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COMMENTARY

WILEY BIRTH ISSUES IN PERINATAL CARE

Informed consent and refusal in obstetrics: A practical ethical guide

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1 | INTRODUCTION

The ethical principle of autonomy gives women a fundamental right to security of person. The principles of beneficence and nonmaleficence are caregivers' duties to "do what is best," and "do no harm." Usually, women and caregivers agree on the best course of action and informed consent is straightforward. Occasionally however, a woman declines recommended treatment or requests treatment that a clinician believes is unsafe. When this occurs, the historical adage: "the doctor knows best" is no longer valid. Ethical tension between autonomy, beneficence, and nonmaleficence may cause conflict between a woman and her caregivers that can impede communication, compromise care, and contribute to poor outcomes. In these situations, negotiating informed consent or refusal can be challenging. By accepting a woman's refusal, caregivers commonly believe they incur ethical and legal liability. Accordingly, they may withdraw care or coerce women to accept intervention. However, coercion negates consent and abandonment is unprofessional. This commentary explores how practical knowledge of the ethical and legal basis of informed consent and refusal can build trust, preserve the therapeutic alliance, and minimize risk when women refuse medical advice.

2 | THE PRIMACY OF MATERNAL AUTONOMY

The Universal Declaration of Human Rights guarantees everyone, including pregnant women, security of person.[1] This includes the right to decline any medical procedure that violates her bodily integrity, even if that refusal increases her or her fetus' risk of death. This right is enshrined in medicine and law as a patient's right to give or refuse consent. Health care practitioners have a duty to inform patients and to respect their choices.

Professionals strive to make recommendations based on evidence and objective estimations of benefit vs risk. Guideline authors have a similar aim. Yet benefit and risk are subjective and vary according to patients' values and beliefs. A patient's view of acceptable risk or worthwhile benefit may differ from that of other patients, caregivers, or guideline authors; however, it is universally accepted that a patient can refuse treatment. A Jehovah's Witness who is bleeding to death may refuse a lifesaving transfusion because of religious belief, even if that belief would qualify as a fixed delusion in the secular world. This right is well laid out in ACOG Committee Opinions and is not diminished if a patient is pregnant.[2,3]

Some suggest a woman has an ethical duty to her fetus that limits her autonomy and imply that physicians have a moral obligation and authority to enforce this duty if a woman neglects it.[4] This stance is paternalistic, condescending, and without ethical or legal basis. Even when based on best evidence, a clinician's estimate of harm vs benefit is imprecise and not infrequently wrong. Since "reasonable risk" and "expected benefit" are subjective, a clinician's belief about what constitutes "neglect" is an opinion based on the clinician's rather than the patient's values. In the United States, Canada, and Britain, a fetus has no legal status as a person. Neither medical professionals nor the State have ethical or legal authority over a woman based on the presumption that they care more for her fetus than she does.

3 | DICHOTOMOUS VS NUANCED THINKING

There is a tendency in human thought toward dichotomous thinking: black or white, right or wrong, safe or unsafe. The truth is more nuanced.[5] For example, every obstetrician would recommend a cesarean section to a woman with a history of prior classical cesarean section; but if she presented pushing in the second stage of labor, it may be quicker and safer to perform an assisted vaginal birth. Most clinicians would recommend a vaginal birth after cesarean (VBAC) for a woman who has already had a successful vaginal birth; however, if she was at 41 weeks with an unripe cervix, many would recommend repeat cesarean rather than induction of labor.

Clinical recommendations are based on the likelihood of benefit vs harm. Benefit that far outweighs harm warrants a strong recommendation. As the degree of benefit drops and the likelihood of harm increases, recommendations become weaker. When the likelihood of benefit approximately equals that of harm, a position of clinical equipoise is reached. In this situation, clinicians are well-positioned to offer either course of action, leaving the choice entirely to the woman's preference. When harm outweighs benefit, clinicians recommend against a course of action—the strength of the recommendation proportional to the amount of expected net harm.

4 | RISK AND BENEFIT ARE SUBJECTIVE

At the inception of the Space Shuttle Program, acknowledging the program's complexity, NASA engineers estimated a 1% risk of catastrophic failure. Out of 135 shuttle missions, the Challenger and Columbia accidents killed 14 of 789 astronauts who flew in the program, for an overall mortality rate of 1.8% (Figure S1).

Since 100 missions were planned, NASA was aware that a failure was likely. Why did they proceed? Why did astronauts take the risk?—Because the flip side of risk is benefit. Shuttle missions launched the Hubble telescope, put countless communications and GPS satellites into orbit, built the International Space Station, and expanded scientific knowledge and understanding of our planet and the universe. Sitting on the launch pad, a shuttle astronaut faced a stark risk–benefit ratio: a 2% chance of not coming back alive and a 98% chance of fulfilling the dream of a lifetime.

The type and amount of benefit that justifies any degree of risk is personal and subjective. Yet some United States hospitals obtain court orders to force women to have repeat cesarean sections to avoid a fetal risk of 0.05%.[6,7] From the largest VBAC study, a trial of labor carries a 1/200 risk of uterine rupture and if rupture occurs, a 1/10 chance of neonatal hypoxic encephalopathy or death. The composite risk to the fetus is 1/2000 (Figure S2).[8] Yet some feel that women choosing to accept this risk to obtain the benefits of labor and avoid repeat cesarean are putting their fetus at unacceptable risk. Shuttle astronauts faced forty times this risk, yet no one sought a court order to ground them. They were not considered misguided or psychologically incompetent; to the contrary, they were among society's highest achievers who competed for the opportunity to go to space. We accepted their autonomous choice to take the risk of achieving their dream. Although physiologically normal birth lacks the glamor of space flight, it is important to many women. Anyone advising a woman to have a cesarean delivery to avoid a 1/2000 fetal risk from uterine rupture should pause to reflect that the risk of maternal death with elective cesarean found in the same study was 1/2400.[8]

5 | OFFER OR RECOMMEND, BUT DO NOT COERCE

Historically, "informed" consent meant the doctor *informed* a patient of his plan. In modern health care, informed consent involves the bidirectional sharing of *information*. The clinician informs a patient of her diagnosis, its natural history, available treatments, and their risks and benefits; the patient tells the clinician about her individual values, circumstances, and preferences. Based on his professional opinion, a clinician then recommends, offers, or recommends against a particular treatment or course of action.

There is a modern tendency to "offer" rather than "recommend" treatments. Perhaps this is to counter historical paternalism in the doctor-patient relationship, or perhaps it is perceived that "offering" a treatment carries less legal risk than "recommending" it. Either way, this approach can be confusing. If a clinician believes that two options have a similar risk-benefit ratio, then "offering" is appropriate. For example, a clinician might offer medical management or endometrial ablation for menorrhagia. Usually, however, a clinician has an opinion about the best course of action: hysterectomy for a woman with large fibroids or intrapartum antibiotics for a woman colonized with group B Streptococcus. "Offering" treatment in these situations is confusing because we are not truly neutral. Stating our recommendation and its strength helps guide consent. For example, a woman colonized with group B Streptococcus *without* risk factors has a modest risk of invasive newborn disease (≈1/200), and the recommendation for antibiotics is moderate. However, if risk factors develop, her risk increases significantly (≈1/25) and a stronger recommendation is warranted.[9]

Patients usually choose a recommended or offered option and consent is straightforward. However, based on their

beliefs and values, patients sometimes decline a caregiver's recommendation. If a clinician believes a patient is taking an "unreasonable" risk, they may be tempted to coerce her into accepting their recommendation.

Coercion is compelling by force of authority. In the clinician-patient relationship, it can take several forms:

1. Magnifying risk estimates to dissuade a patient from an option.
2. Exaggerating benefits or withholding risks of a recommended treatment.
3. Demeaning a woman for putting her fetus at risk.
4. Asserting a woman's decision makes her a "bad parent" and threatening to involve child protection services.
5. Threatening to withdraw care if a woman refuses medical advice.

Hospital policies that restrict patients' right to decline treatment are also coercive—such as those prohibiting a trial of labor after cesarean or vaginal breech birth. Coercing a woman to deliver by cesarean delivery negates consent. Forcing her to leave the hospital is abandonment.

Guidelines that effectively limit choice can also be coercive—for example, historical guidelines "requiring" immediate availability of surgical staff for a hospital to offer VBAC.[10] Technically speaking, only "guidelines," they are often considered law. At night, a community hospital with on-call surgical staff will take longer to mount an emergency cesarean section and the risk of adverse fetal outcome is likely higher: perhaps 1/1000 instead of 1/2000. It is arbitrary and dichotomous to decide that 1/2000 is safe while 1/1000 is not. A more patient-centered approach, recognized in the 2010 ACOG VBAC guideline, is to discuss the higher risk and let women choose to accept it, birth in a larger hospital, or deliver by repeat cesarean section.[11] One may *recommend* repeat cesarean section or delivery in a larger center with immediately available surgical staff; however, if a woman declines, she should still be cared for in the community hospital. Other recent guidelines also incorporate women's values and choice.[12–14]

Why worry about coercion if it improves safety? Informed consent requires a woman's voluntary choice; therefore coercion negates consent. If a practitioner coerces a patient, lack of consent leaves him open to a suit for battery and ethically and legally liable for complications. Conversely, an informed patient who consents to treatment accepts the risk of complications. Provided care is competent, the practitioner is not liable should a complication occur.

Coercion also weakens the therapeutic relationship. When a practitioner says: "My way or the highway," some women choose the highway. This may lead to patients delivering unattended at home or pressuring midwives to attend high-risk homebirths, with potentially tragic consequences.[15]

Avoiding coercion requires intellectual objectivity regarding evidence, awareness of the influence of one's own values, and acceptance of women's autonomy.

6 | PATIENT COMPETENCE

Patients must be competent to consent to treatment. If a woman suffers from significant intellectual disability, competency should be assessed by a psychiatrist. If she is found to be incompetent, an alternate guardian should be found. However, values and beliefs that differ from those of caregivers or society do not indicate incompetence. As the Jehovah's Witness and shuttle astronaut examples demonstrate, sane people choose to accept significant risks.

7 | WEIGHING AUTONOMY, BENEFICENCE, AND NONMALEFICENCE

Historically, when there were disagreements in the doctor–patient relationship, the locus of control resided with the doctor. This is no longer the case. Patient autonomy carries more ethical weight than caregiver beneficence.[2,3] Individuals have a right to the natural course of their condition without intervention, and a clinician's duty of care persists even if a patient refuses a recommendation. A clinician's duty to do no harm (nonmaleficence) justifies refusal to perform an *intervention* he feels will cause harm; however, *the provision of care during birth is not an intervention*. An obstetrician should refuse to induce a woman with a prior cesarean if he believes it is unsafe; however, if she presents in labor he may neither force her to have surgery nor abandon her, regardless of the estimated risk of uterine rupture.

Some suggest that attending a woman who chooses to accept risk enables her choice. They hope that refusing to attend will force her to choose otherwise. This is a coercive and dangerous form of "chicken" that is ethically inappropriate in modern health care. Regardless of her choice, a woman and her fetus will face less risk with professional care than without it.[16] Clear communication and maintenance of a therapeutic alliance will reduce harm and protect the clinician from liability if an adverse outcome occurs. Faced with a woman who decides to accept additional risk, a clinician should:

1. Clearly recommend against the "risky" course of action.
2. Have a second practitioner counsel the patient, if possible.
3. Document informed refusal, using a preprinted form if desired (see Appendix).
4. Reassure her that she will continue to receive courteous, professional care.

8 | THE THERAPEUTIC ALLIANCE AND "DETACHED CARING"

When a patient declines a doctor's recommendation, it strains the doctor-patient relationship. Doctors possess clinical expertise and may feel offended when their judgment is questioned. They care about patients' well-being and often feel a personal responsibility for outcomes. This makes it difficult when a patient wishes to accept additional risk. When a patient refuses medical advice, it can be challenging to maintain the therapeutic alliance.

By exploring the values underlying a woman's refusal, a doctor can ensure that she is informed and establish that her refusal is not a personal affront toward the doctor. Informed refusal confers upon a woman ethical and legal responsibility for harm that results from that decision. This awareness allows a clinician emotional detachment that can help him accept a woman's decision and continue to provide care: in a sense, "detached caring." By relinquishing the locus of control and reassuring a patient that she will continue to be cared for after her refusal, the clinician dissolves tension and strengthens the therapeutic alliance. Enhanced trust can lead to safer decisions and better outcomes.

For example, a woman with a history of two prior cesareans for failure to progress is advised by her obstetrician to have a repeat cesarean. She instead chooses a trial of labor. Confident that she is informed of a lower likelihood of success and higher risk of uterine rupture, her obstetrician respects her choice, and assures her that he will continue to care for her. During labor, progress stalls despite adequate contractions. With increased risk of uterine rupture, her obstetrician now strongly recommends a cesarean. Since he respected her initial choice, the woman trusts his judgment and consents to surgery. Had he tried to coerce her at the outset to avoid a much smaller risk, she might have resisted him when the risk escalated. Accepting informed refusal when the stakes are low builds trust and gives the clinician credibility for when the stakes are high.

Paternalism has a long history in obstetrics. Many women understandably fear that they will lose control over their care decisions and may appear defensive or "difficult." When this tension arises, proactively clarifying the locus of control can work magic. One of the most powerful ways a clinician can strengthen the therapeutic alliance is to tell the patient that his duty is to ensure that she is informed, respect her decisions, and care for her without prejudice, even if she declines his recommendation. This declaration promptly places both the patient and caregiver on the same team, committed to finding care options that match a woman's values and needs. Discussion tools to aid this discussion and declaration are found in the Appendix.

9 | ETHICAL AND LEGAL IMPLICATIONS OF INFORMED REFUSAL

By refusing a caregiver's recommendation, a pregnant woman's choice may put her and the fetus at increased risk of harm. *In continuing to care for her, it must be clear to everyone that her clinician is respecting her right to choose and not endorsing her choice*. If the stakes are high, it is advisable to ask a second consultant to counsel the patient to ensure she is truly informed. Patients, families, caregivers, risk managers, indemnity providers, lawyers, and judges all need to be aware that a patient is ethically and legally responsible for any adverse outcome that results from their refusal.

If a medical complication arises because of a patient's informed refusal (eg, uterine rupture during trial of labor for VBAC), the clinician is ethically bound to continue providing competent care, sometimes under very difficult circumstances. If despite good care an adverse outcome occurs, the clinician has not been negligent. Instead, he has honored his professional duty to provide care in accordance with the patient's beliefs, values, and choice. A legal argument that a clinician should have abandoned a patient or coerced her to accept an intervention to avoid risk is not compatible with modern definitions of professional duty and informed consent.

10 | CONCLUSION

Knowledge of the ethical basis of informed consent can improve communication between clinicians and patients, strengthen the therapeutic alliance, and reduce harm when women refuse recommended care.

1. A woman's autonomy trumps the beneficence of the doctor or State.
2. Coercion and abandonment are ethically abhorrent and inappropriate in modern health care.
3. Caregivers should not perform unsafe interventions; however, attendance in labor is not an intervention.
4. Clinicians continuing to care for women who refuse advice are fulfilling their professional duty of care.
5. Colleagues, professional organizations, hospital administrators, and the legal profession must recognize that respecting a woman's right to choose is not supporting her choice—ethical and legal liability for harm caused by her refusal is hers.
6. Guidelines need to be written in a patient-centered manner that qualifies risk and incorporates women's choice.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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