physician satisfaction in prescribing opioids for patients with chronic pain.⁷ Moreover, the finding that patients and clinicians offer conflicting narratives about chronic opioid therapy underscores the special need for SDM among these patients.⁸

Opioid Start Talking Form and Shared Decision Making

In Michigan, recently passed laws^{9,10,11,12,13,14,15,16,17,18} concerning [outpatient opioid prescribing](#) seek to reduce opioid misuse, addiction, and diversion; prevent opioid overdose deaths; and eliminate inappropriate practice. These laws' provisions for opioid management include providing patients who have experienced an overdose with information about substance use disorder and available services. However, for the purposes of our case discussion, we will focus on the relevant portions of the laws that affect Dr M's prescription of opioids for LJ.

Michigan Public Acts passed in 2017 require prescribers to review with patients the dangers of opioid addiction, how to properly dispose of unused opioids, and that distribution or diversion of opioid medication is a felony.⁹ Prescribers must also review with pregnant patients the risk of exposing a fetus to an opioid.⁹ That prescribers reviewed this information must be documented on the Opioid Start Talking consent form and in the patient's health record.⁹ The Opioid Start Talking form includes patient identifiers, type and quantity of a prescribed drug, and patient acknowledgment that risks, benefits, and proper medication management were reviewed by the prescriber. Additionally, if prescribing more than a 3-day supply of an opioid, prescribers must obtain and review a report from the state's prescription drug monitoring program.¹¹ (In Michigan, this program is known as the Michigan Automated Prescription System.)

How might these laws affect a prescriber's ability or willingness to engage in SDM? Despite its time requirement, the Opioid Start Talking form could be used to facilitate SDM during outpatient encounters. Implementing patient-provider agreements to define patients' roles and responsibilities while using opioids has been shown to be helpful in presenting risks and benefits and in making decisions about treatment.¹⁹ These and other patient-centered approaches improve patient outcomes and satisfaction,^{6,7,8} and, ideally, the administrative and logistical burdens imposed by the new laws would not prevent clinicians from engaging in SDM. However, because these burdens exacerbate time constraints within which physicians already work, they could threaten the patient-physician therapeutic alliance, which needs time and care to build and maintain.

Enter Decision Science

Developments in decision science can help clinicians implement SDM within an increasingly [time-constrained clinic schedule](#). Several decision support techniques, for example, have been inspired by behavioral economics.²⁰ *Choice architecture* is one such

technique described by Moore et al as “the art of shaping decisions by designing choices within a framework that will encourage a certain choice.”²¹ Imagine that Dr M prefers a particular treatment plan for LJ and still wants to use SDM to foster a therapeutic alliance within the constraints of her clinic schedule. One technique in particular—*nudging*—can be especially useful in facilitating SDM in such circumstances.

Nudges can be used to frame decisions about the appropriate treatment without eliminating patient choice.²¹ For example, whether Dr M tells LJ that “continuing your current opioid prescription has a chance of leading to opioid dependence in 15% of cases” or “continuing your current opioid prescription will not lead to dependence in 85% of cases” can influence how LJ frames the decision and chooses to proceed. Dr M’s choice of which phrase to use during shared decision making with LJ would enable LJ to retain decision-making authority and Dr M to bring to bear her clinical expertise and experience.

Although nudges might seem to undermine patient autonomy, Aggarwal et al note that paternalism and autonomy are extremes “not compatible in a ... moral health care environment” and that “some compromise of these values is unavoidable.”²² Fridman et al found that both physicians and nonclinicians viewed using nudges to overcome patient decision-making biases more positively than not using a nudge.²³ Nevertheless, the ethicality of nudges is context dependent, and prescribers should use language to influence the formation of patients’ perspectives and decisions only to promote patients’ best interests.

Framing and Therapeutic Alliance

If Dr M prescribes more opioids for LJ, the approach she takes will influence the nature of her relationship with LJ. Clinicians are not typically required to complete forms when prescribing, and some patients might be offended that their physician requires their signature on a form explaining that dealing opioids is illegal. The Opioid Start Talking form must be thoughtfully introduced and framed to prevent the form from becoming a symbol of distrust or suspicion. However, it should be noted that Tobin et al question the language used in an analogous form, the patient-provider agreement (ie, “pain contracts” for patients receiving chronic opioid therapy), which seems to stigmatize the patient and thereby risk undermining patient-clinician trust.²⁴ Although the Opioid Start Talking form could facilitate shared decision making in some cases, it could threaten the therapeutic alliance in others. Framing the Opioid Start Talking form in terms of shared decision making about opioid management for pain care could help avoid distrust.

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CASE AND COMMENTARY

How Should We Determine the Value of CAR T-Cell Therapy?

Sara Silbert, MD, Gregory A. Yanik, MD, and Andrew G. Shuman, MD

Abstract

In 2017, the US Food and Drug Administration approved the first chimeric antigen receptor (CAR) T-cell therapies for patients with relapsed or refractory B-cell leukemia and selected B-cell lymphomas. This novel form of cellular immunotherapy creates a “living drug” that effectively reprograms a patient’s T cells to target specific antigens on the surface of a tumor. The therapy has high response rates in patients with refractory disease, although a single infusion of CAR T cells costs hundreds of thousands of dollars. A value analysis is required to determine whether and how to offer patients these expensive, customized drugs.

Case

The US Food and Drug Administration (FDA) approved the first chimeric antigen receptor (CAR) T-cell therapy in 2017 for patients with relapsed or refractory B-cell malignancies. This novel form of cancer immunotherapy uses a patient’s own T cells to customize a drug to treat that particular patient’s B-cell malignancy. According to then-FDA Commissioner Scott Gottlieb, this development “marks another milestone in the development of a whole new scientific paradigm for the treatment of serious diseases.”¹

One course of this precision treatment costs \$373 000 or \$475 000 (depending on the type of B-cell malignancy),^{2,3} with high 1-year survival rates in clinical trials (at least 41%, depending on type of B-cell malignancy).² The high costs of CAR T-cell therapy are not unique in the rapidly expanding world of cancer drugs. Using analytical tools, economic principles, and the behavioral psychology of decision science, payers and health care organizations need to do a value analysis to determine whether and how to offer patients these expensive, customized drugs. Such an analysis is necessary to inform policy and practice decisions about potential risks and benefits of making these drugs available for some patients’ needs relative to those of other patients.

Commentary

B-cell acute lymphocytic leukemia (B-ALL) is the most common cancer of childhood.⁴ For most patients, prognosis is good, with 5-year overall survival reaching 90%.⁵ However, for patients who do not achieve remission or experience relapse and require second- and

third-line therapies, prognosis is poor.^{2,6,7} The FDA has now approved the use of 2 novel CAR T-cell therapies to treat B-ALL and diffuse large B-cell lymphoma (DLBCL). In August 2017, the FDA approved tisagenlecleucel, an anti-CD19 CAR T-cell therapy, for use in patients (through age 25) with B-ALL.⁸ In October 2017, axicabtagene ciloleucel was the first CAR T-cell therapy approved by the FDA for use in relapsed or refractory DLBCL.¹ In 2018, tisagenlecleucel also received FDA approval for use in relapsed or refractory DLBCL.⁹ These innovative therapies involve genetic reprogramming of a patient's immune surveillance cells (T cells) and hold great promise for treating these and other malignancies.

Nevertheless, these therapies are expensive, with the 2 approved drugs priced at \$475 000 for B-ALL and \$373 000 for DLBCL.^{2,3} With limited data on long-term survival, questions about the [cost effectiveness](#) and value of these drugs are worth asking.^{2,3} In what follows, we examine whether and how to offer patients CAR T-cell therapy. More specifically, we address (1) value analysis and its application to CAR T-cell therapy, by means of which payers and health care organizations assess whether to offer patients these drugs in light of their expense and the risk of adverse effects on other patients and resources; (2) factors that might complicate equitable access to these drugs; and (3) how much patients and families should be told about these therapies' costs.

Measuring Value

As medicine advances, costs of care tend to rise. In a health system with finite resources, decisions must be made about how to allocate funds, justly distribute risks and benefits of innovations, and assess and interpret new interventions' value. The principle of distributive justice suggests that health care resources should be fairly and equitably allocated. In order to be useful for [resource allocation decisions](#), value-based approaches to care must not only be evidence based but also incorporate quality-of-life considerations and costs.¹⁰ Value is commonly measured via cost effective analysis using measures such as life years (LY), quality-adjusted life years (QALY), and associated incremental cost effectiveness ratios (the net cost divided by the net QALYs gained) that enable comparison of interventions in terms of their value. These measures facilitate a clearer understanding of how to maximize efficiency by quantifying how to spend the least amount for the greatest gain.

The Institute for Clinical and Economic Review (ICER) "evaluates medical evidence and convenes public deliberative bodies to help stakeholders interpret and apply evidence to improve patient outcomes and control costs."² In 2018, ICER analyzed CAR T-cell therapies, comparing their clinical effectiveness (remission rates, event-free survival, adverse events) with that of comparable treatment regimens using projective cost effectiveness models.² For B-ALL, the total cost of therapy was \$667 000 with 10.34 LYs and 9.28 QALYs gained. For a comparable chemotherapy (clofarabine based), the total cost of therapy was \$337 000 with 2.43 LYs and 2.10 QALYs gained. In the model

evaluating axicabtagene ciloleucel for DLBCL, the total cost of therapy was \$617 000 with gains of 7.35 LYs and 5.87 QALYs. For the comparable chemotherapy, the total cost of therapy was \$155 000 with gains of 3.23 LYs and 2.48 QALYs. Despite the higher cost of the CAR T-cell therapy in both groups, gains in life years and QALYs were also greater in both groups. As a result, the incremental cost effectiveness ratios were \$46 000 per QALY gained for CAR T-cell therapy compared to chemotherapy in B-ALL and \$136 000 per QALY gained for CAR T-cell therapy compared to chemotherapy in DLBCL.²

Integrating Equity Into Value Analyses

Decision science involves a multimodal analysis of the economic, political, societal, and ethical implications associated with the outcome of a decision.¹¹ While cost effectiveness measures yield numbers that can be used to define and compare value, we must also consider equity in health care resource allocation decisions.¹² Once QALYs and incremental cost effectiveness ratios have been generated, we must then determine threshold(s) for acceptable value. In the United States, thresholds of \$100 000 or 150 000 per QALY gained have been suggested as a reasonable upper bound for an intervention to be deemed cost effective.¹³ Others, however, argue that what counts as an acceptable threshold is arbitrary and does not necessarily facilitate just resource distribution.¹⁴ In addition, because we are operating under a fundamentally flawed model of how drug prices are set, QALY calculations can in some circumstances not only determine what is cost effective but also how drug manufacturers artificially inflate prices.

Although ICER's cost effectiveness analysis would suggest that CAR T-cell therapy is of value, comparative value does not equate with equity. It does not consider issues of just allocation—including [access to therapy](#)—and individual and institutional bias. Furthermore, given limited short-term outcomes data, it becomes difficult to justify the use of CAR T-cell therapy over alternative therapy options. It is similarly difficult to expect insurers to cover a one-time intervention costing close to fivefold the US gross domestic product per capita.¹⁵ But a purely utilitarian calculus is not appropriate, either. If the goal were to simply maximize health benefit, the majority of funding for cancer treatment would be funneled to improving malaria treatment and water quality in the developing world. We, as a nation and as a society, are comfortable absorbing disproportionate costs, but where the line between acceptable and unacceptable costs should be drawn is much more complicated.

Other Factors and Implications

Despite the promise that CAR T-cell therapy holds, it might be too soon to understand its true value. As discussed, although initial outcome projections show favorable cost effectiveness, questions remain with respect to whether there is equitable and just access to therapy. Let us consider complicating issues of age, insurance coverage,

clinician bias, and disease status, and the effects that these factors might have on just or equitable access to CAR T-cell therapy.

1. The definitive licensing trials of tisagenlecleucel started at age 3 years,¹⁶ yet the drug has been approved for children ages 0 to 25 years.⁸ Is it appropriate to offer and reimburse a therapy for infants or toddlers when efficacy data is limited in this age group? Likewise, should it be offered and reimbursed for young adults with B-ALL over the age of 25?
2. The Centers for Medicare and Medicaid Services recently proposed coverage for CAR T-cell therapy in an approved study registry.¹⁷ While this policy change will expand access to therapy to those covered by Medicare, what does it mean for patients on Medicaid, and how will other insurers respond? How might differing coverage models influence which therapy clinicians choose to offer or what therapy patients are able to choose?
3. The drug manufacturer of tisagenlecleucel has created an outcomes-based agreement that only requires payment for those patients showing morphologic regression within one month of CAR T-cell infusion.³ This begs the question of whether such a payment model could incentivize physicians to use this product. While payment for the drug will occur regardless of outcome, if the company selling the drug takes on the cost (and presumably passes it on to consumers), might that simplify reimbursement and make it a more enticing product to use? If so, it would seem that stakeholders need to be privy to such potential for bias.
4. Not all CAR T-cell recipients are expected to respond the same way. Patients with a higher disease burden have a greater likelihood of developing toxicities following CAR T-cell infusion.¹⁸ Many patients might require an allogeneic bone marrow transplant as consolidative therapy post CAR T cells.¹⁹ These complications could significantly reduce the predicted value of the therapy given its high cost and negative effects on quality of life, raising questions about whether we should be offering CAR T-cell therapy to patients we expect will have worse side effects or require additional intensive therapy.

Patient Involvement and Ethical Implications

As we consider issues of value and equity, we must also assess the degree to which patients should be involved in the decision-making process regarding the use of expensive therapies. In some situations, some or all costs of considered interventions fall to patients, making cost a major factor in patient decision making. A 2009 statement by the American Society of Clinical Oncology "affirms the critical role of oncologists in addressing cost of care with their patients.... [C]ommunication with patients about the cost of care is a key component of high-quality care."²⁰ Financial toxicity is indeed a

major and understudied barrier to medical treatment in the United States and suggests the importance of the question of whether costs should be included in CAR T-cell therapy discussions with patients.

Arguments can be made for limiting patient involvement. Opponents to the notion that cost should be discussed with patients could argue that the majority of costs are not incurred by most patients. Some might argue that disclosure of cost could be interpreted as pressure not to pursue CAR T-cell therapy or that discussion of cost might overwhelm patients already facing difficult situations.

Yet others still might argue that cost information is relevant to patient decision making. Some patients have their own views on public health and resource allocation. Others might find comfort in knowing the amount being spent to try to save their life. For many patients, any cost is a financial toxicity, and having the numbers will factor into their treatment decision even if co-pays are a fraction of total expense. In the case of CAR T-cell therapy, some of the costs are hidden or delayed, as the cost of T cells accounts only for T-cell retrieval, modification, and infusion—not for hospitalization, subsequent therapy, or the inherent complications of cancer treatment, both expected and unexpected.³

Regardless of the merits of these arguments, we must consider that withholding cost information from patients could be unjust. Should not all patients be offered all relevant information, including cost, that could influence their health care choices? Moreover, should they not be offered cost information in a form they can understand? Another key and often overlooked component in disclosure is information evaluability, which requires including “use-relevant contextual information.”²¹ More specifically, price per QALY has no immediate relevance to patients who care most about what they will need to pay out of pocket. It certainly does not relate to how expenses incurred by society at large might influence others. How to efficiently or clearly integrate cost and equity into a decision aid or other discrete-choice tool remains a fundamentally unresolved question.

Conclusion

Decisions about allocation of health care resources require a multimodal approach. While the numbers suggest that there might be great value in CAR T-cell therapy in B-ALL and DLBCL with regard to cost effectiveness, measures of value with regard to equity are less clear. Until access to these therapies expands and more data accrue, we must temper our excitement about CAR T-cell therapies with the reality of their multifaceted impact on our patients, their families, and the health system as a whole.

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CASE AND COMMENTARY

How Should Decision Science Inform Scarce Blood Product Allocation?

Eric Kersjes, MD and Lauren B. Smith, MD

Abstract

Blood products are a scarce resource in our health care system. This article discusses a pediatric case involving large quantities of blood products transfused at the end of life. It argues that decision aids could help clinicians determine when to request ethics consultation or re-evaluation of blood product usage in a specific patient care situation and considers questions about scarce resource allocation, futility, and parental involvement in decision making.

Case

Sam is a 10-year-old boy with influenza who was admitted for respiratory failure. His clinical condition rapidly deteriorated, and he was placed on extracorporeal membrane oxygenation (ECMO). Sam developed sepsis, which led to multisystem organ failure, and now he requires continuous transfusions of packed red blood cells, platelets, and fibrinogen. To date, hundreds of blood products have been administered to Sam without any improvement in hemostasis. After suffering cardiac arrest and cardiopulmonary resuscitation after an ECMO line was lost, Sam is also now suspected to have neurological damage. Sam's chance of recovery at this time is extremely low. The team has discussed Sam's prognosis with his parents, who insist on continuing aggressive care.

Commentary

Pediatric critical care entails unique stressors due to the integral roles parents play in decision making for their minor children. When children become critically ill, parents and families are faced with unexpected choices and demands. Although ethics consultation is available, most children's hospitals receive 10 or fewer requests for ethics consultations annually.¹ And when pediatric ethics consultations are requested, deliberation is commonly about withdrawing or withholding treatment,² as demonstrated in this case. Questions about [scarce resource utilization](#), futility, and navigating conflict between parental preferences and a child's best interest are also common. Here we consider how decision aids can be used in ethics consultation to help facilitate decision making and resolution in these types of cases.

Blood Product Allocation

Blood products are scarce resources that require donation, and shortages occur.³ Often used to treat critically ill patients and those nearing the [end of life](#), blood products can be difficult to ration because they are used frequently and can be vital to survival. In the United States, the moral acceptability of [bedside rationing](#) is debated,⁴ with justice and beneficence being two of the prominent ethical principles in conflict.

Blood product shortages can be compared to drug shortages. For example, hospitals have attempted to make policies guiding fair allocation of chemotherapeutic agents during shortages.⁵ In one hospital, policy stipulates that the allocation committee (which includes ethics representatives) meet if a shortage is projected and that a drug have probable benefit for the patient; the policy was communicated to staff and to patients whose care could be affected by a shortage.⁵ Policies such as this one could be translated into decision aids that would allow clinicians to follow the guidelines more uniformly.

The second author (L.B.S.) and colleagues have similarly proposed guidelines for allocating blood products when supply is low and demand is high.⁶ More specifically, it was proposed that scarce resources be limited for use in palliative care patients, although short-term use for symptomatic relief is acceptable. It was also proposed that transfusions be avoided in cases in which they do not meet goals of care for a patient, particularly in times of shortage. Ideally, decision aids could be created based on these guidelines that would facilitate just blood product allocation in most cases, with unique, unusual, or ethically complex cases being referred for ethics consultation.

In this case, Sam receives large numbers of blood products as part of ECMO, which might be seen by some as overuse or excessive depletion of a hospital's blood product supply. His treatment team has been using maximum interventions, with no improvement in his overall prognosis. Blood transfusions are not clinically appropriate and would not improve his chance of survival; massive transfusion poses risks of coagulopathy, transfusion-related acute lung injury, and systemic inflammatory response syndrome.⁷ These particulars of Sam's case suggest that continued blood product use could be unjust, since it offers no benefit, prolongs his imminent death, and could deprive others of lifesaving interventions. Based on the guideline that transfusions should meet goals of care, one could argue for the ethical permissibility of discontinuing Sam's transfusions.

Yet without a process for reliably distinguishing futile from beneficial transfusion, discontinuing transfusion might seem arbitrary. Sam's case illuminates both our discomfort with rationing and our acceptance of the view that limits are warranted in some cases. This tension is one reason to consider translating guidelines into decision aids for assessing blood product utilization, particularly in pediatric intensive care settings.

Policy-Based Decision Aids

In pediatric cases, parents are typically the decision makers, as children cannot consent unless they reside in a state that recognizes “mature” or “emancipated” minor status.⁸ Parents usually have a child’s best interest in mind. However, as Santoro and Bennett note:

This protective parental role, while critically important and valid, must be balanced and possibly tempered with sound medical practice that weighs quality of life and realistic expectations of outcomes.... It is important to involve parents regarding discussing and educating them on the child’s development and condition.⁹

Honoring parents’ authority to make decisions is particularly challenging when their decisions conflict with a care team’s clinical recommendations. Clinicians also have a child’s best interest in mind, and they have the expertise and knowledge to assess what is medically possible. Pediatric intensive care can place significant psychological stress on parents,¹⁰ and it is one factor among many that can influence parental decision making.^{9,11} An example of a parental decision that would not be honored is one in which the parents refuse recommended lifesaving treatment, such as Jehovah’s Witness parents refusing recommended blood products to save a child suffering massive hemorrhage.¹²

Decision aids could be designed based on organizations’ policy guidelines to facilitate parents’ contributions to treatment planning. For example, decision support systems, which can be thought of as computerized decision aids tailored to individual patients, have been used to improve blood product usage,¹³ overall and in pediatrics.¹⁴ Such support systems could trigger ethics consultations in patient care situations in which standard blood product usage has been exceeded in order to avoid long delays in addressing whether and when a particular case constitutes futility or overutilization.

Futility

Medical futility has no universally accepted definition,¹⁵ but words such as *excessive*, *inappropriate*, *nonbeneficial*, *ineffective*, or *useless* are sometimes used when talking about it, as are concepts such as benefits and burdens, probability of success, resources utilization and cost, personal values, and professional duties.¹⁶ Physician trainees who participate in care they perceive as futile can experience moral distress along with emotional detachment from their patients.¹⁷ Institutional [policies regarding futility](#) can help ease these burdens by clarifying the nature and scope of physicians’ responsibilities in withholding and withdrawing treatments. The University of Michigan Health System, for example, has adopted the following policy:

When a medical intervention is futile, the attending physician is under no obligation to initiate, or to continue such treatment, even though it may have been requested by the patient, or the patient’s family or

representative(s). For the purpose of this section, an intervention is considered futile when it cannot accomplish the intended physiologic goal.... Treatments that the health care team believes have no reasonable medical chance of achieving the outcome sought beyond minor physiologic changes are outweighed by the danger to the patient, and/or would not achieve a medically appropriate goal are considered to be nonbeneficial treatments...

When the attending physician has documented these determinations in the patient's medical record, and another physician with appropriate expertise who has no prior or present relationship with the patient has examined the patient and reached the same medical conclusions and similarly has documented this ... the patient's attending physician is under no obligation to initiate or to continue any interventions deemed inappropriate.¹⁸

Policies like this one can also be helpful for parents like Sam's because they counteract the perception that decisions to withhold or withdraw treatment are arbitrary or nonstandard. In Sam's case, continuing transfusion would meet the University of Michigan Health System's definition of nonbeneficial care as being unable to "accomplish the intended physiologic goal."¹⁸ Since patients and families are the stakeholders most affected by other stakeholder's views of futility, it is important to explore their opinions and have open conversations early.¹⁶

Decision Aid Partnering

For cases involving ECMO or massive transfusions, development of decision aids for intensive care units or early involvement of hospital ethics committees should be considered. Our institution has developed a program of *preventive ethics* wherein an ethics consultant rounds regularly in intensive care settings and attempts to identify ECMO or transfusion cases that might progress to deliberations about futility or resource overutilization. Determining ethically appropriate end-of-life care is a common reason why pediatricians request ethics consultations, and most report that these consultations were helpful in decision making.¹⁹ For patients receiving blood products, clinicians should draw upon available guidelines and decision aids, particularly when using extremely scarce resources such as crossmatched and HLA-matched platelets or in situations in which there is need to reserve blood products for other patients.⁶ If blood products are initiated and warranted, their continued usage must be regularly re-evaluated to ensure that it is consistent with goals of care. Decision aids can assist clinicians in determining when blood product usage should be re-evaluated, perhaps based on the number of units used or the product's scarcity. Decision aids that provide appropriate parameters for transfusion, especially when developed in conjunction with an organization's transfusion medicine service, can promote appropriate utilization.

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STATE OF THE ART AND SCIENCE

Should Clinicians Leave “Expanded” Carrier Screening Decisions to Patients?

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Abstract

Many patients choose to undergo some type of carrier screening when pregnant or planning to become pregnant. “Expanded” carrier screening products test all patients for the same conditions, regardless of family history, race, or ethnicity. Proponents of expanded screening argue that testing everyone for everything can identify more couples at risk of having an affected fetus. However, most conditions on expanded carrier screening panels do not adhere to criteria recommended by professional organizations and can leave patients with a positive test result but little helpful information about actual clinical risk for their future baby. Confusion persists about whether clinicians should leave carrier screening decisions to patients.

Need for More Accurate Carrier Screening

Many patients choose to undergo reproductive genetic testing either when they are planning to become pregnant or once they are pregnant.^{1,2} One type of reproductive genetic test is carrier screening, used to identify people at risk of having a child with an autosomal recessive or X-linked recessive genetic condition. If both the woman and her male partner are found to be carriers, the child has a 25% chance of being affected by the disease and a 50% chance of being a carrier.

But genetic testing can be expensive and cause patients anxiety as they wait for preliminary or confirmatory test results. In an attempt to balance these concerns with the clinical utility of test results, professional organizations such as the American College of Medical Genetics and Genomics (ACMG) and the American College of Obstetricians and Gynecologists (ACOG) generally recommend offering carrier screening on the basis of family history (ie, an affected blood relative), affected race or ethnicity (eg, Tay-Sachs disease screening in Ashkenazi Jews or sickle cell disease screening in African Americans), or because the condition is deemed worthy of universal screening (eg, cystic fibrosis in the United States) (see Table).^{3,4} Receiving positive test results can have serious clinical implications for patients,⁵ including invasive confirmatory testing if available for the condition (eg, chorionic villus sampling, amniocentesis, or fetal sequencing) or even pregnancy termination (a decision often constrained by state law,⁶ such as before 24 weeks). It is therefore critical that patients receive timely genetic

information about their pregnancy that is accurate, reliable, of clinical use, and presented in an understandable fashion.

Table. American College of Obstetricians and Gynecologists' Carrier Screening Recommendations^a

Basis of Screening	Rationale	Example(s)
Family history	Increased individual risk	<ul style="list-style-type: none"> Blood relative affected with inheritable disease
Race or ethnicity	Increased population risk on the basis of race or ethnicity	<ul style="list-style-type: none"> Tay-Sachs in Ashkenazi Jews
Panethnic	"Particular disorders are less likely to be confined only to a specific high-risk ethnic group because of the increasing frequency of ethnic admixture of reproductive partners."	<ul style="list-style-type: none"> Cystic fibrosis Spinal muscular atrophy

^aData and quotation from American College of Obstetricians and Gynecologists.⁷

Currently, the choice between targeted and expanded carrier screening is being approached as a preference-sensitive decision for the patient (and potentially her partner) with the support of her clinician. However, given current high rates of false positive test results and that patients might fail to anticipate how they would react to positive expanded carrier screening results,^{2,8} we argue that this problem is not one of patient values clarification but rather a lack of information at the onset of the decision-making process.

Advantages and Disadvantages of Expanded Carrier Screening

In 2009, expanded carrier screening entered the market.⁹ Expanded carrier screening products test all patients for the same carrier conditions—whatever their reported family history, race, or ethnicity—and are generally exempted from US Food and Drug Administration approval due to the perceived low risk of any one piece of information being a false positive.¹⁰ Currently, 15% of obstetricians report offering expanded carrier screening to all of their patients and 52% of obstetricians report ordering expanded carrier screening upon patient request.^{11,12} Proponents of expanded carrier screening argue that testing everyone for everything can identify more couples at risk of having an affected fetus in an increasingly diverse country and that the use of expanded carrier screening does not rely on patients having accurate knowledge of their ancestry or family history.^{9,13}

However, there are downsides to moving away from a targeted approach to genetic testing. Approximately 73% of conditions on expanded carrier screening panels do not adhere to the narrowly tailored criteria based on the ACMG and ACOG guidelines discussed above,¹⁴ and critics warn that upwards of 24% of patients may test positive for an expanded carrier screening condition that is extremely rare in any population or for genetic variants for which the sensitivity, specificity, and predictive value of the test are based on ethnicity-specific populations.^{11,15,16} As a result, patients could receive a positive test result but very little information regarding actual clinical risk for their future baby. The low-to-no clinical utility of many expanded carrier screening results raises the question of whether the additional information being returned is worth the potential harm of follow-up testing cost and risk (eg, a slight increased risk of miscarriage for an amniocentesis¹⁷) as well as increased anxiety and confusion for patients who often must make critical reproductive decisions quickly.

In addition, the current expanded carrier screening landscape is variable in terms of conditions screened, testing methodology, and genetic variant interpretation and reporting practices.¹⁸ A 2017 global analysis of expanded carrier screening providers (ie, companies, hospitals, and labs) found drastic differences between tests offered by different providers; the number of conditions included ranged from 41 to 1792.¹⁸ Only 3 conditions were screened by all providers. In some instances, expanded carrier screening panels include an autosomal codominant disorder for which testing of asymptomatic adults without prior increased risk is currently discouraged by the American Thoracic Society/European Respiratory Society.¹⁹ Clinicians are currently tasked with maintaining a grasp on this highly variable testing landscape and on evolving variant classifications and test limitations.

Expanded Carrier Screening in Clinical Practice

Here we argue that current confusion about whether targeted or expanded carrier screening is appropriate appears to result not from a failure of shared decision making but from a lack of critical information on the part of both clinicians and patients.^{20,21}

Clinicians. One major concern is that clinicians are not adequately prepared to perform pre- and posttest counseling for expanded carrier screening. This counseling is generally performed by obstetricians without specialized training in genetics—let alone in expanded carrier screening.^{2,12} In one survey, only a third of obstetricians reported comfort in counseling patients on whether to get expanded carrier screening and only a fourth reported comfort with explaining expanded carrier screening test results.¹² In a joint statement of ACOG and several other organizations, recommended best practices for pretest counseling of expanded carrier screening include (1) an explanation of the types of conditions being screened as well as the limitations of screening; (2) a discussion of conditions that have less well-defined phenotypes; (3) a discussion of

disease prevalence, mutation frequencies, and detection rates and of the imprecision of these estimates and the unreliability of residual risk estimates; (4) an explanation of negative test results and how a residual risk of being a carrier always remains, and (5) the recommendation that testing be performed once in a lifetime despite differences between providers and changes in expanded carrier screening over time.²² Despite these high standards for pretest counseling, given that there are approximately 4000 professional genetic counselors in the United States (approximately 1 for every 82 000 persons),²³ it is likely that the majority of communications regarding carrier screening options and results will fall to obstetricians and midwives, who will be challenged to meet such criteria.¹² Implementing these counseling recommendations, let alone communicating the required information effectively to patients, requires substantial time and expertise.

Patients. We know that patients with access to a [genetic counselor](#) are able to more accurately describe the science of carrier screening,⁸ but many patients do not fully comprehend the meaning of expanded carrier results. For example, in one retrospective study of patients who underwent expanded carrier screening, women reported being interested in the information to inform their choice of whether to terminate their pregnancy—despite the fact that carrier screening is nondiagnostic (ie, because even if both the male and female partners are carriers, the child only has a 25% chance of being affected by the disease).⁸ In addition, many women were surprised that they had a positive test result despite receiving counseling on the high rate of false positive findings, and they found the testing process to be anxiety inducing.⁸ Previous research has established that both obstetricians and genetic counselors are skeptical about whether expanded carrier screening offers additional benefits to patients to counteract the potential harms of false positives and additional follow-up testing.^{2,12} Some women also fail to anticipate how they will respond to positive results—and what steps they would be willing to take down the diagnostic pathway—before consenting to the test. In one study, almost half the women who chose to undergo expanded carrier screening and received a positive test result did not take the next step of bringing in their partner for testing, indicating either that they misunderstood the purpose and risks of the test to begin with or that they failed to anticipate how they would respond to receiving a positive result.⁸ Consequently, there has been a clear failure to provide patients the information they need to adequately make this choice.⁸

Thus, while many clinicians are currently approaching the choice of targeted vs expanded carrier screening as one that should be left up to individual patient preference, there are indications that a failure of understanding—on the part of both practitioner and patient—of the risks and limitations of expanded carrier screening is confounding this decision-making process. Given that many clinicians report being uncomfortable with counseling patients on expanded carrier screening,¹² clinicians and patients should

instead rely on current professional recommendations that have already thoughtfully weighed the risks and benefits of individual carrier tests.^{3,4}

Conclusion

Recommendations made by professional organizations can assist clinicians in presenting the risks and benefits of available carrier screening options to patients, whereas manufacturers of expanded carrier screening tests often advocate for a “more-is-better” approach as a marketing tactic to differentiate their services for patients and clinicians.^{24,25} In the face of increased choice and complexity in the expanded carrier screening market, clinicians who are unable to offer patients genetic counseling or to contextualize the carrier screening options within the current literature are encouraged to take professional society recommendations into account.

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MEDICINE AND SOCIETY

How Should Decision Aids Be Used During Counseling to Help Patients Who Are “Genetically at Risk”?

Natalie Evans, PhD, Suzanne Metselaar, PhD, Carla van El, PhD, Nina Hallowell, DPhil, MA, and Guy Widdershoven, PhD

Abstract

People with genetic predispositions to disease are faced with uncertainty about whether, when, and to what extent an illness will actually develop. This prognostic uncertainty, combined with knowledge that preventative interventions (eg, risk-reducing surgeries for familial cancer syndromes) could significantly affect people’s lives, renders prevention decisions especially challenging. This article illuminates ethical questions about the use of decision aids for people with genetic predispositions and calls for approaching individual decisions in light of ongoing communication and reflection about a person’s life goals and values.

Everyone who is born holds dual citizenship, in the kingdom of the well and in the kingdom of the sick. Although we all prefer to use only the good passport, sooner or later each of us is obliged, at least for a spell, to identify ourselves as citizens of that other place.

Susan Sontag¹

Decision Making and Genetic Risk

As Sontag’s quote boldly illustrates, health and illness are generally seen as dichotomous categories: one is either sick or healthy. Yet the rapid development and implementation of genomic medicine is challenging this duality by increasing the presence of yet another type of “citizenship”—namely, for those who are “genetically at-risk.”² In dealing with this new category, health services face several challenges, including how to communicate complex information on individual and familial risk and how to support decision making on preventative treatment options.³

As people become increasingly aware of their genetic predispositions, more will face decisions about prevention efforts such as lifestyle changes and risk-reducing treatments (eg, surgeries for familial cancer syndromes). Prevention efforts might involve difficult trade-offs between quality of life and risk reduction, because in some

cases reducing risk of future ill-health is only possible with some sacrifice of current quality of life. Furthermore, in the case of genetic predispositions, people are faced with uncertainty about whether, when, and the extent to which an illness might actually develop. This prognostic uncertainty, combined with the fact that any preventative treatments might significantly affect people's lives, renders decision making about such interventions especially challenging. It is therefore all the more important that these decisions take into account people's norms, values, and life goals.^{4,5,6} This article examines the need for genetic counseling and decision aids for people with genetic predispositions and calls for innovation in both communication processes and decision aids in order to embed individual decisions in a broader process of ongoing reflection on personal life goals and values.

Genetic Counseling

Current decision-making supports in the context of genetic risk are proving inadequate. Genetic counselors help patients to assess their genetic risk and consider interventions in a nondirective way, which entails providing complete and unbiased information, refraining from revealing their own preferences,^{7,8} and helping align care with a patient's and family's values.⁹ Genetic counseling services are, however, in high demand, and care and treatment [discussions about genetic risk](#) are increasingly occurring outside of the genetic counselling setting, particularly in primary care,^{10,11} oncology,¹¹ and surgery.¹² Patients also discuss known genetic risks with a variety of health professionals—not all of whom are well informed about patients' stated goals and values.¹³ For example, in the case of patients with BRCA 1 and 2 familial cancer syndromes, the availability of multiple (preventative) treatment and screening options means that some patients with a mutation are cared for by a succession of health care professionals in general practice; clinical genetics; and screening, reproductive, and surgical services. Specialization and fragmentation of care can lead to piecemeal, incomplete, and conflicting information about care and treatment options.

In response to the growing need to support communication and decision making in the context of genetic risk in different clinical settings, a variety of decision aids have been developed. For example, in the case of familial cancer syndromes, decision aids have been developed for [diagnostic genetic testing](#),¹⁴ reproductive decisions,¹⁵ and preventative treatment decisions.^{16,17} Decisions about how to respond to genetic risk, however, pose ethical questions that call for innovation. In what follows, we discuss the goals and ethical challenges of using decision aids in the context of genetic risk.

Need for Innovating Decision Aids

Decision aids have been developed for "preference sensitive" decisions, for which the best option depends on a patient's perception of an optimal trade-off between harms and benefits.¹⁸ They have been designed to increase patient participation in decision making and to enhance rather than replace patient-professional communication.

Decision aids have 3 principle goals: to improve patient understanding of risks and benefits, to help patients clarify their values, and to help patients make decisions consistent with those values.¹⁸ Their development should be guided by decision science, which assumes that, in any given context, a best decision can be revealed—or at least approximated—by using a decision-making process or model.¹⁹ Risks that deserve ethical and clinical consideration include decontextualization, detachment, and fragmentation.

Decontextualization. A patient's familial, social, and cultural context are rarely considered in the development of genomic medicine decision aids, despite evidence suggesting that preference-sensitive decisions are influenced by patients' perceptions of successes or failures of approaches taken by other family members with the same condition,^{20,21,22} by perceptions of familial responsibility (eg, parents can be more inclined to choose aggressive preventative options),²³ and by attitudes and preferences of partners or members of their social networks.²⁴ Decision aids' underlying assumptions and value clarification methods (eg, utility theory in decision tree analysis)²⁵ could muddle a patient's decision-making process or be incompatible with a patient's normal decision-making style. Put differently, decision aids can impose a *system* on the decision-making process that alienates a patient from his or her *lifeworld* of shared social experience.²⁶

Detachment. Using decision aids to guide patients' decisions might be particularly tempting in situations in which it is impossible for clinicians to know whether a patient will develop a disease. This uncertainty could lead some clinicians to delegate to a decision aid the tasks of providing risk information, describing options, and clarifying values. The tendency to "retreat behind a technique"²⁷ in the face of ethically and emotionally difficult communication has been described in other areas of health care.^{28,29} Busy health care professionals might also consider the preferences- and values-clarification exercises associated with decision aids an adequate exploration of a patient's values. However, decision aids' effectiveness in elucidating patients' values remains unclear,^{25,30} and using them to replace rather than enhance discussion of a patient's values and preferences is clinically and ethically problematic.

Fragmentation. Technological advances in genetic sequencing mean that future generations could know their genetic predispositions earlier in life and thus might require support from clinicians to reflect on their life goals and to plan care.³¹ Potentially new developments, such as newborn whole genome sequencing, might result in people learning about genes of lesser penetrance (ie, lower risk of developing disease) and receiving polygenetic risk scores for a range of common diseases. As genomic medicine goes mainstream, the number of "patients" with knowledge of their genetic risks from a young age will increase. When people are aware from a young age of their genetic risks, they can experience pressure to anticipate and plan life events³² and future preventative interventions.²² Furthermore, many of these patients, as in the example of BRCA 1 and 2

mutation carriers, will see a host of health care professionals in relation to their genetic risk over the course of their life. Currently, however, decision aids are not developed to facilitate long-term planning or support continuity of care across different settings and with different health care professionals.

In summary, using decision aids in the process of decision making in the context of genetic risk involves considerable risks of decontextualization, detachment from ethically and emotionally difficult discussions, and fragmentation of decisions. These 3 risks are interrelated and reflect a need to understand and discuss a person's biography, context, and treatment trajectory and to anticipate care needs and provide continuity of care.

Dealing With Decision Aids' Risks

Although we cautiously encourage the use of decision aids in the context of genetic risk, we make the following recommendations to minimize the risks outlined above. To minimize decontextualization, we recommend embedding decision-aid use meaningfully into ongoing patient-clinician communications in which a patient's familial, social, and cultural context and other influences are explored and in which opportunities to include family members and loved ones in the decision-making process are presented. Genetic counselors have unique skills and expertise in familial-based counseling that enable them to assume responsibility for this change, although there is a role for nurse navigators, case managers, or even technological solutions such as patient pathway applications. To minimize some clinicians' detachment from ethically and emotionally complex discussions, we recommend meeting clinicians' unmet [genetics education needs](#)¹⁰ with training in how to communicate about genetic risk and in how to use decision aids appropriately. Finally, to minimize fragmentation of decisions among clinicians, the values and preferences a patient shares and explores with one health professional should be available to another.

Experiences of advance care planning for end-of-life care can inform how clinicians plan personalized care and treatment trajectories informed by patient preferences and values within the context of genetic risk. As is the case for successful advance care planning initiatives,³³ health professionals will need to be convinced of the importance of elucidating and respecting patient preferences and values and of ensuring that information is up-to-date and available in health record systems. We also recommend assessing decision aids' value as perceived by patients over the course of their care trajectory and not just assessing their effectiveness in facilitating comprehension or in improving procedural, psychological, or functional measures in the context of individual decisions. Innovations in the design and use of decision aids for people with genetic predispositions will require educating patients and clinicians about interventions and options from a life-course perspective and fostering carriers' reflection on their values, preferences, and life goals across the entire care trajectory.

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MEDICINE AND SOCIETY

Which Ethical Considerations Should Inform Hospice Decisions About Caring for Patients With Obesity?

Chithra R. Perumalswami, MD, MSc, Brycin D. Hanslits, and Susan D. Goold, MD, MHSA, MA

Abstract

Hospice and palliative care clinicians have the potential to advocate for high-quality medical care for patients with obesity. This article explores current evidence on obesity at the end of life and ethical questions that emerge when a decision is made to enroll a patient with obesity in hospice.

Obesity at the End of Life

Hospice is designed to provide dignity in the dying process. The nature of hospice care often requires intense caregiving and close attention to symptom management. Hospice care occurs in various care settings, such as a patient's home, a nursing facility, or an inpatient setting, ideally according to the patient's best medical interests and preferred goals of care.

Given the increasing prevalence of obesity in the US adult population,¹ more hospice providers are enrolling patients with obesity, although these providers are not always thoroughly prepared to address the unique needs of an obese population. Hospice often cares for patients who are underweight or emaciated due to advanced disease or chronic illness, which can contribute to the lack of support some patients with obesity might experience once enrolled in hospice. Patients with obesity in hospice, for example, might have caregivers who are unable to physically attend to their care requirements.^{2,3} Such care requirements can include attendance of several caregivers or use of special equipment to turn the patient.⁴ In general, more resources are needed to support patients with obesity in hospice than to support underweight or normal weight patients.²

There is little research on care provided at the end of life in the context of obesity.^{2,3,5,6} One retrospective study demonstrated that, among community-dwelling Medicare fee-for-service beneficiaries who died between 1998 and 2012, those with a higher body mass index (BMI) were less likely to receive hospice care.² The predicted probability of hospice entry was 40% lower for decedents who were morbidly obese (BMI of 40kg/m²) than for those who were of normal weight (20kg/m²).² Decedents with obesity were

also less likely to die at home and more likely to have higher Medicare expenditures in the last 6 months of life.²

In this article, we first discuss resource allocation for hospice patients with obesity and the moral dilemma that such allocation presents for hospice directors. We then discuss a framework for integrating values into decision making and show how it can be applied in decision making processes for enrolling patients with obesity in hospice.

Justice and Resource Allocation at the End of Life

Patients with obesity in hospice often require more—and sometimes different—resources compared with patients who are normal weight or underweight. In one inpatient hospital sample, patients who were morbidly obese required an average of 4.5 nursing staff to assist them with walking and 2.9 to assist them with bathing.⁷ Although these staffing ratios are necessary to mitigate the risk of back injury for staff,⁸ they are difficult to achieve consistently, partly because of the fixed per diem payment Medicare provides for hospice care.⁹ In the setting of fixed payments, increased staffing needs might create a financial disincentive to enroll patients with obesity. While the per diem reimbursement does not specify that hospice providers cannot enroll patients who will cost more than a specific amount per day, hospice providers need their average total costs to fall below what is reimbursed for services in order to maintain business operations, especially as Medicare imposes an annual cap on the hospice benefit per beneficiary.¹⁰

Hospice directors are therefore faced with a moral dilemma: How might a fixed pool of resources be justly distributed? One argument about resource allocation—that a population with a “self-inflicted illness”¹¹ such as obesity and its sequelae should receive lower priority in accessing health care resources—fails to withstand scrutiny both normatively and empirically.^{11,12} But if patients with obesity require more resources than patients of normal weight, how can hospices treat all groups of patients fairly and compassionately? This question is faced by hospice directors on a daily basis, as patients often have different needs, and the fixed per diem payment for care services does not take medical complexity or the cost of care into account.

Many resource allocation strategies are based on long-term benefit, the most classic example being assigning higher priority for organ transplantation to a younger person than a person who has already lived a long life.¹³ Strategies for allocating resources to promote long-term benefit include maximizing total years of life saved or quality-adjusted life years gained. Another strategy is to provide resources relative to need, which is more likely to be useful for hospices.¹⁴ Patients in hospice are typically not expected to live longer than 6 months¹⁵; life years saved and quality-adjusted life years gained, for instance, might not differ much between patients with obesity and patients of normal weight. Given the high prevalence of obesity in the United States,¹ there will be

a growing number of patients with obesity who are eligible for hospice. While hospices must work within the per diem reimbursement constraints, investment in resources, infrastructure, and staff training that would best serve an obese population might decrease care costs over time.

Value Prioritization in Quality-of-Life Decision Making

A fundamental tenet of hospice is preserving quality of life. It follows that to determine the value of a hospice program, quality-of-life assessments should be employed by hospice directors when assisting in decisions about enrolling and caring for patients with obesity. In order to examine priorities in quality-of-life decision making at different levels within the health care system, Sutherland and Till set forth a 3-tiered framework that includes micro-level decision making (valuing individual benefit), meso-level decision making (valuing needs of specific patient groups), and macro-level decision making (valuing population health and resource allocation).¹⁶ In what follows, we show how this framework might be applied in decision making for patients with obesity.

Meso- and macro-level decisions. Enrolling patients with obesity in hospice involves meso-level decisions about whether and how to meet their needs and what resources will be required to do so. These decisions should be informed by hospice patients with obesity, as healthy patients will have difficulty predicting hospice needs.¹⁷ Macro-level decisions regarding resource allocation involve pooled or shared resources and therefore present difficult trade-offs between competing needs for limited resources.^{16,17,18} It is likely that more—and sometimes different—resources will be needed to adequately care for hospice patients with obesity. Specific examples include (1) availability of larger ambulances or other transport to avoid unnecessary delays of care in hospice; (2) aligning nursing and ancillary staff shifts at inpatient hospices to match the needs of patients, such that more staff are on hand to help at certain predictable times when care needs are greatest; and (3) durable medical equipment capable of meeting the needs of hospice patients with obesity (eg, specialized beds and wheelchairs, mechanical lifts, larger therapy tables capable of supporting higher weight limits, and wider walkers). Some inpatient hospice facilities have delimited spaces specifically for the care of patients with obesity, such as one or two larger rooms with wider doorways to accommodate larger equipment.¹⁹ While other patients may use these resources as well, designating specific resources for patients with obesity is an example of macro-level decision making that recognizes that hospice resources are limited and that enrollment decisions are influenced by the presence or absence of such specialized resources.

Micro-level decisions. Patients with obesity often face bias, [stigma](#), and discrimination from health care professionals.^{20,21} Micro-level decision making by hospice clinicians and patients holds the potential to address these issues by clearly prioritizing the patient's quality of life, tailoring care to the patient's needs, and advocating for needed resources.

Creating policy that enables the best possible care for all patients in hospice, including those with obesity, is important from a justice standpoint. Leaders in the field of palliative care themselves are advocating for a national agenda to address inequities of care.²²

Conclusion

Hospice and palliative care clinicians' fiduciary responsibility to all patients at the end of life is a special one because it encompasses the provision of care to patients with many different types of illnesses requiring many different types of resources, often within a short time frame and within a financially constrained system. Ethical considerations of justice, resource allocation, and quality of life in such a system reveal the moral values and standards of the profession. Although hospice providers have implemented ways of allocating resources to provide quality care for patients with obesity, more research on caring for this population is needed to inform necessary policy change.² Hospice and palliative care clinicians have an important role to play in equitably addressing the needs of patients at the end of life, whether or not they are obese.

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ART OF MEDICINE

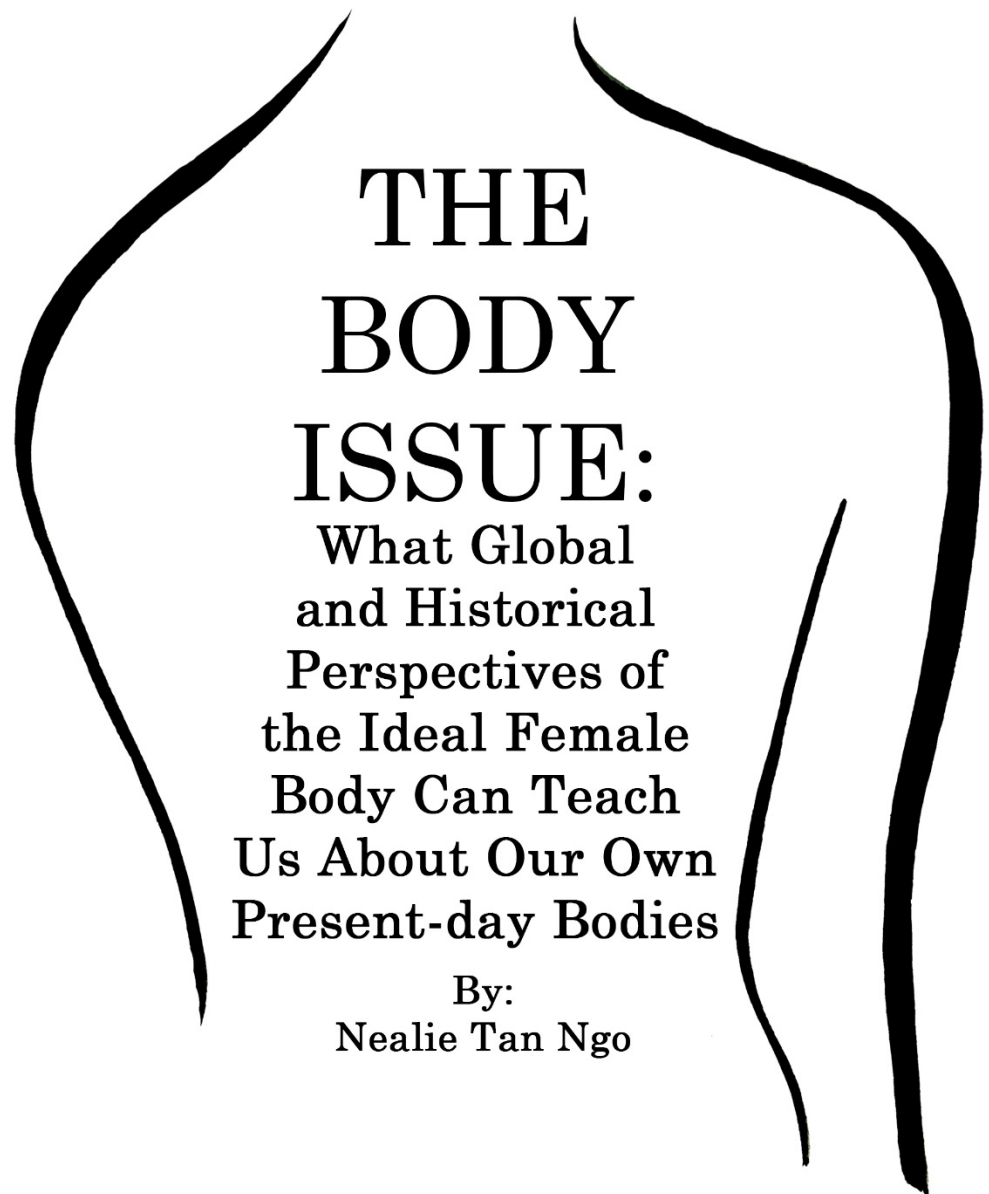
What Historical Ideals of Women's Shapes Teach Us About Women's Self-Perception and Body Decisions Today

Nealie Tan Ngo

Abstract

The Body Issue: What Global and Historical Perspectives of the Ideal Female Body Can Teach Us About Our Own Present-Day Bodies is a graphic memoir that explores cultural and social factors that influence women's body image and restrict their decisions about their bodies. Drawing from historical and contemporary sources, such as advertisements, magazines, and body satisfaction surveys, as well as personal experience, the memoir offers insight into the cultural and social overemphasis on women's physical appearance. This article summarizes key points from *The Body Issue* and invites readers to consider bodies as a means to individuality instead of assimilation.

Figure 1. *The Body Issue*, front piece



Body Image Struggle

The first time I remember wanting to change the way I looked wasn't because I wanted to be healthier: it was because I wanted to be prettier. It happened while I was at the mall, shopping with my mom. I was young—around 10 years old—and we were walking past a window display filled with prom dresses. "You're too fat to wear that," my mom said, pulling me away from the window front.

Figure 2. *Mom's Judgment*, panel 1

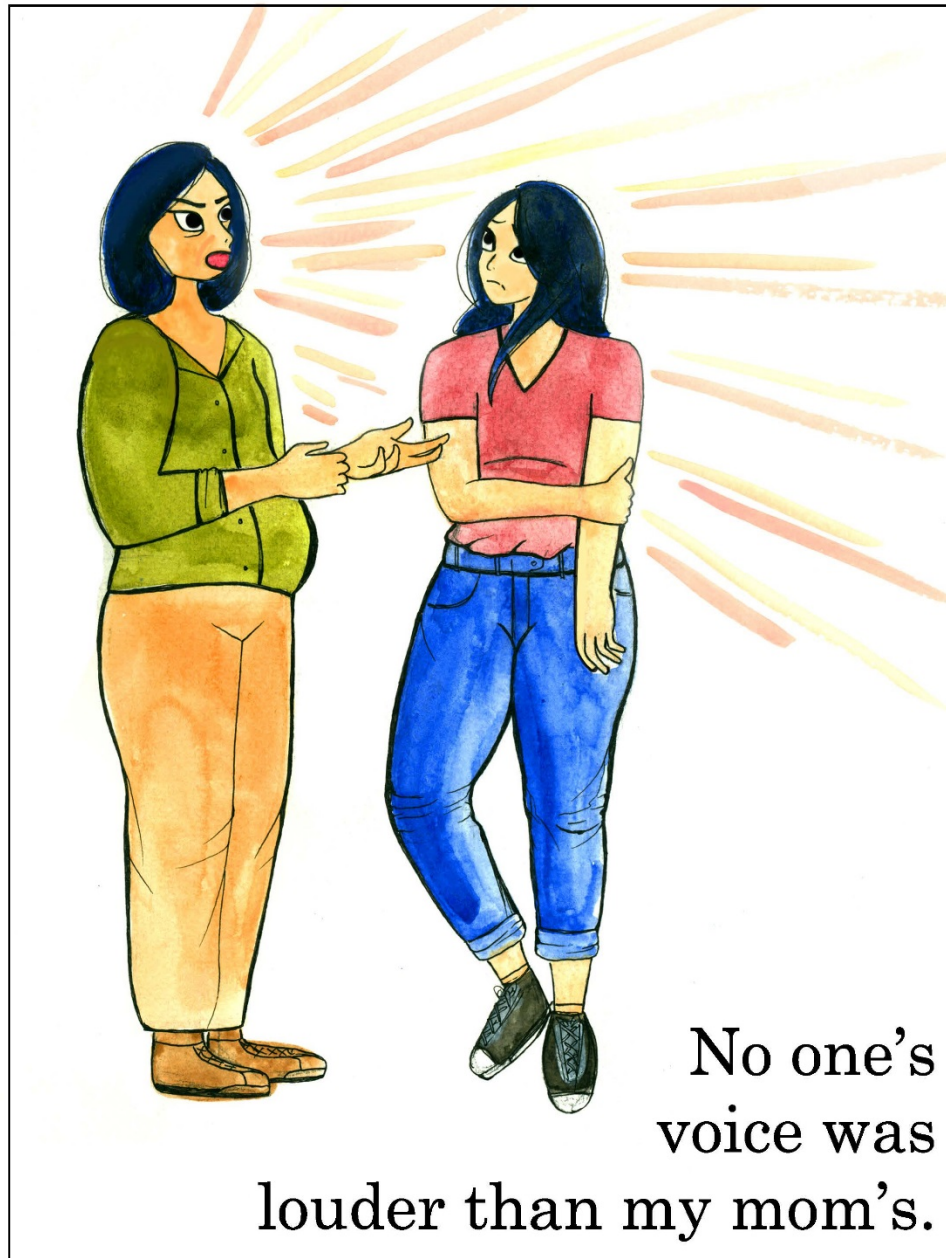


Figure 3. *Mom's Judgment*, panel 2



I already knew that I was larger than some children my age, but I never thought of my size as rendering me incapable of doing something. Two weeks later, I went to my yearly pediatric visit with my mom, at which the clinician suggested a [healthier diet and more exercise](#) to improve my long-term health. I was sent home with a pamphlet depicting the food pyramid, but the only thing I remember from it was the cover, which depicted a cartoon of a tall, lean, and athletic-looking girl, both hands proudly perched on her slim waist. “That’s what I want my daughter to look like!” my mom chuckled as we left.

My health was the last thing on my mind when I first began dieting. All I really wanted was to fit into that dress. I wanted to look like all the other tall, slim Asian girls in my class—because they could all probably fit into that dress. Most of all, I wanted to prove my mom wrong: I am skinny enough, good enough, and worthy enough to fit into that dress. I never realized that at such a young age I had already started measuring my success and self-worth by my body’s appearance, thinking that I had to look a certain way to even be worth looking at.

Media Body Images

The prevalence of poor body image, especially among women and girls, is evident in the medical literature. For example, a 2017 Australian survey of 24 055 young people ages 15 to 19 years found that 87.9% of adolescent girls were concerned about their bodies.¹ The survey also found that body image ranked third in issues of personal concern for both genders (behind coping with stress and school or study problems),¹ a trend that has been consistent since 2013.^{2,3,4,5} Another study found that, over time, more girls consider themselves to be “too fat,” with slightly more older girls than younger girls reporting feeling too fat (45.5% v 40.9%).⁶ The study also found that girls increasingly dieted as they grew older.⁶

Statistics like the above prompt us to wonder: How did we get here? Why do we have a global epidemic of poor body image among children as young as five years old?⁷ Why must a woman’s waist be thinner than a standard 8.5" x 11" piece of paper in order for her to be considered beautiful?⁸ Body dissatisfaction has detrimental effects on health and is associated with impaired emotional well-being, low self-esteem, elevated depressive symptoms, low physical activity, and [disordered eating](#).^{9,10,11,2,13,14,15} Body dissatisfaction is now even a potential issue for children of primary-school age.¹⁶

Historical Highlights

I both wrote and illustrated *The Body Issue*, a personal and historical graphic memoir that explores largely western narratives of women’s bodies that have global implications. The memoir explores “ideal” bodies and attempts to investigate sources of pressure—especially on young girls today—to achieve a “perfect” body, despite the fact that no such thing exists. Through historical and cultural case studies that speak to certain bodily ideals and why women were expected to achieve them—with parallels to the present

day—the memoir also aims to document the historically fluid definition of *ideal* to help inform current conversations about body image and to place my own story in that history. I argue for the importance of viewing one's body as a source of personal empowerment, regardless of how well it conforms to an ideal body type. The memoir also addresses my own struggles with body image, how my mother helped shaped those struggles, and how both have influenced my life.

In what follows, I present selected images from *The Body Issue* in the context of discussion about the ideal female body—past, present, and future.

Figure 4. *Women Must Be Small*



Figure 5. *Survival Decisions*



Historically, a woman's body was her best survival tool in patriarchal societies; expectations about a woman's size and physical characteristics were dictated "by male desire and marriageability."¹⁷ Therefore, a woman's body, appearance, and health were (and still are) heavily influenced by social and cultural ideologies, beliefs, and values as well as by technology.¹⁸ In turn, these influences tend to work by restricting the notions of selfhood available to women, forcing women to make decisions to comply with social

and cultural demands that they transform their bodies into an idealized shape. An idealized physical body becomes a social body,¹⁹ and, as Deborah Sullivan notes, it “bears the imprint of the more powerful elements of its cultural context ... providing important clues to the mechanics of society.”²⁰ Historically, bodies closer in appearance to ideal bodies gave some women power.

For example, in Victorian England, women used corsets and crinolines to physically mold their bodies into ideal hourglass shapes, enabling some women to accrue social power and successfully attract a husband. The corset was not limited only to middle- and upper-class women, however, as by 1824 it was reported that even the poorest streetwalkers in London wore corsets,^{18,21} which signaled that they were “decently dressed.”²¹ Corsets’ restriction of women’s waists to 18” became so culturally and socially powerful that, in 1843, *Les Modes Parisiennes*, a Parisian fashion magazine, declared that wearing a corset was necessary in order to be beautiful.²¹ Effects of corseting, however—especially tight lacing—had consequences for women’s health. As documented in the 1890 and 1892 articles, “Death From Tight Lacing” and “Effects of Tight-Lacing,” in the *Lancet* as well as in Ludovic O’Followell’s *Le Corset*, women frequently fainted due to diminished lung capacity, restricted digestion, heart palpitations, and, in more serious cases, deformed ribs, misaligned spines, and muscle atrophy.^{22,23,24} In *Le Corset*, x-rays reveal how dramatically and harmfully corsets sculpted a woman’s body.²⁴ Regardless of these health consequences, women donned corsets to comply with *de facto* cultural requirements of what Valerie Steele terms a “socially acceptable form of erotic display.”²¹

Figure 6. *Victorian Ideal*, panel 1

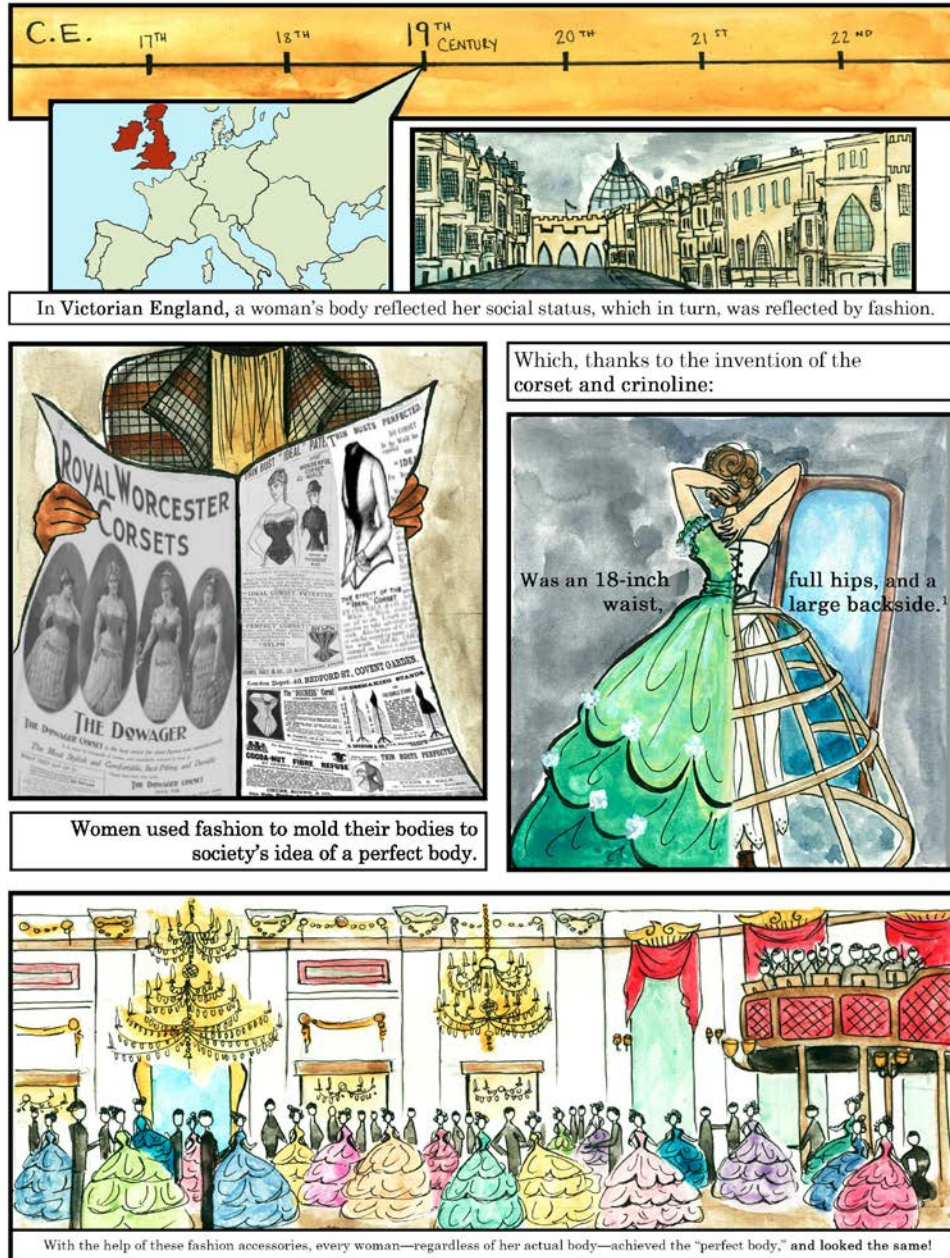
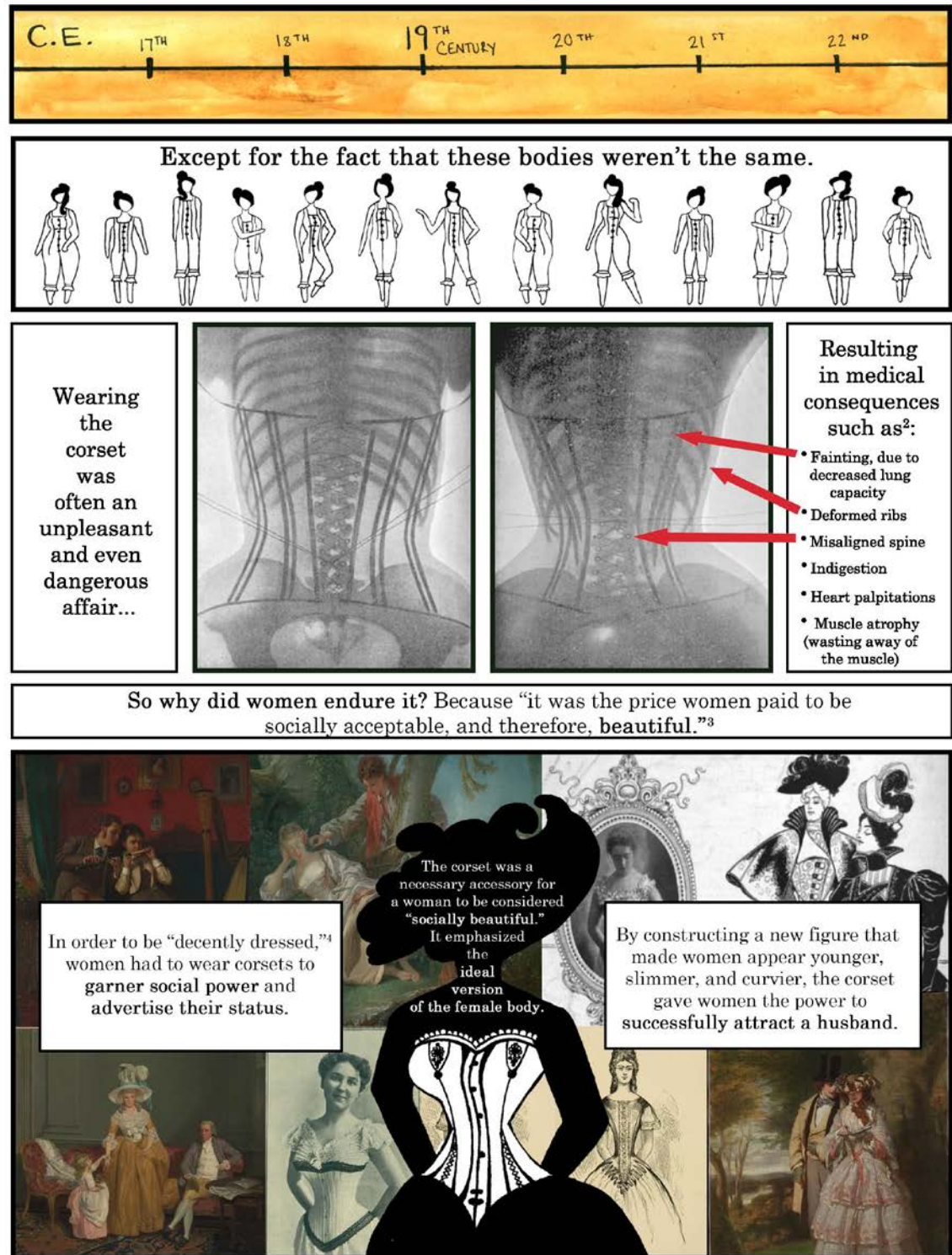


Figure 7. *Victorian Ideal*, panel 2



Other historical case studies, such as the Tang Dynasty in China, tell similar stories of the relationships between women’s bodies and sociocultural pressures.

Figure 8. *Tang Dynasty, panel 1*



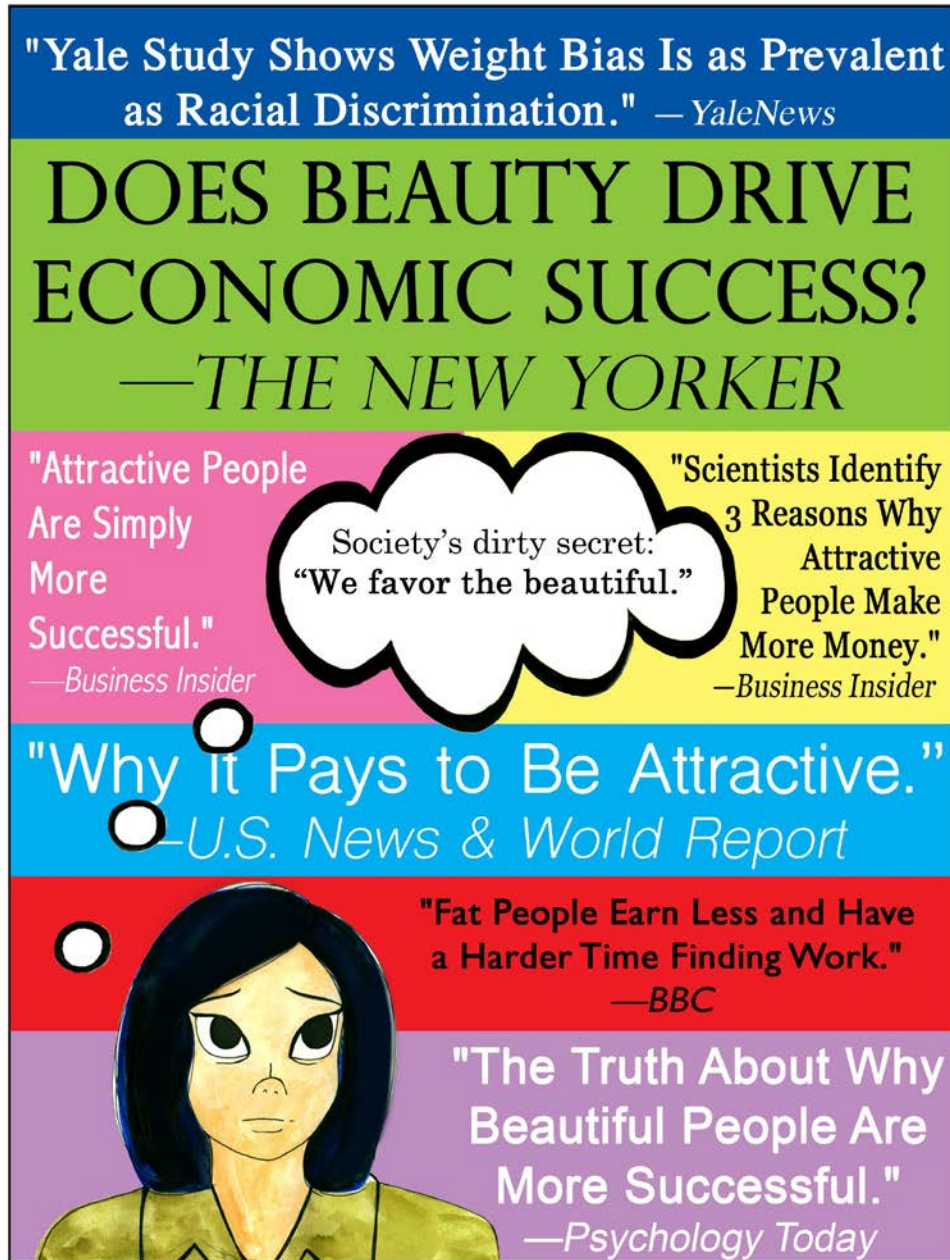
Figure 9. *Tang Dynasty*, panel 2



Parallels to Today

Somehow, my mom already understood society's dirty secret: we favor the beautiful. She wanted me to be successful, and, for her, beauty was the best route to success.

Figure 10. *Slim Chance of Success*



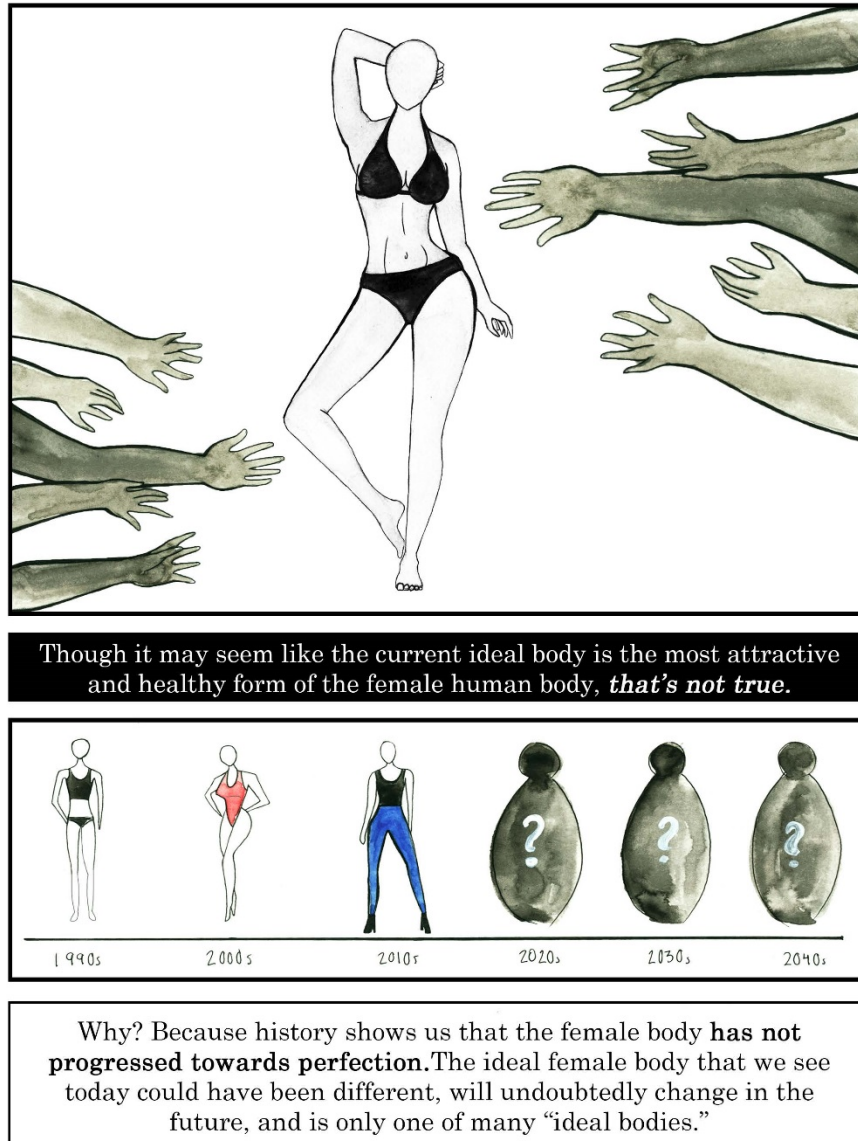
The constant comments my mom made about my body were not meant to shame me; they were reminders for her that she wasn't doing her job of making sure I was ready to face a world full of criticisms and biases. When social and cultural factors dictate how a woman should look, more than just her self-esteem is damaged. She allows a part of her identity to be overwritten by social standards, causing a deeper type of harm that Hilde Lindemann Nelson terms *infiltrated consciousness*. As Nelson writes in her book, *Damaged Identities, Narrative Repair*, "A person's identity is injured when she endorses, as a portion

of her self-concept, a dominant group's dismissive or exploitative understanding of her group, and in consequence loses or fails to acquire a sense of herself as worthy of full moral respect."²⁵ Accordingly, poor body image is more sinister than just not feeling happy with the way one looks. As discussed earlier, physical bodies are social bodies; beauty is linked to our perceptions of health, wealth, power, and overall success, which affect the range of decisions available to women and women's overall views of their capabilities, strengths, and worth.

Ending Body Image Tyranny

Poor body image is currently a worldwide public health crisis disproportionately affecting women and girls.^{26,27,28} We must re-evaluate how we see, treat, and think of our bodies. History helps expose ideals of women's beauty as arbitrary, which suggests the fluidity and subjectivity of the very notion of perfection.

Figure 11. Truth and Perfection



Education about this history and its influence on women's and girls' identities, self-conception, and health can promote open conversation and perhaps change for the better how parents talk to their children about their bodies.

Figure 12. *Difference is Normal*, panel 1

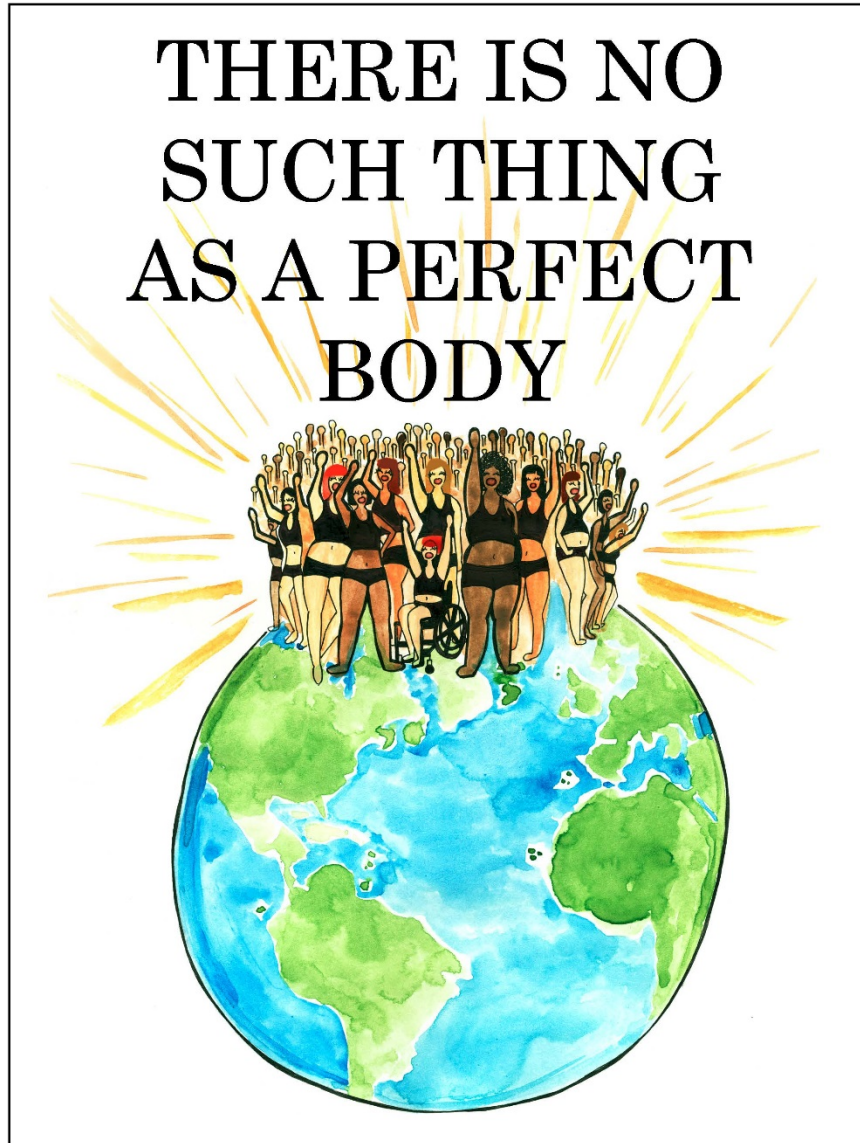



Figure 13. *Difference is Normal*, panel 2

We know these pressures to be one extreme or the other can be physically and mentally unhealthy, even deadly...and we know that if we keep changing ourselves for these external pressures, **we'll continue to pass this ancient playbook on to our future daughters.**



So, what do we do?

1

Realize that **you are not alone**: according to a survey done by Glamour magazine in 2011, **97% of young women currently struggle with their body image¹**—this has been an issue that women all around the world have struggled with since ancient times.

2

Remember that **history has not progressed the female body towards perfection**: the ideal body now is not a result of an evolution of the “best bodies” in history.

3

Prioritize your body's health and find a balance between the extremes. **Appreciate the spectrum of health and beauty that exists!**

4

Instead of emphasizing how your body looks, appreciate it for what it can do. **DEFINE YOUR OWN IDEAL BODY** based on who **YOU** are and what **YOU** want. Ask not what you can do for your body but what your body can do for you!

The Body Issue is intended to help readers better understand the importance of valuing self-validation over social validation with respect to their bodies and to decide for themselves the terms on which they'd like to think about their own bodies in diverse social, cultural, and ever-changing environments.

Figure 14. *Talk*

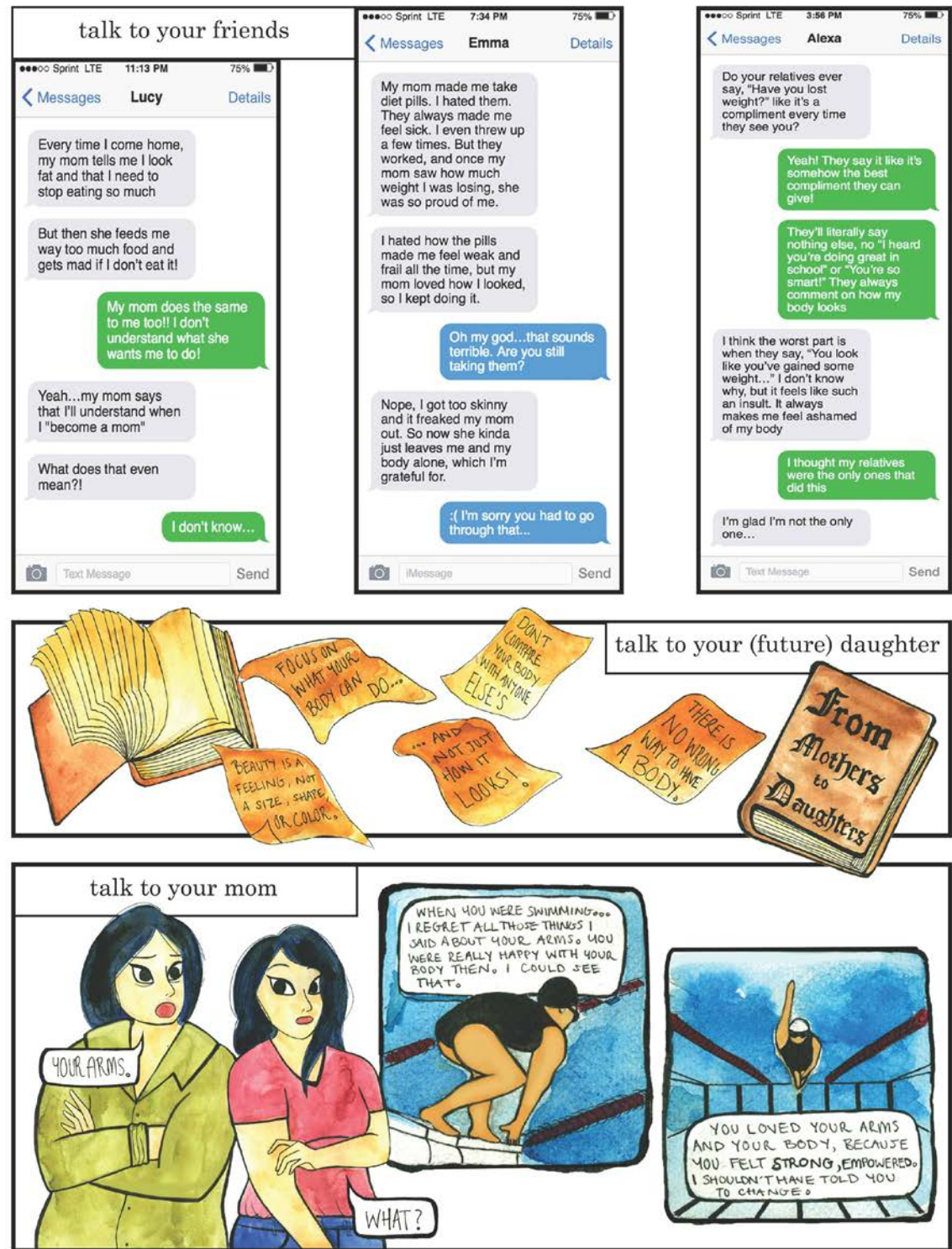


Figure 15. *Me*



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ART OF MEDICINE

When Good Women Decide to Do Nothing

Phoebe Cohen

Abstract

Many health professions students struggle with deciding whether and when to challenge their teachers. This graphic memoir, *When Good Women Do Nothing*, conveys what happened one day in the life of a paramedic student called to help an incarcerated, handcuffed woman in labor who gave birth on a stretcher. The memoir documents numerous clinical and ethical disagreements and decision points throughout the paramedic team's time with this patient.

Figure. Detail From *When Good Women Do Nothing*



([Click here](#) to view the entire graphic narrative.)

Media

Pen and ink and watercolor.

Once, as a paramedic student, I assisted an incarcerated woman who was in labor. She gave birth handcuffed to my stretcher. My duty to be a patient advocate conflicted with my duty to obey law enforcement protocol, and I haven't forgotten how that conflict felt

as I made decisions about what to do that day. My graphic memoir, *When Good Women Do Nothing*, documents the numerous disagreements and decision points throughout our paramedic team's time with this patient.

I obeyed my preceptor's orders while our patient labored feet from where we stood. I did not stand up to his authority and demand that her left hand be uncuffed as she struggled through her contractions. I was like many health professions students who struggle with deciding whether and when to challenge their teachers. I did make a decision at one point to close a curtain to offer our patient privacy from my preceptor's gaze.

My closing the curtain was a critical ethical action in our intervention and perhaps suggests that I didn't really do "nothing," as the title of the memoir suggests. This is 1 of 2 panels of the graphic memoir with no words. The visual in this panel is divorced from the narrative of the graphic memoir, and I'll let readers decide whether and to what extent this disconnect emphasizes my decision's and action's importance in the care of this patient.

Phoebe Cohen has walked many paths in life, including living in the middle of the Gobi Desert as a Peace Corps Volunteer and working as a paramedic in several states. She has also been drawing cartoons since she was 8 and has occasionally been known to go for up to 5 hours without coffee.

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ART OF MEDICINE

A Matter of Words

Jessica S. Yang

Abstract

Word Choices is a mixed-media digital illustration that explores the importance of clinicians' word choices during their encounters with patients. Clinicians often face ethical questions about sharing information with vulnerable patients, dimensions of which are represented by the illustration's content and colors.

Figure. *Word Choices*



Jessica S Yang

Media

Acrylic on canvas and digital illustration.

Word Choices is a mixed-media digital illustration that explores the importance of clinicians' word choices during encounters with patients. Clinicians often face ethical questions about sharing information with vulnerable patients, dimensions of which are represented by the illustration's content and colors. In the illustration, the subjective, objective, assessment, and plan (SOAP) note in the background represents a physician's framework for understanding a patient's clinical picture. Should deception be used if the intention is benevolent? Framing a diagnosis or other relevant information in a way that a patient or surrogate can understand and that is beneficial for a patient's well-being is important when considering this question. How this framing is done varies and thus is represented by a blank speech bubble.

Although a patient-clinician encounter can be based on lab numbers and information exchange, it's also important to remember the encounter's humanistic features. How a patient feels and responds can depend on how a clinician frames information and sets the tone of a conversation, so the speech bubble is highlighted in the foreground. This encounter's potential for complexity and intensity is suggested by bright colors.

How should clinicians explain a patient's diagnosis and condition? Like the empty speech bubble, this question can be seen as a start of a conversation.

Jessica S. Yang is a medical student at Rowan University School of Osteopathic Medicine in Stratford, New Jersey. In addition to her scientific interests, she has interests in literature and art.

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VIEWPOINT

What Clinical Ethics Can Learn From Decision Science

Michele C. Gornick, PhD, MA and Brian J. Zikmund-Fisher, PhD, MA

Abstract

Many components of decision science are relevant to clinical ethics practice. Decision science encourages thoughtful definition of options, clarification of information needs, and acknowledgement of the heterogeneity of people's experiences and underlying values. Attention to decision-making processes reminds participants in consultations that how decisions are made and how information is provided can change a choice. Decision science also helps reveal affective forecasting errors (errors in predictions about how one will feel in a future situation) that happen when people consider possible future health states and suggests strategies for correcting these and other kinds of biases. Implementation of decision science innovations is not always feasible or appropriate in ethics consultations, but their uses increase the likelihood that an ethics consultation process will generate choices congruent with patients' and families' values.

Elements of Decision Science in Clinical Ethics

When we first raised the idea of connecting decision science to the practice of clinical ethics, we got some strange looks. After all, the phrase *decision science* might evoke images of mathematical decision trees and computational modeling, whereas the prototypical picture of a clinical ethics consultation is one of health professionals, ethics consultants, patients, and family members gathering to interpret ethical dimensions of health care experiences. From this perspective, there wouldn't seem to be much overlap.

Yet while few would argue that a mathematical decision tree is critical in ethics consultation, multiple concepts that fall under the broader umbrella of decision science are indeed relevant to clinical ethics practice. *Normative decision analysis*, which encompasses analytical modeling of decisions and calculation of expected value or decision utility,^{1,2} provides important reminders that any decision about uncertain risks or benefits requires assessing as precisely as possible the likelihood and severity of all relevant possible outcomes. *Informed decision-making standards* identify the critical information that stakeholders must know before making their decisions.³ For example, a "reasonable" person standard requires that decision makers know all that a reasonable person would want to know prior to choosing.⁴ *Decision psychology* provides insights into

the predictable biases that influence people's perceptions of the health risks they face^{5,6} and the ways that decision making about risk is simultaneously analytical and emotion driven.⁷

In particular, clarifying decision-making processes can enable all-important shifts from considering only what needs to be discussed in an ethics consultation to considering how a decision process unfolds and *should* unfold.^{8,9} For example, it is important to ask questions such as (1) How do clinicians or patients actually go about the process of making their difficult decisions, both individually and collectively? (2) More specifically, how is the decision process incomplete or biased (eg, due to failures to search for relevant information, recognize relevant options, or incorporate individual perspectives)? (3) How can systematic consideration of individual and collective decision-making processes help to improve outcomes and decrease future regret?

Below, we discuss how key features of high-quality decision-making processes can be applied in clinical ethics.

Good Decision-Making Processes

Decision science suggests that ethics consultations can aspire to support the following characteristics¹⁰ of good decision-making processes:

1. *Identify a complete option set.* Good decision processes require understanding of the full option set, including inaction when appropriate.¹⁰ When parties disagree about the options among which they are choosing, **consensus** rarely results. Ethics consultants can engage health professionals early in case reviews to ensure that all options (not just those preferred by one stakeholder, for example) are raised for consideration.
2. *Learn about relevant possible outcomes.* Good decision processes require information about possible outcomes, in terms of both their likelihood and their character and severity.¹⁰ Since most outcomes have multiple components, a good information-gathering process involves clarifying different dimensions of a choice and ways in which outcomes' severity or likelihood could differ. For example, ethics consultations can help to ensure that all stakeholders learn about and consider issues such as possible changes in quality of life over time, the presence of rare but significant complications, barriers to treatment adherence, or practical implications of different options for the patient or family.
3. *Consider personalized impact of possible outcomes.* Good decision processes require recognition that outcomes can be perceived differently by different stakeholders.¹⁰ Aside from mortality and morbidity risks of a particular intervention for a particular patient, how good or bad an outcome is for that

specific person at that specific time should be considered from that patient's perspective, not the clinician's perspective. Ethics consultations can help cultivate opportunities for patients and family members to consider and voice what different outcomes could mean from their perspectives. Asking *What would the implications be for you if that were to happen?* can promote self-reflection and help patients and family members to concretely envision the impact of different possible outcomes.

4. *Integrate decision makers' core values.* Good decision processes require assigning value and importance to different possible outcomes, trade-offs, or other aspects of a decision.¹⁰ It requires decision makers to state, for example, "I care a lot about X" or "Whether Y happens doesn't matter much to me." For example, survival is not always valued over other attributes. This stage in a decision-making process is often referred to as *values clarification*.¹¹ Values clarification references relatively stable values people hold as a result of personal, familial, or cultural experiences with health care and examines how those values inform a specific decision. Ethics consultations can facilitate stakeholders' reflections about how their values should inform their decisions, especially when the available options reflect trade-offs between short- and long-term outcomes.

Value Congruence

Implementing these 4 steps during ethics consultations tends to produce choices that are values-congruent.¹¹ In other words, what gets chosen tends to align with what decision makers care about. Someone who values maximizing quality of life over quantity of life might choose to pursue hospice care earlier after a terminal diagnosis than someone with different values; this is an example of a values-congruent care plan. Someone who values minimizing pain but chooses to undergo a painful intervention, particularly if less painful options are available, is not receiving values-congruent care. A values-incongruent choice could be made for a number of reasons (eg, misunderstanding an option set, misunderstanding options' implications) and should probably be regarded as a clinically and ethically problematic outcome of a health care decision process, particularly one that was aided by an ethics consultation.

There are 3 important facts that stakeholders in ethics consultations need to understand about value congruency in health decision making. First, while people's values tend to be relatively stable (ie, we generally care about the same things in most situations), their preferences are sensitive to context and constructed at the moment of a decision.^{12,13} Hence, people's preferences can be influenced by how a decision is framed or how it is made.¹⁴ Framing outcomes in terms of chances of survival, for example, can lead to different choices than when the same information is framed in terms of chances of death.^{5,15,16} Second, preferences can be role dependent: even given the same information, people express different preferences when making decisions for themselves than for

others.^{17,18,19} Finally, societies at large can have preferences that differ from those of individuals.²⁰ Appreciation of these 3 factors can help illuminate how stakeholders' values and patterns of assigning value to different possible health outcomes play out during ethics consultations.

Barriers to Values-Congruent Decision Making

Pursuing value-congruence in ethics consultation and health care decision-making processes can help to maximize inclusive stakeholder value and minimize decisional regret. Yet there are many reasons why decision making about ethically complex cases might not result in values-congruent outcomes.

First, there can be barriers to gathering all relevant information. Certain options might be excluded from consideration due to external constraints such as insurance rules or patients' inability to travel. Critical information might be unavailable, or there might be insufficient time to absorb and consider the relevant information. In particular, there is often substantial uncertainty regarding either the likelihood of outcomes or their severity. In truly unusual situations, medical professionals might not know what kinds of outcomes are even possible.

Second, a more general but pernicious barrier to value-congruence is affective forecasting errors.^{21,22} Health decisions often require people to make choices about states of being with which they have no experience. Depending on context, people might think some outcomes or experiences are much worse or much better than they actually are. Even when people accurately anticipate what a health state or treatment experience will be like for them and how mild or severe it might be, they might not be able to appreciate its impact on their lives or feelings. A key part of decision support, therefore, involves identifying when forecasting errors might occur or be corrected. For example, one approach to addressing affective forecasting errors involves patients who have "been there" sharing their experiences to help address the misperceptions of patients trying to imagine what it would be like for them.^{23,24}

Third, there are also limits to the deference that can or should be accorded some values of some individuals,^{12,25,26} particularly when those values conflict with other important ethical values. When relevant stakeholders' values are in conflict, a good decision-making process will clarify when it is differing values, rather than misunderstandings of other information, that is at the heart of the disagreement. At such moments, clarity regarding which stakeholder holds decisional authority is essential.

Not every ethics consultation or medical decision, however, needs to involve a detailed deliberation that elicits every stakeholder's values in a shared decision-making process. While that vision is a worthy aspiration in many contexts, it is impractical or inappropriate in others. Being aware of potential barriers to effective decision making

can help to suggest situation-appropriate approaches when values-congruent decision making is not possible.

Decision Science in Ethics Practice

Clinical ethicists can support informed, value-congruent decision making in ethically complex clinical situations by working with stakeholders to identify and address biases and the kinds of barriers just discussed. Doing so requires constantly comparing actual decision-making processes with ideal decision-making processes, responding to information deficits, and integrating stakeholder values. One key step involves regularly urging clinicians to clarify both available options and possible outcomes and encouraging patients to consider both their values and the possible meanings of different outcomes. Decision science suggests the importance of thoughtful definition of an option set, clarification of the relevance of information, acknowledgement of the heterogeneity of stakeholders' experiences and values, and acceptance of the plurality of stakeholder perspectives about health experiences and the desirability of health outcomes. In turn, health care deliberations remind decision science that application of these principles will always be complex when decisions pose real and important consequences for stakeholders.

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VIEWPOINT

How Moral Case Deliberation Supports Good Clinical Decision Making

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Abstract

In clinical decision making, facts are presented and discussed, preferably in the context of both evidence-based medicine and patients' values. Because clinicians' values also have a role in determining the best courses of action, we argue that reflecting on both patients' and professionals' values fosters good clinical decision making, particularly in situations of moral uncertainty. Moral case deliberation, a form of clinical ethics support, can help elucidate stakeholders' values and how they influence interpretation of facts. This article demonstrates how this approach can help clarify values and contribute to good clinical decision making through a case example.

Values in Decision Making

Values can be thought of as "the essential *texturing* of everything we perceive, believe and aim for."¹ Values inform our views of how things ought to be and guide us—either implicitly or explicitly—when difficult choices need to be made.^{2,3} Clinical decision making is not any different. Decision science, which focuses on how the best scientific evidence can inform decisions and how to deal with [bias](#) and confounding factors in decision making,^{4,5} can help render patients' and clinicians' values explicit and mobilize them in clinical decision-making processes. In this article, we argue that stakeholders making their values explicit and exploring them together can set the conditions for a more informed and morally sensitive decision-making process, especially in situations in which there is a lot at stake and the right thing to do is not that obvious for everyone involved.⁶

We maintain that the use of moral case deliberation (MCD) supports a clinical ethics process of elucidating and exploring both values and facts and promoting the inclusion of the values of all those involved in considering what to do so as to promote morally informed clinical decision making.^{7,8,9,10,11} This approach is particularly valuable in situations of moral uncertainty, ie, in cases in which there is disagreement among stakeholders about what should be done or when there is doubt about the right thing to do.

Facts and Values in Decision Making

Although the best available evidence and clinical experience are fundamental for good clinical decision making, they do not provide a sufficient basis for deciding what to do in any particular situation.¹² Eliciting and weighing stakeholders' values—particularly, patients' and family members' values and preferences—is essential to good clinical decision making.^{13,14} However, the [values of clinicians](#) should also be explicitly taken into account in good clinical decision making because the selection, interpretation, and communication of clinical facts and the evaluation of the clinical situation are always mediated by clinicians' normative assumptions about what is important or worth striving for in the situation at hand.⁶ For instance, in end-of-life decisions, a physician's proposal of palliative care will be influenced by the meaning that he or she attributes to persistent pain and to a "good" death; both considerations express a normative stance on the relationship between quality of life and survival.

One way for a clinical team to explore values or normative assumptions and how they influence the experience of a clinical situation and motivate a decision for a certain course of action is MCD, a structured dialogue among members of a multidisciplinary group of health care professionals (eg, nurses, physicians, physiotherapists) about a difficult situation in which stakeholders experience moral disagreement or uncertainty. Dialogue and ethical reflection are guided by a trained MCD facilitator who uses a specific conversation method, such as the dilemma method.⁸ By means of a joint exploration of stakeholders' perspectives, participants come to a better understanding of a disagreement or the uncertainty within a situation, along with relevant values. After stakeholders' values have been explored, participants express their own views about which values are most important, investigate similarities and differences among stakeholders' values, and listen to each other's arguments. This process can lead to a joint solution, compromise, or better understanding of various positions. Results and insights from an MCD session support decision making by those who have formal decision-making responsibility.

During MCD meetings, scientific facts are also important, as disagreement and uncertainty can come from a lack of information or misunderstanding of available scientific evidence. Yet disagreements can also be due to differences in values and in how the facts of the situation are valued. By focusing on how values influence the ways in which stakeholders view a situation and its facts, differences in normative presuppositions of participants can be explored and the most relevant values prioritized.

Moral Case Deliberation

MCD differs from [shared decision making](#) in several respects. In contrast to shared decision making, in which the values of the patient or family members and the caregiver are explored to arrive at a patient-centered decision, MCD focuses on dealing with ethical dilemmas and deepening understanding of situations involving moral uncertainty.

Although mutual understanding and consensus might be achieved by exploring different values and perspectives, reaching a shared decision is not the primary aim of MCD. Furthermore, in most cases, deliberation takes place not between patient and treating physician but among caregivers in an interprofessional context. Deliberation aims to elucidate values and consider courses of action that follow from them, but a treating physician remains in charge and responsible for the decision-making process—in contrast to shared decision making, in which a physician shares this responsibility with a patient.

Dialogue plays a fundamental role in MCD. By engaging in dialogue, participants postpone first judgments and investigate their views and assumptions in a joint learning process. The purpose is not to convince others of a particular view but to foster exchange of perspectives and establish deeper understanding of the situation.¹⁵

In MCD, both facts and values are addressed. First, in order to clarify facts in an ethical dilemma, factual questions—which might address not only clinical knowledge and scientific evidence, but also how a situation relates to a patient's history and options—are posed. After factual questions have been considered, participants are asked to make all stakeholders' values explicit. Although the patient and family generally will not be present, their views and values can be elucidated by professionals involved in the case (eg, physicians, nurses). Of course, making values explicit requires accurate interpretation and a joint endeavor, as all participants contribute to the elaboration of values important to each stakeholder. Through this process, values are made concrete and translated into norms for action.

This process also shows how values influence the understanding of facts and suggest possible courses of action. After elucidating stakeholders' values, MCD participants are each asked to formulate what they consider to be the right action, what value is behind their choice, and how this value relates to the facts of the situation at hand. The participants' individual judgments are further explored through continued collaborative dialogue that enables a richer, collective understanding of the case—one that can account for various perspectives, including those of patient and physician. This process might result in consensus or at least foster acknowledgement of and openness to a plurality of views. In either case, a basis may be created for improving decision making in morally difficult situations.

Case

To illustrate MCD, we present a case example in which deliberation was led by one of the authors (G.W.) who, in his capacity as an ethics consultant, was asked by neonatal intensive care unit (NICU) staff to provide ethics support. A baby born at 40 weeks had been admitted to the NICU. The child suffered from congenital ichthyosiform erythroderma, and both parents were familiar with the TGM 1 mutation which caused

this condition. Newborns affected by this genetic condition are encased in a collodion membrane, which cracks before or after birth and takes 2-to-4 weeks to peel off. During this period, there is a high risk of infection. After this period, however, the skin of the baby is neither expected to require further (intensive) medical treatment nor to pose a direct risk to the child's health.¹⁶

In accordance with standard procedure, the baby was treated with Vaseline (every 3 hours) and an anti-infective agent (every 12 hours), which necessitated changing bandages every 3 hours. The baby received maximum pain medication but cried heavily when nurses removed bandages. The care team, including physicians and nurses, was unsure how to respond. Should the baby's pain and crying be accepted as merely temporary? Or should the baby be sedated? Sedation is a common practice in the NICU¹⁷; babies are often treated while sedated, and sedation is stopped when it is no longer needed.

An MCD was organized to reflect on this difficult situation. During the MCD, it became clear that participants had different understandings of the situation influenced by what they valued most. On the one hand, nurses emphasized that the baby was seriously ill and suffering. Their core value was comfort, and accordingly they deemed it important that the baby's suffering be diminished. Therefore, they considered sedation to be the morally best option. On the other hand, the treating physician regarded the baby as healthy relative to other babies in the NICU since he was full-grown and could breathe on his own. She argued that sedation would imply ventilator support, which would come with infection risk, hinder lung development, and prevent the baby from interacting with the environment and people around him, temporarily inhibiting his social development. Her core value was noninterference, and she thus regarded enduring the situation as the morally best way to handle it.

Interestingly, the facts of the situation were not questioned: the nurses knew that sedating the baby would risk iatrogenic harm, and the physician knew that, without sedation, the baby's suffering could not be relieved. They did, however, value the facts differently. For the nurses, relieving pain was more important than risking harm; for the physician, abstaining from interfering with the baby's physical and social functioning was more important than relieving suffering. The nurses' and the physician's value-laden perceptions are also evident in their descriptions of the baby as ill or healthy. The nurses regarded the baby as seriously ill; the physician regarded the baby as relatively healthy compared to other babies on the ward, who needed ventilator support to survive.

During reflective dialogue, participants' perspectives became explicit and were jointly explored. It became clear to participants that they were motivated by different values that influenced their judgments about what to do. Acknowledging these differences enabled team members to understand each other better and search for consensus. The

nurses, understanding the priority placed by the physician on uninhibited development, acknowledged the value of not interfering with physiological and social functioning by offering sedation. The physician, understanding the nurses' concerns about the baby's suffering, recognized the nurses' distress. Both parties came to appreciate how behavior that seems to indicate illness (crying out of pain) can be regarded as a sign of health (being able to breathe and express emotions). As the baby's condition was expected to last only a limited period of time, all members of the team agreed that it was right to refrain from sedation and to continue treatment. In addition, to reduce the nurses' distress, their shifts were changed so that each provided care to the baby for a shorter period of time. When this plan was proposed and explained to the parents, they agreed.

Conclusion

Decision science focuses primarily on how to make decisions based on (clinical) facts and how to avoid bias and confounding factors in decision making. Less attention, however, is paid to ways in which patients' and clinicians' values influence decision making, how to make these values explicit, and how to deal with them in decision making processes. We have argued that clinical team members exploring values together in a methodical and structured way can support informed and sensitive decision-making processes, especially in high-stake situations of moral uncertainty or disagreement. MCD contributes to good clinical decision making by focusing on questions such as "'Why do we think it is important to act in a certain way?'... 'What values are behind our inclinations and intuitions?,' 'What values may be relevant to other stakeholders,' and 'how can we take them into consideration?'"¹⁸ By focusing on these questions, MCD offers a way to integrate values with facts in clinical decision making.

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LETTER TO THE EDITOR

Response to “Emerging Roles of Virtual Patients in the Age of AI”

Frederick W. Kron, MD, Timothy C. Guetterman, PhD, and Michael D. Fetters MD, MPH, MA

We appreciate the *AMA Journal of Ethics*’ forward-looking issue on artificial intelligence (AI), and we select ideas in C. Donald Combs and P. Ford Combs’ article, “[Emerging Roles of Virtual Patients in the Age of AI](#),” for further discussion.

1. *Conflation of virtual patients and virtual humans.* The term *virtual patient* (VP) has been applied to numerous applications with different designs, technologies, and educational objectives. This heterogeneity can lead to confusion.¹ The Association of American Medical Colleges’ definition of VP that the authors reference was developed in 2006 and refers to computerized clinical case simulations.² These applications, which are largely text based with multimedia content, focus on clinical reasoning and decision making and do not utilize AI.^{1,3,4} The authors conflate VPs of this type with virtual humans (VHs), computer-driven conversational agents with human form that interact with humans using the full range of behaviors found in human-to-human, face-to-face interaction.⁵ VHs utilize AI in computer-based interpersonal communication training simulations—as virtual standardized patients,^{4,6} physicians, or any other human across the health care enterprise.
2. *Overstatement of virtual patient perils.* The authors present material about “sexist AI,” cybercrime, malicious intent in programming, and psychopathic AI. Without an accompanying account of educational software, AI, or VH development, readers may overestimate the risk of using these agents. The following clarification should mitigate the sense of menace the article evokes.

AI is broadly defined as any task performed by a program or machine that, if performed by a human, would require applied intelligence to accomplish.⁷ The current state-of-the-art is *narrow AI*,⁸ which might utilize natural language processing and machine learning to solve specific problems. By contrast, *strong AI* is an assemblage of cognitive processes sufficient to enable self-awareness and intentionality. Strong AI is far removed from realization and may not even be possible.^{9,10,11} Personified as Norman Bates, the serial killer in Alfred Hitchcock’s *Psycho*,¹² the Norman program mentioned in the article is suggestive of the strong AI of dystopian films like *Ex Machina* and *Blade Runner*. By referring to the

program using the personal pronoun “he” and stating that “Norman was subjected to the darkest corners of Reddit,” as if a person had been subjected to a terrifying ordeal, the authors make Norman seem much “stronger” than it is. Norman is merely a sensationalized example of narrow AI that was *intentionally* derived using data-driven machine learning applied to an unvetted set of data from a now-banned Reddit website where users posted videos of people dying and gave textual explanations of the manner of death.^{13,14} When shown a series of Rorschach inkblots, Norman unsurprisingly interprets inkblots as people dying, because that’s what MIT researchers trained it to do.¹⁴

By generalizing from this example to VH creation, the article misses the point that development of VHS for medical education is wholly under the control of medical educators and trusted experts. It would be ethically irresponsible for educators to use unvetted data sets to train a VH, to implement AI algorithms that allow unwanted degrees of freedom from desirable VH behaviors, or to abrogate responsibility for human oversight in VH program development.¹⁵ To ensure positive learning outcomes, educators must stipulate evidence-based design requirements, create content, and then iteratively evaluate the sufficiency of materials passed back to them by software engineers. This agile development process^{16,17} requires transparency to stakeholders, effectively eliminating the “black box” of programming and minimizing the risk of VH applications being tainted by the unintended introduction of undesirable content.

3. *VH opportunities.* The article overlooks the most noteworthy opportunity that AI-enabled VH simulation offers to medical education: training in basic *and complex* communication skills (eg, facial expression, verbal and nonverbal behaviors) along with cultivating awareness and application of ethical principles. Communication and ethics are deeply interrelated. Verbal and nonverbal communication proficiency^{18,19,20} is necessary for clinicians to develop trust, encourage patient disclosure, and determine patients’ needs, values, beliefs and concerns.^{21,22,23} Good practice in complex communication is therefore inseparable from the ethical practice of medicine.^{24,25} Ethics and communication have both proven challenging to teach, however.^{26,27,28,29}

With its capacity for standardized presentation of materials, distributed learning across institutions, and fine-grained uniform assessment, AI-enabled VH simulation can help address the variability of current undergraduate and graduate *ethics education*.^{30,31} Learners can engage one-on-one with VH patients, family members, or colleagues in realistic situations drawn from everyday clinical encounters that focus on ethical challenges and complex communication.^{32,33,34,35} These simulated situations can pose a range of ethical challenges for learners—from informed consent to breaking bad news, dealing

with cultural disparities, and more. AI-enabled VH simulation can improve how students learn, remember, perceive, and make decisions.²⁹ By scaffolding learning materials, simulations can increase in complexity as learners advance along their educational trajectory from premedical study to postgraduate continuing medical education. Moreover, their round-the-clock accessibility provides flexibility for busy learners.

In summary, VH education offers a promising frontier in health care education into which educators should not fear to stride.

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LETTER TO THE EDITOR

Response to “Will We Code for Default ECMO?”: Clarifying the Scope of Do-Not-ECMO Orders

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In “[Will We Code for Default ECMO?](#)” Brauner and Zimmerman draw parallels between the history of cardiopulmonary resuscitation (CPR) and current developments in extracorporeal membrane oxygenation (ECMO). They fear that, as occurred with CPR, indications for ECMO will expand until cardiac arrest becomes a “blanket indication” for ECMO as an adjunct to CPR. If ECMO becomes a default treatment for patients experiencing cardiac arrest, patients and surrogates will likely need a mechanism to opt out of this default. As Klugman, a clinical ethicist, recently blogged: “Is It Time for the DNE: Do Not ECMO?”¹ This question has also been raised in the bioethics and critical care literature.^{2,3} We agree with Brauner and Zimmerman that the best course of action would be to prevent ECMO from becoming a default treatment.

However, we should also consider how to proceed if ECMO does, in fact, become part of the default treatment for cardiac arrest. Such considerations include implementation challenges that would likely arise if do-not-ECMO (DNE) orders were to be incorporated into hospital code status systems. Specifically, we are concerned with implementation challenges related to the scope of DNE orders. We can gain insight into these challenges by comparing DNE orders with do-not-resuscitate (DNR) orders, which have faced scope-related implementation challenges since their adoption in the 1970s.^{4,5} DNR orders allow patients and surrogates to refuse CPR that would otherwise be provided by [default](#).⁴ DNE orders could function similarly by allowing patients and surrogates to refuse ECMO that would otherwise be provided by default. By examining the scope-related implementation challenges associated with DNR orders, we can predict some of the challenges likely to arise when incorporating DNE orders into hospital code status systems.

First, clinicians sometimes erroneously infer patient preferences for treatments outside of cardiac arrest on the basis of a DNR order.^{5,6,7} For example, a clinician might assume that a patient with a DNR order would not want other life-sustaining interventions, such as dialysis. As Yuen et al explain, these erroneous inferences “may be due to misunderstanding the *scope* of DNR orders [italics added].”⁵ Despite decades of efforts to clearly define the scope of DNR orders in national guidelines,^{8,9} DNR orders have continued to shape clinical management decisions for treatments other than CPR.^{6,7} To prevent clinicians from misinterpreting DNR orders, some hospitals have implemented

broadened DNR orders that explicitly communicate patient preferences for treatments other than CPR.^{10,11,12,13,14} However, there is limited data on whether this strategy is effective.^{10,11} We have little reason to believe that DNE orders will not also be subject to misinterpretation; clinicians may assume that patients with DNE orders do not want other life-sustaining interventions.

Second, the scope of DNR orders is unclear because many of the components of CPR, such as intubation and mechanical ventilation or intermittent mandatory ventilation (IMV), can be indicated in other contexts.^{15,16} For example, a patient who refuses CPR in the event of a cardiac arrest (and thus refuses IMV in this context) could want IMV for chronic obstructive pulmonary disease exacerbations. This contextual variation creates challenges in understanding the scope of DNR orders. For example, does a DNR order imply a do-not-intubate order and, if so, in what clinical circumstances? Or does a DNR order preclude intubation entirely? Some organizations and clinicians have navigated these questions by implementing “partial” code orders, although these are controversial.^{17,18} Similar to IMV, ECMO can be a component of CPR but can also be indicated in other contexts. Thus, ECMO would likely be subject to similar questions: Should a DNR order be interpreted as implying a DNE order and, if so, in what clinical circumstances? Or should a DNR order preclude ECMO entirely?

To address these questions, clinicians and bioethicists should proactively consider how to limit the scope of DNE orders before ECMO emerges as a default treatment for patients experiencing cardiac arrest. In particular, code status systems that incorporate DNE orders should prevent physicians from acting on erroneous inferences about patient preferences and should clearly define the conceptual and practical relationships between DNR and DNE orders.

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