

Retrieving the Moral in the Ethics of Maternal-Fetal Surgery

A Response to “Fetal Repair of Open Neural Tube Defects: Ethical, Legal, and Social Issues by Julia Radic, Judy Illes, Patrick McDonald” (CQ28(3))

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Open-uterine surgery to repair spina bifida, or ‘fetal surgery of open neural tube defects,’ has generated questions throughout its history—and continues to do so in a variety of contexts. As clinical ethics consultants who worked (Mark J. Bliton) and trained (Virginia L. Bartlett) at Vanderbilt University—where the first successful cases of open-uterine repair of spina bifida were carried out—we lived with these questions for nearly two decades. We worked with clinicians as they were developing and offering the procedure, with researchers in refining and studying the procedure, and with pregnant women and their partners as they considered whether to undergo the procedure. From this experience in the early studies at Vanderbilt, we learned that pregnant women and their partners approach the clinical uncertainty of such a risky procedure with a curious and unique combination of practicality, self-reflection, fear, and overwhelming hope. These early experiences were a major contributing factor to the inclusion of an ethics-focused interview in the informed consent process for the Management of Myelomeningocele Study (MOMS) trial study design.

The MOMS trial protocol included an extensive, three-day process of education and medical evaluation, culminating in meetings with a social worker or clinical ethics consultant, so that women and their families had the opportunity to learn, ask questions, and reflect with others—about the uncertainty of potential benefits and risks for their child—*before* consenting to participation in the randomized trial. This process emphasized the importance of addressing uncertainty, the pregnant women’s vulnerability, and the values that guide decisionmaking *in addition to, and separately from,* the medical considerations.¹ From the beginning, then, the moral and ethical considerations were ‘baked in’ to the protocol as part of the development of this procedure. And, as two of those clinical ethicists involved in this work (one since almost the beginning), we have presented and published extensively about the moral and ethical challenges this procedure has raised over time. In this context, then, we experienced real puzzlement and even concern when reading the introduction to the article by Julie A.E. Radic, Judy Illes, and Patrick J. McDonald, where they assert that, “This paper is the first to

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focus on the fundamental ethical issues arising from a novel neurosurgical intervention whose use is continuing to expand."²

Certainly Radic et al.'s article provides an overview, broadly framed, of the ethical issues about which much ink has been spilled before, during, and since the open-uterine procedure was developed and the MOMS trial designed, implemented, and completed. Because we endorse the fact that these issues remain relevant and require ongoing attention, we have no intention of rehearsing, point for point, the moral and ethical questions identified and addressed in the history of this procedure or the robust literature available (some of which are even cited by Radic et al.!) regarding the issues of fetal personhood, informed consent, equipoise, and the disability versus lethality justifications for high-risk procedures. Nor do we intend to do more than notice that their final concerns about the 'ethics' of future procedural modifications appears to slip back into the very focus on the technical which Radic et al. decry at the beginning of their article (while it also seems to overlook the history of this surgery as one of continual modification and thus requiring equally constant reevaluation of the 'ethics.')

For example, the initial four maternal-fetal surgeries to repair fetal myelomeningocele performed at Vanderbilt used endoscopic techniques.³ Of those four fetuses, two died perinatally and two required surgical revisions of that initial repair soon after birth. In response, the shift was made to refine and use an open-uterine approach.⁴

We will, however, reintroduce to the discussion and the field that which is missing: the moral elements overshadowed by the style of bioethics discourse in Radic et al.'s re-presentation of the ethical issues. Our concern is that any work done appealing to the 'ethics' of fetal surgery must be rooted in and

responsive to the clinical: the practical idea that moral decisionmaking in clinical settings must be informed by values and beliefs, factors and circumstances that are specific to each situation. Engaging the 'ethics' of maternal fetal surgery cannot simply echo the typical bioethics discourse or perceived need to regulate innovation. It must be attentive and responsive to the clinicians and pregnant women for whom the 'ethical' questions have real life implications—i.e., are moral and experiential concerns. These experiential and moral components, we argue, are equally relevant as the theoretical, framing concerns revisited by Radic et al., especially now. These components should be recognized as an important part of any careful and historically accurate review of the literature about the ethical, legal, and social issues—of the *context* of practical, moral concerns—that this procedure has generated for decades.

For example, since the earliest attempts at prenatal surgery for spina bifida, it has been widely recognized by physicians providing maternal-fetal surgery, and researchers, that many pregnant women (and their partners) who decided for the surgery or to enroll in MOMS had vivid and strong religious beliefs. Most shared a kind of fundamental Christian ethos which they used to explain their pregnancy and their experience of those initial ultrasound images that showed spina bifida. The ethos accounted for everything—even finding out about the surgery centers offering the surgery or the MOMS trial—with many saying that God was guiding them and had plans for their child. Much of this was expressed in fervent religious hopes—at times even assertions—that God would cure the spina bifida.^{5,6} Many of these moral concerns were articulated in early work by ethics consultants involved with the procedure—at Vanderbilt, at University

of California, San Francisco, and at University of North Carolina-Chapel Hill—and in conferences and conversations about the developing procedure.⁷ None of this, however, is addressed in Radic et al.'s theoretical stylings and focus on equipoise, informed consent, or even fetal personhood. The moral goes missing in the echoes of a bioethics debate.

In that light, our aim in responding to Radic et al. is to direct attention to the extensive, complex, and robust work that has been done to clarify the moral and ethical challenges shared by the pregnant women who considered the procedure (before and after the MOMS trial) as well as by the clinicians, researchers, and scholars who wrestled with the *Whether* and *Why* as well as the *How* during the ongoing development of these procedures.^{8,9,10,11,12} On that basis, we offer insights from our clinical ethics consultation work—and research around that ethics work—both to highlight the professional and institutional efforts to address these concerns, as well as to describe how 'ethics,' identification and clarification of moral concerns, and consultation practice were included in the MOMS trial protocol. Thus, in addition to resurfacing the deep moral engagement and ethical reflection that informed the MOMS trial protocol, we offer some concerns raised around the publication of the MOMS trial results—namely, the erasure of 'ethics' from the protocol. Specifically, we saw a risk of ethics fading from the post-MOMS conversations—and thus losing the insights from the pregnant women and clinicians who struggled with these moral and ethical challenges.

That hazard and potential harm has been borne out by the fact that Radic et al. appear to reinvent several previously created wheels (for example, noting the challenges in obtaining robust informed consent for a procedure that offers no physiologic benefit to the

pregnant woman at the risk of substantial harm¹³) when, in fact, their article seems to reaffirm that the moral and ethical issues have never really gone away, even if they have not received the attention they deserved. No matter how obscured they become by the clinical statistics and outcomes compiled with the spreading utilization of the procedure, including the ongoing technical variations noted by Radic et al., these concerns persist—vivid and wrenching for pregnant women and their clinicians.

Thus, proceeding with further innovations without recognition of and learning from the 'moral pioneers' who have done this difficult moral work before, does a disservice to those considering participation in future clinical and research developments. So, by way of a summary at the conclusion of this response, we offer two suggestions for further work that takes into account not only the broad ethical themes, but also the deep moral work engaged in by pregnant women, their families, and the clinicians caring for them—without which the 'ethical, legal and social issues' simply become fodder for theoretical and intellectual exercises. Given our work and first-hand experience with the compelling moral significance of these themes and questions, our intent is to remind others how crucial it is to refocus on the actual moral circumstances amid the discourse of bioethics and expansion of clinical innovation.

If I Could Turn Back Time¹⁴: Maternal Fetal Surgery and Ethics Consultation Across Time

While Radic et al. offer their work as the first to tackle serious ethical questions about prenatal surgery for spina bifida, we must plainly disagree and, instead, welcome Radic et al. to a long standing

conversation on this topic.^{15,16,17,18,19,20} For any era of medical ethics you choose—from the 1950s to the Baby Doe regulations in the 1980s, right up to the recent controversies about the Groningen Protocol, spina bifida has generated unresolved, hot-button moral issues.^{21,22,23} Spina bifida, the incomplete closure of the spinal column and exposure of the spinal cord, is the most severe congenital anomaly consistent with meaningful life. The variability of functional, cognitive, and developmental outcomes for spina bifida²⁴—the uncertainty and unpredictability of diagnosis and prognoses that range from mostly manageable to life-threatening, even with increasingly precise lesion-level identification—creates social, moral, and medical challenges for children born with the condition, their parents, their communities, and their care providers. Historically, children born with spina bifida died during or shortly after birth, but with the development of antibiotics and sterile surgical procedures, a variety of treatments have been proposed over the last 50 years, with variable rates of success.^{25,26,27} In large part, it is the variability of prognosis and outcomes—with or without treatment^{28,29,30,31}—that has raised difficult decisions about which treatments to pursue for which children.

Back in the Day³²: An Absurdly Brief History of Spina Bifida Treatment

As reviewed by Radic et al.,^{33,34} in the late 20th century, advances in imaging and surgical techniques (along with the idea that the earlier the repair, the less the secondary and ongoing damage to the spinal cord and brain ventricles) led to the possibility of prenatal repair of spina bifida.^{35,36,37} The procedure represented a technological *tour de force* with what are sometimes compelling results, but which come with equally

compelling risks and harms.^{38,39} The results—and the attendant risks to pregnant women and their fetuses—were so compelling that in the United States, the National Institutes of Health and specifically, the National Institute of Child Health and Human Development, funded a multicenter, randomized controlled trial, the first for an open-uterine procedure, to determine which of prenatal surgical repair and post-natal repair of myelomeningocele was more beneficial.

The results from the nine-year Management of Myelomeningocele Study (MOMS Trial) were published in the February 9, 2011 *New England Journal of Medicine*, indicating that prenatal repair lowered the risk of needing a shunt placed (from 80 percent to 40 percent) and, in some cases, reduced the severity of hindbrain herniation (a secondary effect of myelomeningocele, also called the Chiari II malformation). The results were striking, and the success of the study's coordination and execution equally so, but after all the well-deserved excitement of publication receded, it appears that so too have some recognitions of the moral and ethical quandaries that challenged pregnant women considering the procedure. Pregnant women and clinicians are left with the same questions they have always faced: which treatments are best for which children? Will this child benefit or be harmed? The same questions persist for two reasons in two related categories: one technical/medical, and the other social and moral.

First, as the lead author on the MOMS trial, Scott Adzick, notes in the *NEJM* article that, "Although the prenatal-surgery group had better outcomes than the postnatal-surgery group, not all infants benefitted from the early intervention, and some had poor neuromotor outcome."⁴⁰ Thus, clinicians and pregnant women are confronted with

the same challenge they have had since those initial stages of development: would this surgery offer more benefit than harm to *this fetus* / to *my child* with spina bifida, or do the risks outweigh the benefits? Overall, the surgery appears to lower some medical risk. Individually, however, it may or may not help. And the risks to the fetus with spina bifida and to the pregnant woman who would undergo surgery have remained very similar over time. When the technical/medical picture is not much clearer for the individual making decisions, the nonmedical factors—moral and social—emerge as powerful influences on decisionmaking about which treatment is best for a particular child with spina bifida.

As noted, spina bifida has always raised medically and morally troubling questions regarding disability and medically appropriate treatment, and since the 1970s (with the landmark legal case *Roe v. Wade*, and the development of prenatal diagnosis via ultrasound), abortion has played a significant part in the public debates about spina bifida as well. Because both discourses—disability and abortion—are deeply contested in highly public and political ways, the serious and provocative moral controversies raised by this surgery and by offering open-uterine fetal surgery to a pregnant woman with a diagnosis of fetal spina bifida occur in a volatile social context. What is the right thing to do, when faced with a prenatal diagnosis of spina bifida? What treatments ought to be offered? With prenatal diagnosis of spina bifida, the questions have shifted from ‘Which treatments are appropriate to offer any child born with spina bifida?’ to ‘Is it morally permissible to terminate a pregnancy after prenatal diagnosis of spina bifida?’ and now to ‘Is it morally permissible to offer treatments that may benefit the fetus or child-to-be with spina bifida, when those treatments will cause

direct physiological harm to the pregnant woman, without direct medical benefit?’

Thus, even with positive results from the randomized trial, renewed efforts will need to be directed toward identifying and establishing legitimate processes to evaluate the ethical issues created by maternal and fetal vulnerabilities, especially at previable gestational ages. These issues persist and continue to evolve because, as even the study’s authors observed, “The results of this trial should not be generalized to patients who undergo procedures at less experienced centers or who do not meet eligibility criteria.”⁴¹ More than anything, the MOMS trial demonstrated that the procedure is not a cure, it will not work for everyone, and it will not work in the same way for anyone, or, to put it bluntly, ‘results may not be typical’—something Radic et al. also note as an ethical issue.⁴² It seems clear, then, that the moral concerns and the lessons from the women who participated in the elective series at Vanderbilt and the MOMS trial remain the same for pregnant women, post-MOMS: what do these statistics, risks, and potential benefits mean for *me*, *my family*, *my child* who will have spina bifida? Likewise, the questions plainly remain the same for clinicians and institutions: how do we help these multiply-vulnerable pregnant women make a medically and morally appropriate decision—a decision that fits their lives and values and hopes and fears about the future for their children?

Those questions have not been alleviated or resolved by the publications of the results from the 9-year-long MOMS study—or in the 9 years since the study’s end. Indeed, moral candor requires that the acclaim for this technological *tour de force* is not allowed to distract us from the desperate fact that this surgery taps into deep currents of social unease and

wariness directed toward birth defects, physical disabilities, and especially neurological deformities of any kind.⁴³ So, in what ways can and should clinicians and pregnant women engage these kinds of troubling ethical and medical questions? And how can clinicians and scholars remember and recognize that such engagement is still ongoing, still a part of the moral landscape of this procedure—and hence still deserving of careful attention and explicit consideration of these ethical and social issues?

Nothing is New Except What Has Been Forgotten⁴⁴: Ethics Consultation in Moral Moments

What we have learned from our experience with ethics consultations at Vanderbilt is relevant to the issues Radic et al. have noted and that others are encountering in the proliferation of this prenatal surgery to other fetal intervention centers. Reviewing our work, along with the combined numbers from the published Vanderbilt series and MOMS, what we find is that there was a group of 361 pregnant women who were willing to do *almost anything*, short of terminating the pregnancy, in order to alter the course of personal deficits directly associated with spina bifida. Further, as noted above, in discussions leading up to their decisions about whether to have fetal surgery (or enroll in MOMS), many pregnant women and partners expressed a vigorous and explicit spiritual commitment. They infused spiritual and religious language, mainly Christian terms and themes, into their experiences of pregnancy and explanations about the choice to seek maternal-fetal surgery. Given the straightforward statements by many couples that their religious beliefs were a significant factor in their decisionmaking—having said that they were being guided by God, or by prayer—we sensitively pursued discussion of those

religious factors. What we learned was that many couples insistently saw themselves as having embarked on a significant journey, with many obstacles to be surmounted, and whose burdens should be endured with courage and faith. With just a little gentle probing and patient listening, we learned that for many this travail was filled with emotionally difficult and dark places, with hardly a glimmer of hope anywhere. These stories about being on such a ‘journey’ seemed then to carry along with it the sense that the prospect of maternal-fetal surgery emerged into that gloom like a ray of hope, a way to rescue them from grief and disaster. This complex set of attitudes cannot be simply subsumed under altruism because one of the most complicated ethical factors was that, in deciding to have the surgery, the sense of ‘benefit’ they spoke of was spiritual—a fervent kind of hope. So much so that their explanations were that only in trying ‘to help’ would their religious faith be redeemed.⁴⁵

Thus, while Radic et al. make reference to the presumption that nonmaleficence and beneficence shape women’s motivation from “a combination of self-interest, as well as altruism towards her future child, in minimizing her parenting workload by doing what she can to optimize function and health outcomes for her child,”⁴⁶ the *New England Journal of Medicine* commentary by Joe L. Simpson and Michael F. Greene, rooted in the experiences of both pregnant women and the clinicians caring for them, goes so far as to say that couples who do not terminate will feel pressured “to do everything possible.”⁴⁷

And yet, as we also learned in our direct interactions during our ethics consultation work: scholars and clinicians—and pregnant women—need to consider that through the experience in the Vanderbilt series, the Vanderbilt team met with 230 couples, and *almost a quarter*

declined the surgery.⁴⁸ Despite all the panic and despair after a prenatal diagnosis of spina bifida, and despite all the religious and technological hope vested in this procedure, 23 percent of women chose not to undertake the risks, even for the possibility of benefit, even with the hope against despair, the pressure to ‘do everything,’ and the powerful seduction of the ‘therapeutic misconception’ and ‘technological imperative.’ That number of women declining the procedure gave pause to the clinicians at Vanderbilt, and to those designing the MOMS protocol.

This is Not Really Happening / You Bet Your Life It Is⁴⁹: How the Moral Grounds the Ethical

Typical informed consent processes and documentation leave little time or space for discussions of such motivations—so the Vanderbilt protocol deliberately included the opportunity for women and their families to discuss and “to examine what they have learned about the study in the course of their evaluation and to discuss how they feel about enrolling in the study.”⁵⁰ The need to have dedicated time and space—and even personnel—to address such issues was not new even when we were engaging with women considering the elective procedure and, later, considering participation in the MOMS trial at Vanderbilt. Even a cursory glance back in time shows that similar considerations were outlined in very early discussions about fetal surgery, for example, where William Ruddick and William Wilcox highlight the need for a reasonable Ethics Consultant.⁵¹ Similarly, in response to a series of meetings by the International Fetal Medicine and Surgery Society (IFMSS), John Fletcher and Al Jonsen included Ethics Consultation as a key component to address controversial and complex issues that seem, almost by necessity, to

accompany these interventions.⁵² Further, in developing the procedure, Vanderbilt University Medical Center took the call for attention to ethical concerns seriously. With Wilcox and Ruddick along with Fletcher and Jonsen as ethical background, Table 1 (below) offers a very abbreviated sketch of the history and development of ethics consultation for maternal-fetal surgery at Vanderbilt, which established an ethics team as a key component for promoting patient understanding throughout the counseling and evaluation process. This component was then argued for and established as the standard for informed consent for in the MOMS study with the idea of an ‘ethics focused interview.’

More explicitly, as part of the final screening for inclusion in the trial, the MOMS protocol required “An *ethics focused interview* to afford potential participants a formal opportunity to examine what they have learned about the study in the course of their evaluation and to discuss how they feel about enrolling in the study.”⁵³ The *ethics focused interview* was considered to be as crucial for participation as the fetal MRI or as maternal clearance for surgery by anesthesia.

The relevance of this history, post-MOMS trial, is straight-forward, although not simple: it is quite likely that many women who seek to have this surgery will have attitudes quite similar to those we have described and, if asked, would express similar beliefs and would likely benefit from time and explicit attention to those attitudes and beliefs—from the attention to their moral experiences that undergird the ‘ethics’ of their informed consent (or refusal). Therefore, moral candor *additionally* requires that we address in clear language, with other women with similar attitudes, the plain circumstances that the results from the MOMS study will not alleviate maternal or fetal

Table 1. Abbreviated History of Ethics Consultation at VUMC

1992	• Met with Neonatology, Neurosurgery and MFM to discuss animal studies for fetal repair of Neural Tube Defects
1994	• Provided ethics consultation for initial endoscopic repair of fetal spina bifida
1996	<u>May:</u> • Established, at request from Chair of Ethics Committee, Maternal-Fetal Surgery subcommittee Oct–Nov: • Put together—with input from OB/GYN and Neonatology—a Fetal Surgery team
1997	<u>Jan:</u> • Established multidisciplinary process for maternal- fetal surgery consultations <u>April:</u> • Reviewed protocol and procedures for open fetal surgery to repair fetal myelomeningocele • Provided ethics consultation for first open-uterine fetal repair <u>Aug:</u> • Began review of initial patients under protocol <u>Sept:</u> • Generated a set of guidelines regarding how to respond to inquiries for maternal-fetal surgery
1999	<u>Feb:</u> • Reviewed protocol and procedure for in utero placement of shunt for hydrocephalus <u>Aug:</u> • Reevaluated criteria re: Feb. and July meetings
2000	<u>Jan.</u> • Discussed moratorium for maternal-fetal surgery at VUMC • Began weekly Fetal Surgery team meetings <u>March:</u> • Prepared and directed 2-day conference: <i>Fetal Surgery & the Moral Presence of the Fetus</i> <u>Nov:</u> • Focused on development of MOMS Study
2001	• Focused on development of MOMS Study including the idea that Vanderbilt had established the standard for informed consent, which was then included in the Protocol for MOMS

vulnerability—that in terms of difficulty, uncertainty, and existential doubt, the choice and challenge is the same as it ever was.

**Everything Old is New Again⁵⁴:
Lessons Pre- and Post-MOMS Trial**

Yet, ten years after the publication of the MOMS trail, Radic et al. revisit “fundamental ethical issues” as if they were previously unknown, and they claim that the focus has been “on the technical aspects of the procedure and clinical outcomes.”⁵⁵ And they are not entirely wrong about the emphasis on the clinical and procedural over the ethical and certainly the moral: even in the *published* protocol of the MOMS trial, the *absence* of ethics is prominent. Quite curiously,

and most troubling, in the trial protocol—published as a Supplementary Appendix—there is no mention of the ‘ethics focused interview’ that had been a part of the procedure since the earliest days of the experimental, elective series. Instead, the protocol lists, simply, a ‘focused interview.’ Ethics—in that final and formal presentation of decades of work—was erased, and so it is little wonder that, now, a decade later, the questions around ethics and open fetal surgery for spina bifida emerge as if *de novo*. We raised concerns at the time of the MOMS trial publication, when the *operational* protocol included (and the trial was conducted using) ‘*an ethics focused interview*,’ but the published, post-trial protocol (which would, one assumes, guide current and future institutional

practices) describes only 'a focused interview.' Those concerns remain in the obvious and disturbing question: "What happened to Ethics? How do we address the moral moments?"

This question is disturbing to those of us who have provided 'ethics focused interviews' to women—both in the Vanderbilt elective series and as part of the MOMS trial at Vanderbilt—for reasons worth repeating: though the MOMS trial provided a great deal of clinical information to researchers and clinicians, it does not make the decision for pregnant women any easier, or any less fraught with medical and moral uncertainty. This may seem counter-intuitive: after all, some would argue, the study shows great results for the group of children who had their spina bifida lesion closed *in utero*. Yet, again worth repeating: "Although the prenatal-surgery group had better outcomes than the postnatal-surgery group, not all infants benefitted from the early intervention, and some had poor neuromotor outcome."⁵⁶ Post-MOMS, individual women face similar risks and benefits as the women pre-MOMS, and (if we are to learn anything from the women who considered this procedure between 1997 and the MOMS trial publication in 2009), it is likely that post-MOMS women arrive at maternal-fetal surgery centers bearing with them all the nonmedical concerns identified by pre-MOMS women in their own publications,⁵⁷ in reports from ethics consultants,^{58,59,60,61} and in qualitative research, including the research described below.^{62,63} Since the post-MOMS decisionmaking for this surgery appears to look a lot like the pre-MOMS decisionmaking, the question seems to us not *why should institutions offer an 'ethics focused interview'* but, *why would they not? Or, more pointedly, how could they not?*

What Difference Does it Make?⁶⁴: A Preliminary Report on Why Ethics Should Remain Explicit in Future Protocols

To address this question, we want to offer a brief snapshot to corroborate and illustrate the importance of ethics consultation for maternal-fetal surgery to repair spina bifida. The question of how women made the medically, socially, and morally complex decision about this procedure was a compelling question for Bliton, as the primary ethics consultant involved with the procedure at Vanderbilt, and for Bartlett, as a graduate student exploring clinical ethics consultation and decisionmaking. Thus, Bartlett designed a dissertation research project around the question of women's experiences with open-uterine surgery to repair spina bifida. What was their experience in making such a decision—whether they chose prenatal repair or post-natal—and living with their decision? What actually mattered when women were making their decision? What did women think of the ethics consultation process? Had the ethics consultation process helped?

The pilot study participants were women who had come to Vanderbilt between 1996–2001 to consider prenatal surgery for their child's spina bifida when the procedure was still experimental—and elective. They agreed to participate via semi-structured, qualitative interviews conducted in 2009. The interviews began with an invitation for the women to tell their story, to describe what happened, or what they remembered. What was it like to go through the innovative and odd ethics consultation process? What was important to them? And what did these women want to share with researchers, clinicians, and other women facing similar choices? Though this was a small, pilot study, the interviews with these women

revealed multiple areas of moral concern that should be addressed by further research with this cohort of women, and with women from the MOMS trial and beyond. We will briefly note four key elements that were crucial for these women's experiences, and that indicate some of what is required to support women considering this procedure electively in the future.

On a Lonely Road and Traveling⁶⁵: Four Key Elements of Women's Decisionmaking

First, getting detailed and accurate medical information was crucial in their decisionmaking, rather than the instant 'doom and gloom'—and offers of, or pressure for abortion—that often made their initial diagnosis so devastating. Second, all of the nonmedical aspects were important for these women: concerns about family, disability, finances, faith, and responsibility played a huge role, along with deep uncertainty, fear, and doubt. These themes echoed the moral calculus practiced by women since the beginning of prenatal surgery.^{66,67} Third, for almost all the women interviewed, the importance of having someone to help identify and address all those ethical issues, to think aloud about all those shifting moral concerns in the middle of the changing clinical situation turned out to be crucial. All of the women described the process as challenging—'hard,' 'difficult,' 'tough,' but (with one exception) the women interviewed said the experience was good—and for very specific reasons: it was a chance to clarify their questions, and to process all the education they were receiving about spina bifida in general and their child's spina bifida in particular. It helped them prepare for the questions and curiosity of others in their family and in their communities. The ethics consultation process allowed these women the chance to

reflect on these moral concerns: a chance to identify and articulate their decision-making, and a chance to talk to someone who had no other agenda but to take the time to help them think it through. Finally, time emerged as a key element in their decisionmaking: after all the rushing, the panic, the urgent appointments and deadlines from various institutions—and the ticking clock of their child's gestation—having a moment to 'put on the brakes,' 'trying to slow the urge to "act quickly,"' mattered. It was important, as one woman said, to "reinforce that it's a permanent weight that will remain for longer than you have to decide." The element of time and the idea of a decision that carries weight for a span of years that seems disproportionate to the time allotted for the decision turns out to be important.

To be crystal clear about that last point: 5–10 years out from making their decision about maternal-fetal surgery, every woman interviewed was still bearing the weight of that decision and, equally relevant, each of the women reflected on their decision as being a good one. They described being at peace after (and, in the one case, despite) the consultation process, and being at peace with the decision they made. They praised the time offered and the questions asked in the ethics-focused interview. They appreciated the process because it meant they did not have to keep agonizing over their decisions, but, when they do reflect back, they can go over the steps they took. They could know, as one woman said, "it was not a fly by night decision." As one woman said, "we did all the hard work on the front end." The women interviewed were explicit that it mattered and helped for them to think about, talk about, ask, and answer questions about their decisions, *before* they made these decisions. These responses, even the outlier, indicate

that having ‘ethics consultation’ is important for women who consider this surgery, as suggested by Ruddick and Wilcox in 1982, and reaffirmed by Fletcher and Jonsen and the IFMSS well before the MOMS trial began or ended. And this is the lesson for the post-MOMS maternal-fetal medicine community.

Talkin’ About a Revolution⁶⁸: the Radical Return to the Moral in the ‘Fundamental Ethical Issues’ of Open-Uterine Surgery to Repair Spina Bifida

In light of the counter-history provided and the concerns raised by missing the moral and clinical elements of this procedure, we will extend two explicit and directive challenges for the next generation of clinicians, of ethicists, and of women considering open-uterine surgery to repair spina bifida in the years to come. The first challenge is for institutions to include an explicitly ethics-focused interview in their own protocols when offering this procedure—even if they have not done so yet. Procedural approaches (that focus on information, autonomy, nondirective counseling) are insufficient—they are not enough^{69,70,71}—no matter how many times scholars and clinicians want to revisit these broad frames and theoretical concerns. Women’s stories—published, in this research, and available in the broader media—indicate that there is (much) more going on that must be addressed.⁷² There continue to be clear indications of the need to provide space, time, and nonmedical, ethics-focused personnel to help women explicitly address the moral issues they confront and experience. In failing to provide this assistance, institutions and clinicians are at best missing an important opportunity to help these women and at worst, at risk of causing significant moral and emotional harm. Proceeding straight

from exam table to conference table to operating table with the same doctors (or medical and surgical team) is not sufficient for such a morally and socially complex procedure—it never has been—let alone for the necessary and appropriate informed understanding needed for consent.⁷³ The letter of the law of informed consent may be met by typical informed consent practices, but based on our clinical and research experiences with women who considered this procedure, we contend that the spirit of informed consent is not fulfilled. With the inescapable and significant moral and social issues it raises, this procedure is not the same as an appendectomy or even a complex cardiac procedure, and an extra layer of appraisal (not in the sense of judgment, but in the sense of recognized complexity) is required. Bluntly, the bar is higher when the stakes are higher, and when the questions are about abortion, disability, parental responsibility, the foundations of one’s moral life, *in the context of* the risk of maternal or fetal morbidity and or mortality, the stakes are about as high as one can imagine: individually, ethically, socially.

Second, the maternal-fetal medicine community—clinicians, researchers, and patients—needs more research and follow up with the women from the elective series and from the women with the MOMS trial. Future research should not focus only on the child’s shunt status or the women’s own Beck Depression Index—but should explore the actual, experiential details of what it was like to make these kinds of decisions (and what it is like to live in them) within the immediate as well as the longer-term aftermaths. The research presented here was from a pilot study—diving in deeply to the few interviews that fit within the scope of this project—and it was intended to learn if there was a need for more research. There is such a

need: to value the contributions of these women toward the development of the procedure; to understand the complexity of their ongoing lived experiences after considering the procedure; and to reflect on and learn how these insights can inform and improve both the processes and experiences of decisionmaking going forward.

Once in a Lifetime⁷⁴: Challenges for the Next Generation

For the women and their families considering this procedure—the decision is a once in a lifetime moment. It is medically and morally challenging, and they deserve the fullest in both medical and moral support, especially since clinicians are still learning from every surgery they perform—from every woman who consents and from every woman who declines. In the same vein, this is also a once in a lifetime moment for the clinicians and institutions who have offered the surgery after the MOMS trial. It is a chance to go forward with the lessons learned from the elective series and from the MOMS trial: that for these women, the ethical issues are always front and center and must be explicitly addressed—with each potential patient.

Robert Heinlein noted, somewhat cynically, “Human beings hardly ever learn from the experience of others. They learn; when they do, which isn't often, on their own, the hard way.”⁷⁵ While recognizing the truth in Heinlein's observation, we are also optimistic enough to keep insisting that clinicians involved with open-uterine surgery for spina bifida—surgeons, physicians, nurses, and ethics consultants—are able to and are obligated to learn from the experience of others. We learned a lot from the elective series and the MOMS trial, but we need to make sure that we take all the lessons learned forward—sharing Radic et al.'s

concern that we value more than the lessons about surgical outcomes and the data on shunting.

To conclude with our musical metaphor, if sharply and only momentarily, in a once in a lifetime moment, everyone may ask the question *Am I right, or am I wrong?* But without carrying forward what we learned, without paying attention to the moral elements—without offering an ethics focused interview to these women—we all (clinicians, researchers, ethicists, and patients) risk waking up one day and asking not only, *Well, how did I get here?* with Radic et al., but wondering, years later—alone and together—*My God, what have I done?*

Notes

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