#### "WE'RE HAVING THIS BABY TONIGHT!"

#### INFORMED CONSENT AND MEDICAL DECISIONMAKING REGARDING OXYTOCIN AUGMENTATION

By

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#### ABSTRACT:

The medical indications for oxytocin augmentation in childbirth are inconsistent, the benefits of the intervention are often ambiguous and value-dependent, and there are significant risks, which are still being evaluated and elucidated. Providers tend to make the decision to augment labor without inquiring into patient preference. Rather providers declare their intent to augment with little or no discussion with patients, not even regarding risks, benefits and alternatives. In this thesis I argue that augmenting with oxytocin, in the absence of informed consent, violates norms of ethical clinical practice: seeking consent in cases of significant risk or ambiguous indications, avoidance of the generalization of medical expertise and bias in medical decisionmaking, and incorporation of patient preferences in shared decisionmaking. The introduction examines the goals and requirements of informed consent in general and as they relate to oxytocin augmentation. Chapter 1 argues that determination of medical need for oxytocin augmentation is complex and controversial. Chapter 2 explores a distinct hierarchy of stakeholders involved in the decision to augment, many of whom have self-interests that should be elucidated with patients when oxytocin is used. Chapter 3 argues, with particular attention to

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recent feminist work, that informed consent for oxytocin augmentation should be a meaningful process that promotes patient autonomy and well-being, not just an expansion of a range of choices. Using this construction of informed consent as process, it may, at least, be possible to address all three of the violated norms of ethical clinical practice, even those concerned with bias, power structure, and preference. In addition to extensive research of the literature, the material presented here draws from the author's observations during shadowing, experiences on the labor and delivery ward as a medical student, and from discussions with clinicians, nurses, and other medical students.

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#### I. INTRODUCTION

The use of exogenous, synthetic oxytocin (simply "oxytocin" from here onward) to augment uterine contractions in childbirth is a highly complex and multifaceted medical intervention that providers tend to regard as straightforward and as requiring little or no discussion with patients. In this thesis I will argue that informed consent is ethically required for oxytocin augmentation of labor *and* that it can be achieved consistently and in a way that privileges patient preference through re-structuring the patient-physician interaction to acknowledge differences in relative power and to begin to alter the existing power structure regarding oxytocin augmentation. The medical indications for oxytocin augmentation are inconsistent, the benefits of the intervention are often not clear, and there are significant risks, which are still being evaluated and elucidated. The decision occurs in a setting with a distinct hierarchy of stakeholders, many of whom have self-interests that should be elucidated with patients when oxytocin is used. The decision also concerns an aspect of childbirth about which patients have preferences and an intervention that can significantly change the experience of birth for laboring women, making it important to include patient preference in the decision to augment.

Oxytocin augmentation is a frequent topic in discussions of the medicalization of childbirth among midwives, low intervention family practitioners and obstetricians, and patients actively trying to avoid intervention. In books and internet media, there are stories of doctors

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ordering oxytocin<sup>1</sup> with scant justification to nurses and patients and with little to no opportunity for either party to ask questions or to refuse, and of persistent pressure on those who initially manage to refuse the intervention to subsequently accept it. Upon hearing the general topic of oxytocin for this thesis, my medical school colleagues consistently mention that during their obstetrics rotations nearly every laboring patient has been on an oxytocin drip. This observation was confirmed through my own observations and clinical rotations in research for this thesis project. The most common justification for oxytocin augmentation was "*We* '*re* having this baby tonight!", a phrase that reveals the presumed agency of the provider in the birth, particularly regarding when it occurs.

I was very fortunate to have the opportunity to shadow and work with multiple midwives, OB/GYN-trained resident, attending, and private physicians, and family practice-trained physicians working in two small cities on the East Coast. I was also able to speak with numerous family practice-trained physicians and residents in multiple cities on the East and West Coasts about the topic. I observed OB/GYN-trained physicians and a midwife on the labor and delivery ward, spoke informally with numerous family practice-trained physicians on the subject of oxytocin augmentation, and observed all groups in prenatal visits. My observations and experiences provide examples of the problematic ways doctor-patient conversations can be conducted, and why at least some providers and institutions need to address the approach to oxytocin augmentation in discussions/interactions with patients and why all use of oxytocin for augmentation requires informed consent.

In my own observations, attitudes among providers regarding oxytocin augmentation were varied across and within groups of like-trained providers. The physicians I observed

<sup>&</sup>lt;sup>1</sup> Oxytocin is known more widely by its pharmaceutical name, pitocin.

practicing in a few cities on the East Coast, particularly those who were OB/GYN-trained but not exclusively so, largely assumed that oxytocin augmentation was of minimal decisionmaking import to their patients, was within their purview to give or not to give, and was a convenience to themselves *and* the patients receiving it by affording "control" over the pace and, therefore, duration of labor. In a Northwest city, in contrast, family practice-trained physicians with whom I spoke did not see oxytocin used much by their family practice colleagues or by OB/GYNtrained physicians and thus thought even my interest in the subject undue. Some family practicetrained physicians in a few Northeast cities, however, echoed my concerns and had themselves confronted colleagues, often OB/GYN-trained, about the exclusion of patient preference from the decision to augment. Indications for use were numerous and varied, and providers sometimes got angrily defensive when asked about their oxytocin related views and practices.

Whether the usage pattern was ninety percent of births or zero,<sup>2</sup> few providers thought it important to dedicate time for specific discussion of oxytocin as a possible birth intervention (unless the patient specifically requested a discussion); in general, providers, midwives and physicians alike, considered the intervention within their realm of decisionmaking, whether for or against its use.<sup>3</sup> Only two providers with whom I spoke, both family practice-trained physicians, reported offering augmentation to patients as an option, at the point in labor when each provider thought it was indicated. In general, though, when oxytocin augmentation was

<sup>&</sup>lt;sup>2</sup> These are subjective estimates of oxytocin augmentation given to me by providers with whom I worked. Ninety percent was an estimate from a private OB/GYN-trained physician. In these cases, oxytocin was used at some point during active labor, even if for a short duration of time. The midwives at the independent birth center, however never augmented labor with oxytocin. Midwives who delivered at the local hospital, however, were more willing to use oxytocin to augment, though not at the same level as their physician colleagues.

<sup>&</sup>lt;sup>3</sup> Midwives, in general, chose not to recommend oxytocin augmentation at all and therefore chose not to discuss it with patients. Physicians, on the other hand would make a statement about starting oxytocin and then order it, with little to no input from the patient.

mentioned to a laboring patient, it was typically within a statement about an imminent use of oxytocin to hasten labor, as a deterrent of the slowing effects of epidural analgesics, or as a possibility later in the labor if the labor were to progress "slowly." The topic of oxytocin augmentation was infrequently, if ever, framed as a question. In practice these attitudes regarding oxytocin augmentation result in the provision to patients of inadequate or no information regarding oxytocin. This creates an environment in which patients cannot give *informed* consent, and patients are denied the space and time to determine their preferences regarding oxytocin administration.

## A. THE ABSENCE OF INFORMED CONSENT REVEALS A MISUNDERSTANDING OF INFORMED CONSENT

My first discussion with an obstetrician about oxytocin augmentation during my shadowing experience illustrates the need for a discussion of informed consent in the context of oxytocin augmentation. When I explained the project prompting my time with her, this physician insisted that an ethical exploration of consent and decisionmaking practices regarding oxytocin augmentation is not necessary. Even if it is not discussed at all in person with patients, this physician argued, it is listed in the informed consent document all patients sign upon admission to the hospital for labor, and therefore patients are "informed" about the intervention in an ethically satisfactory way. After finding the childbirth consent form, which did *not* actually include oxytocin augmentation, the physician said that oxytocin used to be on the form; its absence from the form, however, did not prompt her to consider a more thorough discussion of

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consent or decisionmaking. Instead the obstetrician concluded that oxytocin does not have serious risks and therefore does not require any discussion with patients in person or on paper.

Even if oxytocin augmentation *is* listed on the consent form, that does not mean that the patient understands when, why, and how oxytocin is used and what to expect about its effects to a sufficient degree that she can meaningfully participate in a decision about whether or not to use oxytocin, as she should be able to do through informed consent. The above physician's practices and attitudes toward oxytocin augmentation, the lack of informed consent processes surrounding its use, and her assumption of the normalcy of her stance vividly illustrate the insight grounding my argument: oxytocin augmentation too often falls in the realm of the doctor's largely unilateral decisionmaking. Such attitudes and informed consent practices create an environment that privileges certain information and excludes patient preference. These attitudes and practices also reinforce a physician role that generalizes technical medical expertise to determining a patient's preference and assuming her values, particularly in a way that ignores the physician's biases.<sup>4</sup> In such an environment, it is difficult and perhaps impossible to give an informed consent *or* an informed refusal.

#### **B. INFORMED CONSENT REGARDING OXYTOCIN AUGMENTATION**

As is evident in the anecdote above, this physician, and many others I would later meet, misunderstood the goals and requirements of informed consent. The conception of informed consent as a *form* is simplistic and denies patient agency in the decision-making process, even though it might satisfy minimal institutional informed consent requirements, one of the next

<sup>&</sup>lt;sup>4</sup> R. M. Veatch, "Generalization of Expertise," *The Hastings Center Studies* (1973) 1:2, 29-40.

topics for consideration. My argument is concerned with enabling the obstetric patient to participate in decisionmaking with regard to the administration of oxytocin. The goals, process, and requirements of informed consent thus constitute an appropriate starting point for this analysis, as the argument shares its goal with the goals of informed consent, that is, preservation of patient well-being and patient autonomy.

The goals of informed consent in clinical care are generally understood to include the promotion of patient welfare and respect for patient autonomy. Informed consent may be thought of in at least two senses: as autonomous authorization and as a norm-governed process involving patient and provider. One of the classic sources for a theoretical understanding of informed consent is Ruth Faden and Tom Beauchamp's *A History and Theory of Informed Consent*.<sup>5</sup> Sense<sub>1</sub> informed consent is "autonomous authorization."<sup>6</sup> As such, it is not just an agreement with a recommendation superficially explained and understood.<sup>7</sup> "An informed consent in sense<sub>1</sub> is given if a patient or subject with (1) substantial understanding and (2) in substantial absence of control by others (3) intentionally (4) authorizes a professional" "to involve the subject in research or to initiate a medical plan for the patient (or both)."<sup>8</sup> Informed consent in sense<sub>2</sub> is "effective consent," in that it satisfies institutional policies.<sup>9</sup> "The social and legal practice of requiring professionals to obtain informed consent emerged in institutional contexts, where conformity to operative rules was and still is the sole necessary and sufficient condition of informed consent is an informed consent in sense<sub>2</sub> if it satisfies whatever operative

<sup>&</sup>lt;sup>5</sup> R. R. Faden and T. L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986).

<sup>&</sup>lt;sup>6</sup> Faden and Beauchamp, p. 277.

<sup>&</sup>lt;sup>7</sup> Faden and Beauchamp, p. 278.

<sup>&</sup>lt;sup>8</sup> Faden and Beauchamp, p. 278.

<sup>&</sup>lt;sup>9</sup> Faden and Beauchamp, p. 280.

rules apply to the practice of informed consent.<sup>10</sup> The observed obstetrician's idea of informed consent discussed above perhaps fulfills this sense<sub>2</sub> definition of informed consent in a very minimal way,<sup>11</sup> but does not necessarily satisfy the informed consent goals of well-being or autonomy. Disclosure has historically been, and remains by some definitions, a part of informed consent in sense<sub>2</sub>.<sup>12</sup> For instance, the legal context considers disclosure integral to its sense of informed consent. In the medical context, however, disclosure is just the starting point of an effective and adequate discussion with a patient about a treatment plan.

Both the institutional norms regarding informed consent and the goals of informed consent in sense<sub>1</sub> are relevant to examination of current oxytocin administration practices. First, when patients are asked to authorize oxytocin augmentation at all, they rarely have all the requisite information to decide whether to authorize its use. Though some patients come with information from books, friends, family, or labor preparation classes, this may only constitute partial fulfillment of sense<sub>1</sub> informed consent. When patients are not asked for authorization and their consent is presumed, or when patients are asked to make decisions without critical information, providers are violating the goals of sense<sub>1</sub> of informed consent. Patients typically do not authorize oxytocin administration in an informed manner specifically; rather, patients may consent to it and other birth interventions "as deemed necessary by the managing physician." <sup>13</sup> Second, providers do not engage patients in an informed consent process involving disclosure of

<sup>&</sup>lt;sup>10</sup> Faden and Beauchamp, p. 280.

<sup>&</sup>lt;sup>11</sup> Though sense<sub>2</sub> may be fulfilled in the anecdote above, depending on the institutional standards for informed consent, the fulfillment is minimal because of the physician's emphasis on the *form*, as opposed to an embrace of informed consent as a norm-governed *process* that takes place across time and involves disclosure by physician and dialogue between physician and patient. <sup>12</sup> Faden and Beauchamp, p. 281.

<sup>&</sup>lt;sup>13</sup> This is an example based on some of the consent *forms* I have seen for childbirth. I am providing it to give a sense of the type of vague and broad statements that hospitals and providers make on and through these *forms* that patients sign. This is not a direct quote.

oxytocin's potential risks, benefits, and alternatives, or attempt to ensure that patients understand that information and make a decision in keeping with their preferences, as would be consistent with many institutions' norms for any medical intervention. This type of informed consent approach already occurs for other birth interventions like epidural analgesia. The way that many providers considered the *form* and/or its contents standard, "effective" informed consent regarding oxytocin augmentation may well mean these individuals thought that they were meeting their institutional standards for informed consent. The institutional sense of informed consent, however, can be achieved for augmentation in a way that is more enriched by sense<sub>1</sub>, thereby fulfilling the goals of sense<sub>1</sub> as much as possible.

Many recent works on informed consent concern the difficulty of truly achieving the ideals of informed consent, as classically defined by Faden and Beauchamp. Neil Manson and Onora O'Neill articulate an alternative conceptualization of informed consent that may be used to clarify why its requirements apply in the context of oxytocin augmentation. They emphasize that informed consent is a means whereby one party (the patient) waives the requirement of others (the physician) to forebear from acting in ways that would, in the absence of such consent, violate norms, standards or expectations.<sup>14</sup> Oxytocin augmentation without informed consent constitutes a violation of norms and expectations of clinical practice: decisions about medical interventions with either significant risk to the patient or ambiguous indications should take patient preference into account; physicians have a responsibility to reflect on the power structures and external influences and pressures factoring into medical decisions; and childbirth is a natural process about which patients have preferences to be incorporated into decisions regarding care.

<sup>&</sup>lt;sup>14</sup> N. C. Manson and O. O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007), p. 75.

This account of informed consent as waiving the requirement to forebear from interference does not by itself delineate the scenarios that require informed consent. In the case of emergency interventions regarding childbirth, it is important to note that the requirement of informed consent is legally and ethically waived as it is for all emergency care. Some might argue that oxytocin is at least an urgent, if not emergent intervention, in which case there might be a weaker argument, ethically and legally, for informed consent. The absence of informed consent for oxytocin augmentation, as is current clinical practice, would be ethically acceptable if, and only if, oxytocin augmentation were to be considered an emergency intervention.

It cannot be, however, that the administration of oxytocin in childbirth is routinely an emergent intervention. Though childbirth can have many unexpected, unpredictable moments, the common possibilities are known and certainly can be discussed during pregnancy in anticipation of their potential occurrence. Labor events can be emergency situations, and there may not be time to go through a complete discussion satisfying either sense of informed consent. In general,<sup>15</sup> however, our structures of maternity care, unlike with emergency treatment, provide unique opportunities during prenatal care for childbirth preparation and for specific discussions about potential interventions in the birthing process. In the context of prenatal care eventuating in childbirth, it is therefore possible to achieve the goals of informed consent before the moment of urgent decision. Thus even some emergencies in childbirth may be "planned for" to a degree, and may not, then, have the same exemption from informed consent as other types of emergency care.

<sup>&</sup>lt;sup>15</sup> Of course, some women first interact with the healthcare system when in labor for a variety of reasons, including lack of access to prenatal care. For these women, the best possible version of informed consent may be along the lines of the event model, as will be discussed in Chapter 3.

The current approach to decisionmaking regarding oxytocin augmentation violates three important norms: seeking consent in cases of significant risk or ambiguous indications, avoidance of the generalization of medical expertise and bias in medical decisionmaking through reflection on the hierarchy and resulting power dynamics involved, and incorporation of patient preferences in shared decisionmaking. Informed consent is required in the case of oxytocin augmentation to help avoid violation of at least two, and ideally all three, of these norms of ethical clinical practice. In the argument that follows, I will establish the relevance of these three norms to the case of oxytocin augmentation to show that informed consent is required for this medical intervention. In Chapter 1, I will dispute claims that oxytocin need is clear and that the intervention is safe, as the physician in the anecdote contended. Determination of medical need is, in reality, complex and controversial, making informed consent that much more vital for this intervention. In Chapter 2, I will explore the roles and interests of stakeholders that establish the labor and delivery suite as an environment in which informed consent is infrequently attempted and patient preference is often not sought regarding oxytocin augmentation. In Chapter 3, building from the exploration of relative power in Chapter 2, I argue, with particular attention to recent feminist work, that informed consent for oxytocin augmentation should be a meaningful process that promotes patient autonomy and well-being and incorporates patient preference, not just a process that provides an expanded range of choices. Using this construction of informed consent as process, it may, at least, be possible to address all three of the violated norms of ethical clinical practice, even those concerned with bias, power structure, and preference.

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## II. CHAPTER 1: LABOR PROGRESSION AND OXYTOCIN AUGMENTATION

Labor augmentation with exogenous oxytocin is a medical intervention administered in a context of scientific ambiguity. Medical complications of oxytocin use are relatively rare, but they are serious, and response to the hormone is highly variable and therefore unpredictable. The use of exogenous oxytocin for labor augmentation, however, reinforces restrictive perceptions about normal labor progression. These perceptions, in turn, reinforce use of oxytocin augmentation in labors that are already progressing at a healthy and normal (even if not average) pace. The example of oxytocin highlights how vital open dialogue is for patient-physician interactions, particularly in circumstances, as with oxytocin augmentation, of ambiguous evidence.

## A. ENDOGENOUS AND EXOGENOUS OXYTOCIN

Oxytocin is a hormone naturally produced in the human body, with a variety of physiological effects. Most notably for the purposes of this project, it is elevated in the female body at the time of childbirth via mechanisms that are not completely understood. It is a hormone produced in the pituitary, first synthesized in the 1950s.<sup>16</sup> There are oxytocin receptors in many tissues in the

<sup>&</sup>lt;sup>16</sup> M. Winkler and W. Rath, "A risk-benefit assessment of oxytocics in obstetric practice," *Drug Safety* (Apr 1999) 20:4, 323-45; p. 338.

body, most critically in the muscle layer of the uterus. The strength of the effect on any tissue depends on the amount of hormone released, the type of receptor, and the number of receptors in the target tissue. The effect can differ greatly between individuals and result in extremely varied responses to the same amount of hormone, particularly throughout pregnancy, during which time sensitivity increases. The half-life of oxytocin is between two and ten minutes.<sup>17</sup> Exogenous oxytocin is used at various points in pregnancy for different effects. High doses can be used at any point in pregnancy to abort a fetus by initiating contractions. More moderate doses are used for medically indicated induction of labor, augmentation of labor as part of the active management of labor (AML), augmentation of labor to manage dystocia, and prevention of postpartum hemorrhage due to uterine atonia.<sup>18</sup> The female body continues to produce oxytocin after birth to direct milk letdown, and suckling reinforces this hormonal response. Low numbers of oxytocin receptors are also thought to be a major contributing factor to the asocial and repetitive behaviors in autism, as oxytocin has an as-yet unclear role in emotional trust and bonding.<sup>19</sup>

For augmentation of labor, the laboring patient is given an intravenous drip of oxytocin. Contractions are monitored for strength and frequency, and the fetal heart rate is measured continuously and evaluated frequently.<sup>20</sup> Contraindications to oxytocin administration include

<sup>&</sup>lt;sup>17</sup> Winkler and Rath, p. 338.

<sup>&</sup>lt;sup>18</sup> Winkler and Rath, p. 339. Definitions: **dystocia** is slow or difficult labor or delivery slow labor and includes both protraction, slowing of labor and arrest, cessation of labor, though these definitions are not used consistently, as will be discussed later; **postpartum hemorrhage** is more than 500cc of bleeding that occurs in the third stage of labor when the placenta is delivered, after the delivery of the fetus; postpartum hemorrhage can occur due to **uterine atonia**, which is lack of muscle tone in the muscles of the uterus.

<sup>&</sup>lt;sup>19</sup> E. Hollander et al., "Oxytocin Infusion Reduces Repetitive Behaviors in Adults with Autistic and Asberger's Disorders," *Neuropsychopharmacology* (2003) 28, 193-198.

<sup>&</sup>lt;sup>20</sup> For instance, a safety protocol designed by the Hospital Corporation of America's Perinatal Safety Division, studied by Clark et al., recommends re-evaluation every 30 minutes. For the

"placenta or vasa previa, umbilical cord presentation, prior classical uterine incision, active genital herpes infection, pelvic structural deformities, or invasive cervical cancer."<sup>21</sup> One method of medical management for "slow" progression of labor that involves oxytocin administration is called the active management of labor, or AML, which was introduced by O'Driscoll and others at the National Maternity Hospital in Dublin, Ireland in the 1960s for nulliparous women.<sup>22</sup>

According to Frigoletto et al., AML

was introduced to shorten labor at a time when the rate of cesarean section was under 5 percent. Active management of labor includes strict criteria for the diagnosis of labor, early rupture of the amniotic membranes, prompt intervention with high-dose oxytocin in the event of inefficient uterine action, and a commitment never to leave a woman unattended during labor. As the rate of cesarean section rose in most industrialized countries during the 1970s and 1980s, the persistently low rate of cesarean delivery at the National Maternity Hospital led other obstetrical services to use active management of labor as a means to reduce rates of cesarean section.<sup>23</sup>

The Dublin group used AML with most nulliparous laboring patients.<sup>24</sup> Various combinations of interventions have been called "active management of labor," so in the United States, there is no one protocol that is universally understood to be "active management of labor." Oxytocin is an oft-researched component of the AML regimen, but it is not required for AML nor is it only used in the context of strict AML adherence.<sup>25</sup> AML can also include patient education through

<sup>22</sup> ACOG, p. 1449; F. D. Frigoletto et al., "A Clinical Trial of Active Management of Labor," *New England Journal of Medicine* (1995) 333:12, 745-750.

detailed protocol, see S. Clark et al., "Implementation of a conservative checklist-based protocol for oxytocin administration: maternal and newborn outcomes," *American Journal of Obstetrics and Gynecology* (Nov 2007) 197:5, 480.e1-e5; p. 480.e4.

<sup>&</sup>lt;sup>21</sup> American College of Obstetricians and Gynecologists, "Practice Bulletin #49: Dystocia and Augmentation of Labor," *Obstetrics and Gynecology* (Dec 2003) 102: 6, 1445-1454; p. 1446.

<sup>&</sup>lt;sup>23</sup> Frigoletto et al., p. 745.

<sup>&</sup>lt;sup>24</sup> Nulliparous patients are those who have never gone through childbirth before. Multiparous patients have borne children previously.

<sup>&</sup>lt;sup>25</sup> ACOG, p. 1449.

Lamaze classes, "strict criteria for the determination of abnormal progress of labor, [...] strict criteria for interpretation of fetal compromise, and peer review of operative deliveries."<sup>26</sup>

Multiple studies have compared the effectiveness of AML with "usual care" labor management, the definition of which is also highly variable and institution-dependent.<sup>27</sup> Overall, it has been found to shorten the total length of labor to less than 12 hours, a reduction of 102 minutes on average, even in the presence of epidural analgesics, which can slow birth.<sup>28</sup> Across three studies, including Frigoletto et al., 91-98% of subjects delivered in less than 12 hours, up from 73-81% in the "usual care" groups.<sup>29</sup> In the Frigoletto et al. study, oxytocin augmentation was used in up to 70% of cases in the AML group versus 56% in the "usual care" group.<sup>30</sup> Over the three different studies, oxytocin was used for augmentation an average of 58% of the time in the "usual care" group and 65% of the time in the AML group.<sup>31</sup> In these studies, it is striking how similar the rates of oxytocin augmentation are, suggesting that oxytocin augmentation is used in over half of all births with "usual care" practices.<sup>32</sup> AML has also been found to decrease

<sup>&</sup>lt;sup>26</sup> ACOG, p. 1449.

 <sup>&</sup>lt;sup>27</sup> ACOG; Frigoletto et al.; R. Rogers et al., "Active management of labor: does it make a difference?" *Am J Obstet Gynecol* (1997) 177, 599–605.

<sup>&</sup>lt;sup>28</sup> Rogers et al. The authors' definition of labor onset is based on effacement (80%) and regular painful contractions (</=5 minutes between contractions). In terms of the effects of an epidural on labor progress and duration and need for augmentation, according to ACOG, "[1]ess controversial is the causal role epidural analgesia plays in prolonging labor by 40–90 minutes and in the approximate 2-fold increased need for oxytocin augmentation. These findings are supported by most prospective studies as well as meta-analyses. An increased risk of a second stage of labor longer than 2 hours in women with epidural analgesia likely contributes to the higher rates of operative vaginal delivery seen in most prospective studies" (ACOG, p. 1448).</p>
<sup>29</sup> Frigoletto et al., Table 6, p. 749.

<sup>&</sup>lt;sup>30</sup> Frigoletto et al., Table 4, p. 748.

<sup>&</sup>lt;sup>31</sup> Frigoletto et al., Table 6, p. 749.

 $<sup>^{32}</sup>$  On a national level, CDC data suggest lower rates between 10 and 19% from 1989 through 2006. Possible reasons for usage significantly lower than the >50% suggested by Frigoletto et al.'s studies include the voluntary nature of data recording and submission to the CDC and the fact that only 19 states, of diverse geographical location and varied population density, submitted data to the CDC for review. Of note, the CDC did not collect data on oxytocin augmentation, or

rates of maternal fever without having a significant effect on cesarean section rates.<sup>33</sup> There has been little success in the United States on this front,<sup>34</sup> however, where 32.9% of births nationwide end in cesarean section, which has risen for the 13<sup>th</sup> year in a row, as of the most recent birth certificate data for 2009.<sup>35</sup>

### **B. DEFINING AND DIAGNOSING NORMAL LABOR**

One of the most subjective aspects of oxytocin administration is determining when to initiate it for a patient in labor because data about the diagnosis of labor, prolonged labor, and labor arrest are ambiguous and sometimes conflicting. Identifying the "need" for oxytocin in low-risk childbirth is rarely done consistently beyond the practice patterns of individual providers. The determination of need for oxytocin augmentation depends upon the diagnosis of dystocia, or abnormal labor progress. Before examining *abnormal* labor criteria, I will first explore the definition and diagnosis of normal labor, which are themselves rather vague. According to the American College of Obstetricians and Gynecologists (ACOG),

labor is the presence of uterine contractions of sufficient intensity, frequency, and duration to bring about demonstrable effacement and dilation of the cervix. At present, there is much uncertainty about the definition of the latent phase of labor, but there is agreement that women in labor enter the active phase when cervical dilatation is between

"stimulation of labor" until 1989. The CDC stopped reporting oxytocin augmentation in its annual public reports on birth statistics after 2006. For detailed annual reports, see <u>http://www.cdc.gov/nchs/nvss.htm</u>, particularly S. J. Ventura et al., "Advance Report of New Data From the 1989 Birth Certificate," *National Vital Statistics Reports* (1992) 40:12, 1-32; M. J. K. Osterman, J.A. Martin , and F. Menacker, "Expanded Health Data from the New Birth Certificate, 2006," *National Vital Statistics Reports* (2009) 58:5, 1-24; J. A. Martin et al., "Births: Final data for 2009," *National Vital Statistics Reports* (2011) 60:1, 1-104. <sup>33</sup> Frigoletto et al., p. 748.

<sup>&</sup>lt;sup>34</sup> Rogers et al., p. 599.

<sup>&</sup>lt;sup>35</sup> Martin et al., p. 13.

3 cm and 4 cm. The active phase is characterized by the most rapid changes in cervical dilatation as plotted against time. The active phase of labor includes both an increased rate of cervical dilation and, ultimately, descent of the presenting fetal part.<sup>36</sup>

The above definition refers to the first stage of labor, which includes both latent and active labor. The second stage of labor occurs when full dilation (widening of the cervix to 10 cm) and effacement (shortening and thinning of the cervix) have been achieved. This is usually when the woman begins to feel a strong urge to push. The third stage of labor begins immediately after the fetus is delivered and primarily consists of delivering the placenta, which can be pushed out or manually extracted.<sup>37</sup> This is a time of high risk for hemorrhage because the highly vascular placenta is separating from the uterine wall. One of the largest risk factors for third stage hemorrhage is uterine atonia (lack of uterine muscle tone resulting in reduced compression of the vessels, allowing excessive bleeding to occur). Third stage hemorrhage can be effectively, and often prophylactically, treated with an oxytocin IV bolus, which causes the uterine muscles to contract, thereby stopping the bleeding.<sup>38</sup>

The "normal" duration of these stages of labor and what constitutes abnormal labor are imprecisely understood. Zhang et al. offer the most recent installment in the effort of the last two decades both to address the accuracy of the labor curves developed by Friedman in the 1950s and 1960s and to redefine normal labor patterns and duration. Zhang et al. base their research on data from the National Collaborative Perinatal Project, a "large, multicenter, prospective,

<sup>&</sup>lt;sup>36</sup> ACOG, p. 1445. The use of both "dilatation" and "dilation" to mean widening of the cervix is present in the original text. "Dilatation" is the correct spelling, although "dilation" is widely used. I will use "dilation" for consistency, as the majority of the sources I have used employ this spelling.

<sup>&</sup>lt;sup>37</sup> "Management of the Third Stage of Labor" in "Chapter 17: Normal Labor and Delivery." *Williams Obstetrics*, 23<sup>rd</sup> ed., F. G. Cunningham et al., eds, Last accessed 21 Jan 2012, <u>http://www.accessmedicine.com/content.aspx?aID=6023669</u>.

<sup>&</sup>lt;sup>38</sup> *Williams Obstetrics*, Chapter 17. The oxytocin bolus is 20 units per liter of saline if the patient already has an IV in place or 10 units directly into the uterine wall at the time of hemorrhage.

observational study conducted between 1959 and 1966."<sup>39</sup> The data come from a time when "obstetric interventions in the first stage of labor were less common […providing] a unique opportunity to observe what may be closest to the natural process of labor in a large population."

Zhang et al. redefine the clinical dilation thresholds of active labor and, in so doing, make steps toward clarifying abnormal labor as well. They found that even multiparous women did not enter active labor until 5 cm dilation, surmising that nulliparous women would enter active labor even later.<sup>40</sup> This is quite different from the 3 or 4 cm threshold for active labor put forth earlier by Friedman and used extensively in clinical diagnosis and management, even by ACOG as recently as 2003.<sup>41</sup> Zhang et al. found that it "may take more than 4 hours for nulliparas to progress from 4 to 5 cm" (into active labor).<sup>42</sup> In addition, "nulliparas may start the active phase even later [than at 5cm] and may not necessarily have a clear active phase characterized by precipitous dilation."

According to Zhang et al., their data "suggest that a 2-hour threshold [for diagnosis of dystocia] may be too short before 6 cm whereas a 4-hour limit may be too long after 6 cm. Given that the speed of cervical dilation is not constant, a graduated threshold based on the level of cervical dilation may be a more appropriate approach to defining labor arrest than a 'one-size-

<sup>&</sup>lt;sup>39</sup> J. Zhang et al., "Natural History of the Normal First Stage of Labor," (April 2010) 115:4, 705-710; p. 705. For other attempts to clarify medical understanding of labor progress, see, for example, L. Impey, J. Hobson, and C. O'Herlihy, "Graphic analysis of actively managed labor: Prospective computation of labor progress in 500 consecutive nulliparous women in spontaneous labor at term," *Am J Obstet Gynecol* (2000) 183:2, 438-443; L. L. Albers, M. Schiff, and J. G. Gorwoda, "The length of active labor in normal pregnancies," *Obstetrics and Gynecology* (1996) 87, 355-9; D. B. Peisner and M. G. Rosen, "Transition from latent to active labor," *Obstet Gynecol* (1986) 68, 448-51.

<sup>&</sup>lt;sup>40</sup> Zhang et al., p. 709.

<sup>&</sup>lt;sup>41</sup> E. A. Friedman, "Primigravid labor: a graphicostatistical analysis" *Obstet Gynecol* (1955) 6, 567–89.

<sup>&</sup>lt;sup>42</sup> Zhang et al., p. 709.

fits-all' method.<sup>43</sup> The authors suggest, with caution, that the data indicate a more gradual rate of change in cervical dilation than previously reported in the literature. They argue that the overall shape of the curve they generated can guide revisions of clinical timelines for labor, with the caveat that the current laboring patient may be different from those in the study's cohort because of differences in both average weight for woman and fetus and maternal age, as well as higher levels of early childbirth intervention, like oxytocin and epidural analgesia administration. An earlier study by Zhang and colleagues found that, even with the inclusion of patients receiving oxytocin augmentation, the slope of the labor curve is less steep and the duration of the active phase longer than Friedman's curves suggest.<sup>44</sup>

In another article seeking to redefine normal labor, Albers, Schiff, and Gorwoda write

specifically about some of the reasons for wide variations in the measured duration of labor and

the resultantly limited possibility for accuracy:

Measurement of the length of labor is inherently imprecise for several reasons. The starting point cannot be identified by objective means. The cervix undergoes various structural alterations in late pregnancy, and women do not begin labor with identical cervical anatomy. Labor onset is a self-diagnosis, and women vary in their recognition of and response to painful contractions. As such, the duration of the latent phase is particularly difficult to quantify. Therefore, cervical dilatation on admission to the hospital is often used as the first data point. The frequency of cervical examinations to assess labor progress varies by care provider and institution, and no consensus exists on examination intervals during labor. The reliability of cervical assessments is rarely verified and cervical change is assumed to be continuous rather than a step function. Recognition of the onset of the second stage of labor is also variable for both patients and care providers.<sup>45</sup>

<sup>&</sup>lt;sup>43</sup> Zhang et al., p. 710.

<sup>&</sup>lt;sup>44</sup> J. Zhang, J. F. Troendle, M. K. Yancey, "Reassessing the Labor Curve in Nulliparous Women," *Am J Obstet Gynecol* (2002) 187:4, 824-828.

<sup>&</sup>lt;sup>45</sup> Albers, Schiff, and Gorwoda, p. 355. Participants in the study were non-Hispanic white, Hispanic, and American Indian women whom midwives delivered at the University of New Mexico Hospital between July 1991 and June 1994. They gave birth at term after spontaneous onset of labor. Active dilatation was considered to be 4 cm.

These authors found that among 949 total study participants, none of whom received epidural analgesia or oxytocin augmentation, the average duration of active phase of the first stage of labor for nulliparous women ranged from 7 hours to 8.3 hours by ethnic group, with upper normal limits of up to 21.8 hours; for multiparous women, the active phase ranged from 5.3 to 6.1 hours, with an upper normal limit of 12.5 to 15.1 hours.<sup>46</sup> These are much longer active phases than the 2.5 hour average that Friedman reported in 1955 for 500 nulliparous women in his study, but similar to the 5.5 hours reported by Zhang, Troendle and Yancey in 2002 for 1162 nulliparous women, about half of whom received epidurals and/or oxytocin augmentation. One of the strongest recommendations from Albers, Schiff, and Gorwoda and from Zhang, Troendle and Yancey logically follows from their findings: if normal labor durations are this variable, and on average this long, then new and better data and analyses are needed to establish more realistic diagnostic criteria for labor protraction and arrest.<sup>47</sup> The current understanding of labor

# C. DEFINITION AND DIAGNOSIS OF ABNORMAL LABOR: A CRITICAL READING OF THE LITERATURE ON DYSTOCIA

Dystocia (slow or difficult labor or delivery) can result from a number of different mechanisms, and dystocic disorders are generally classified as protraction (slow progress) and arrest (no progress) disorders.48 Williams Obstetrics, a reference text in obstetrics, and the ACOG

<sup>&</sup>lt;sup>46</sup> Albers, Schiff and Gorwoda, p. 357, Table 2.

<sup>&</sup>lt;sup>47</sup> Albers, Schiff, and Gorwoda, p. 359; Zhang, Troendle, and Yancey, p. 827.

<sup>&</sup>lt;sup>48</sup> ACOG, p. 1446; *Williams Obstetrics*, "Chapter 20: Abnormal Labor," subsection "Overview of Dystocia," Table 20-1.

guidelines use different types of criteria for diagnosing dystocia and outline different indications for oxytocin augmentation and cesarean section, to the point of conflict in their definitions and in their recommendations. Such conflict shows that indications for oxytocin augmentation are controversial topics that necessitate subjective decisions for medical providers.

#### 1. Definition and diagnosis of protraction and related indications for oxytocin augmentation

According to *Williams Obstetrics*, protraction is "simply" slow labor and is measured by cervical dilation of less than 1.2 cm/hr for nulliparous women and 1.5cm/hr for multiparous women and/or fetal descent of less than 1cm/hr for nulliparous women and 2 cm/hr for multiparous women. The authors recommend that protraction be managed expectantly and supportively without oxytocin augmentation.<sup>49</sup> According to ACOG, however, *protraction* disorders usually describe labors that are "slower-than-normal" due to problems with maternal expulsive forces caused by nerve or muscle damage from trauma or autoimmune disease and/or insufficient strength and frequency of contractions.<sup>50</sup> These descriptions of etiology are implied to apply to *protraction*, but are directly discussed under the broader term *dystocia* by ACOG.<sup>51</sup> They do not specify a length of time that defines "slower-than-normal" or criteria for determining adequate strength or frequency of contractions here. They essentially choose not to attempt to develop diagnostic criteria for *protraction*, beyond "slower-than-normal." Thus the "objective" measures detailed by *Williams* and ACOG are entirely different: *Williams* focuses on cervical dilation and fetal descent while ACOG recommends monitoring the strength and frequency of contractions.

<sup>&</sup>lt;sup>49</sup> *Williams Obstetrics*, Chapter 20, Table 20-2.

<sup>&</sup>lt;sup>50</sup> ACOG, p. 1446.

<sup>&</sup>lt;sup>51</sup> ACOG, p. 1446.

ACOG's guidelines lump the two issues of *arrest* and *protraction* together for management and state that oxytocin augmentation is warranted "when spontaneous contractions have failed to result in progressive cervical dilation or descent of the fetus,"52 provided an anatomical arrest disorder<sup>53</sup> has been ruled out. Cervical dilation and fetal descent criteria go without description for the entirety of the recommendation document, so the provider is left to define them independently from other sources, presumably largely influenced by predominant practice at his/her training and/or employment institution. ACOG authors do delineate contraction frequency and pressure parameters for consideration of augmentation: "if the frequency of contractions is less than 3 contractions per 10 minutes or the intensity of contractions is less than 25 mm Hg above baseline or both." <sup>54</sup> ACOG then provides four diagnostic criteria for protraction, but only if one considers the indications for oxytocin augmentation to be the same as diagnostic criteria for protraction. These criteria consist of cervical dilation, fetal descent, contraction frequency, and contraction strength. The criteria for the strength and frequency of contractions in their specificity could at least provide some consistency of diagnosis, but dilation and descent are of no help in this regard because they are not specified. Interestingly, ACOG uses its diagnostic criteria as thresholds for intervention with oxytocin augmentation, thereby leaving no situation in which protraction might be expectantly managed. Their specific frequency and strength criteria also suggest that ACOG considers these

<sup>&</sup>lt;sup>52</sup> ACOG, p. 1446.

<sup>&</sup>lt;sup>53</sup> Anatomic arrest disorders, which are managed with cesarean section, include cephalopelvic disproportion, where the fetal head is larger than the pelvic passageway through which it must travel, and problems of fetal position such as breech. Skilled and experienced providers sometimes attempt vaginal delivery for breech position (depending on the perceived fetal orientation in each individual, unique case) in hospital and insurance settings that permit such attempts. In many places, however, breech positioning is considered a contraindication to vaginal birth.

<sup>&</sup>lt;sup>54</sup> ACOG, p. 1446.

stronger indications for oxytocin augmentation than the vague dilation and descent indications. ACOG implies that once a labor is deemed "slower-than-normal" intervention is warranted, and ACOG gives a fair degree of subjective control to the provider over whether or not to augment. *Williams*, on the other hand, is more specific with "objective" parameters for diagnosis of protraction, but recommends expectant management, implicitly acknowledging the wide range of "normal" labor rates and durations, encouraging much more conservative use of oxytocin for augmentation when specifically discussing *protraction* than currently occurs in practice.

Indications for oxytocin augmentation span scenarios considered to be both *protraction* and *arrest* in *Williams* as well as in ACOG. According to *Williams*' authors the indications include prolonged latent phase, defined as lasting more than 20 hours and arrest disorders including prolonged deceleration phase, secondary arrest of dilation, or arrest of descent.<sup>55</sup> However the description of augmentation indications by the *Williams*' authors could well pertain to *protraction* as well as *arrest*: "if contractions are not adequate—less than 200 Montevideo units<sup>56</sup>—and if the fetal status is reassuring and labor has arrested, an oxytocin infusion dose greater than 48 mU/min *has no apparent risks*."<sup>57</sup> By focusing on risk, or, rather, their interpretation of its absence, *Williams*' authors avoid discussion of any other factors that might

<sup>&</sup>lt;sup>55</sup> Williams Obstetrics, Chapter 20, Table 20-2.

<sup>&</sup>lt;sup>56</sup> This is a measure of contraction pressure and a threshold typically considered to indicate inadequate contractions. The import of such pressure parameters have been challenged by Rouse et al., who found that this threshold was not predictive of delivery method in oxytocin augmented births: of nulliparas, 83% of women who never achieved 200 M. units delivered vaginally after a minimum of 4 hours of oxytocin augmentation for labor arrest compared to 75% of women who inconsistently achieved 200 M. units delivering vaginally and 85% of women who consistently achieved greater than 200 M. units; of multiparas, 97% of women who never achieved 200 M. units delivered vaginally, compared to 94% of women who inconsistently achieved greater than 200 M. units; of women who inconsistently achieved greater than 200 M. units; of women who inconsistently achieved greater than 200 M. units; of women who inconsistently achieved greater than 200 M. units; of women who inconsistently achieved greater than 200 M. units; of women who inconsistently achieved greater than 200 M. units delivering vaginally and 94% of women who inconsistently achieved greater than 200 M. units (D. J. Rouse et al., "Active Phase Labor Arrest: Revisiting the 2-Hour Minimum," *Obstet Gynecol* [October 2001] 98:4, 550-554, p. 553, Tables 2 and 3). <sup>57</sup> *Williams Obstetrics*, "Chapter 22: Labor Induction," subsection "Labor Induction and Augmentation With Oxytocin," subsection "Maximal Dosage," emphasis added.

go into the decision to augment, such as patient preference or other subjective factors. As should be evident, ACOG and Williams measure and handle these abnormal labors differently, and it is quite difficult to compare management strategies when the Williams authors and ACOG use different terminology and different diagnostic criteria. What is clear, however, is that this lack of consistency sets the stage for a lack of clinical consensus regarding the indications for oxytocin augmentation. This environment of scientific uncertainty or inconsistency, in turn, makes the role of patient preferences and the need for informed consent all the more acute.

#### 2. Definition and diagnosis of arrest and related indications for oxytocin augmentation

Oxytocin augmentation for arrest disorders specifically is muddled, since arrest and protraction can be defined in overlapping ways. The lack of clarity in Williams and ACOG derives from using the single word "arrest" when discussing different problems at different stages of labor. A graduated, or step-wise, approach for diagnosis and treatment of arrest is implicit in these sources but not fully explained. Arrest disorders are diagnosed when "complete cessation of progress" has occurred, according to ACOG.<sup>58</sup> A few etiologies of *arrest* disorders are actually contraindications to oxytocin augmentation, including the anatomic etiologies of arrest mentioned earlier like cephalopelvic disproportion or breech fetal position. These are largely known before labor onset, yet make it that much more important to correctly determine the cause of an arrest disorder before intervening.<sup>59</sup> Oxytocin is generally only used for first stage arrest (before pushing begins), which should only be diagnosed after 4 cm dilation or once active labor has begun. According to Williams, the most common criterion for diagnosis of first stage labor

<sup>&</sup>lt;sup>58</sup> ACOG, p. 1446. <sup>59</sup> ACOG, p. 1446.

*arrest* is a lack of progress for more than two hours, though it is unclear in *Williams* whether this time limit is a threshold for putting patients on an oxytocin drip or a threshold for resorting to cesarean section, for the nature of the "intervention" is not specified.<sup>60</sup>

ACOG, on the other hand, uses the criteria delineated earlier for indications to augment in the management of arrest, but also admits that a more expectant protocol for *arrest* management by Rouse, Owen and Hauth "appears effective."<sup>61</sup> In this protocol, Rouse, Owen, and Hauth encourage more expectant management after starting oxytocin and before diagnosing full labor *arrest* and resorting to a cesarean section by recommending at least 4 hours of oxytocin augmentation. In their study group, they found that up to 6 hours for women whose contractions were below the 200 Montevido unit level was safe.<sup>62</sup> Most (92%) of their study group achieved a vaginal birth.<sup>63</sup> This 8% cesarean section rate would have been 26% if they had gone to cesarean section after seeing no progress with 2 hours of oxytocin augmentation. It is worth noting that 93% of their study group had epidural analgesia before oxytocin augmentation was started.<sup>64</sup> Based on these findings, ACOG reports that 4 to 6 hours, as outlined above, appear to be acceptable new minimums of oxytocin augmentation duration, depending on a patient's strength of contractions.

<sup>&</sup>lt;sup>60</sup> *Williams Obstetrics*, "Chapter 22. Labor Induction." Section "Labor Induction and Augmentation with Oxytocin," subsection "Duration of Oxytocin Administration," subsection "Active Phase Arrest." Typical understanding and practice of the 2-hour minimum is explained by Rouse, Owen, and Hauth as follows: usually two hours with little to no cervical change (1 cm or less in 2 hours) justifies oxytocin augmentation, and no progress two hours after the start of oxytocin has been the threshold for a diagnosis of full arrest, for which cesarean section is indicated (D. J. Rouse, J. Owen, and J. C. Hauth, "Active-Phase Labor Arrest: Oxytocin Augmentation for at Least 4 Hours," *Obstetrics and Gynecology* [March 1999] 93:3, 323-328; p. 324).

<sup>&</sup>lt;sup>61</sup> ACOG, p. 1447.

<sup>&</sup>lt;sup>62</sup> Rouse, Owen, and Hauth p. 326.

<sup>&</sup>lt;sup>63</sup> Rouse, Owen, and Hauth, p. 327.

<sup>&</sup>lt;sup>64</sup> Rouse, Owen, and Hauth, p. 327.

Much of the work discussed here is a start toward redefining normal and abnormal labor, but there is still much work to be done and decisions to be made in the meantime as to how to manage normal birth and how to determine what is abnormal. The conflicting and confusing state of the recommendations right now means that it is largely up to individual providers and their local colleagues such as fellow members of a practice or hospital department to decide how and when to use oxytocin augmentation.

In practice, exogenous oxytocin is widely used for labor that is "slow to progress," without a strict diagnosis of dystocia, protraction, or arrest because guidelines are inconsistent, as discussed above. Data about the point in labor at which oxytocin is administered have not been broadly or uniformly collected, except from those institutions and states submitting data on oxytocin augmentation to the CDC between 1989 and 2006. In acknowledgment of this, the Institute for Healthcare Improvement, an "independent not-for-profit organization helping to lead the improvement of health care throughout the world [...] by building the will for change, cultivating promising concepts for improving patient care, and helping health care systems put those ideas into action" recently led an initiative to get more specific data about oxytocin augmentation.<sup>65</sup> Their chart review form for obstetrical providers, which was publicly available on their website in 2010, included five recommended documentation components to encourage and assess clinical practice of safety measures regarding oxytocin administration: estimated fetal weight prior to oxytocin administration, normal fetal status before and during oxytocin administration (two components), written indication of a complete pelvic examination, and evidence of evaluation for, recognition of, and management of tachsystole of uterine contractions

<sup>&</sup>lt;sup>65</sup>Institute for Healthcare Improvement, "About IHI," (2011) Last accessed 21 January 2012, <u>http://www.ihi.org/about/pages/default.aspx</u>.

(more than 5 contractions in 10 minutes averaged over 30 minutes).<sup>66</sup> It is important that hospitals and providers choose to record their data so that usage patterns can be broadly evaluated.

#### **D. THE DANGERS OF LONG LABOR**

As I have shown, diagnosis and management of "slow" or abnormal labor progress is vague at best. Implicit in interventions that shorten labor is the belief that long labor is dangerous. Long labors have been associated with particular negative outcomes, which shortening labors could theoretically help to avoid. Albers, Schiff, and Gorwoda looked for associations between prolonged labor and four different labor complications that have been associated with long labors: "postpartum hemorrhage, defined as estimated blood loss of greater than 500 mL after delivery; postpartum fever, defined as an oral temperature of greater than 100.4 F within 24 hours of delivery; infant resuscitation, defined as assisted ventilation with bag and mask or endotracheal intubation; and a 5-minute Apgar score less than 7.<sup>567</sup> In their assessment, patients did not receive epidural analgesia or oxytocin. They did not find a greater association between

<sup>&</sup>lt;sup>66</sup> Institute for Healthcare Improvement, "Augmentation Bundle Data Collection Tool," (2010) Last accessed 20 June 2010,

<sup>&</sup>lt;u>http://www.ihi.org/about/pages/default.aspx>http://www.ihi.org/IHI/Topics/PerinatalCare/Perina</u> <u>talCareGeneral/EmergingContent/AugmentationBundleDataCollectionTool.htm</u>. Data collection for this project closed in August 2010 and the website was no longer accessible when checked on January 21, 2012.

<sup>&</sup>lt;sup>67</sup> p. 356. The Apgar score is a subjective scale of neonatal well-being that involves the assessment of muscle tone, color, breathing, heart rate, and reflexes.

<sup>&</sup>lt;sup>68</sup> Albers, Schiff, and Gorwoda, p. 357. Their definition of prolonged labor is as follows: greater than 19.4 hours for the active phase in nulliparous women and 12.7 hours for the active phase in

Schiff, and Gorwoda, research on this subject is limited, and further investigation is warranted. Based on the findings of this study, however, long labor may not be as risky as the frequent evaluations of labor progress and the prevalence of intervention to hasten labor might suggest. The findings do not suggest that long labor is benign, either; rather, the authors encourage patience and more expectant, watchful management of labor than is typical practice currently as the medical community continues to learn more about normal and abnormal birth.

#### E. OXYTOCIN: BENEFITS AND RISKS

The risks and benefits of oxytocin and their significance are debated in the literature. Oxytocin has well-established benefits through administration at specific junctures in labor. For instance, it is widely used in the third stage of labor to reduce bleeding as the placenta is delivered. This provides significant protection against uterine atonia, which can lead to lifethreatening post-partum hemorrhage.<sup>69</sup> To prevent or limit postpartum hemorrhage, a large bolus dose is administered to the patient right after delivery of the baby (called the third stage of labor), which has been shown to greatly reduce maternal blood loss.<sup>70</sup>

There are undeniable time-related benefits of oxytocin augmentation for patient and provider.<sup>71</sup> Many people who are in any type of pain would welcome an offer to shorten the duration of that pain through medication when possible. As found by Frigoletto et al., oxytocin

multiparous women; greater than 147 minutes for the second stage in nulliparous women and 57 minutes for the second stage in multiparous women.

<sup>&</sup>lt;sup>69</sup> Winkler and Rath, p. 324 and 339. <sup>70</sup> Winkler and Rath, p. 339.

<sup>&</sup>lt;sup>71</sup> S. L. Clark et al., "Oxytocin: new perspectives on an old drug," *Am J Obstet Gynecol* (2009) 200, 35.e1-e6; p. 35e3.

administration keeps 91-98% of labors studied under 12 hours.<sup>72</sup> There are certainly some direct benefits to the laboring patients in shortening labor such as avoiding exhaustion and shortening the length of suffering. Moreover, providers may feel like they have more control with oxytocin because labor is more predictable. I explore the implications of this perception of control in Chapter 2.

Despite these advantages, the medical administration of oxytocin has some severe side effects, some of which can be extremely dangerous to both mother and infant. One of the more common side effects of oxytocin administration is increased pain and discomfort due to greater strength and frequency of contractions and, therefore, increased pressure, which was the major finding of a 2009 meta-analysis of 9 different clinical trials of oxytocin augmentation.<sup>73</sup> Wei et al. chose studies which compared patient outcome after early oxytocin administration for slowness of a spontaneous, low-risk labor to progress or as part of AML to the outcomes of groups more conservatively managed (slower to use oxytocin); the criteria for "slowness" varied significantly between studies.<sup>74</sup> The authors sought to "estimate the effects of early oxytocin augmentation for delay in labor on method of delivery and on indicators of maternal and neonatal morbidity."<sup>75</sup> They found that early oxytocin had some benefit: it increased the number of vaginally completed births by 1 per 20, decreased the need for antibiotics during and after labor (need defined by presence of fever), and slightly reduced (though not enough to be statistically significant) both the cesarean section rate and the operative delivery rate. However, early oxytocin increased the risk of uterine hyperstimulation and was associated with lower

<sup>&</sup>lt;sup>72</sup> Frigoletto et al., p. 749, Table 6.

<sup>&</sup>lt;sup>73</sup> S. Q. Wei et al., "The Effect of Early Oxytocin Augmentation in Labor: A Meta-Analysis," *Obstet Gynecol* (Sept 2009) 114: 3, 641-649 ; p. 641.

<sup>&</sup>lt;sup>74</sup> Wei et al., p. 643.

<sup>&</sup>lt;sup>75</sup> Wei et al., p. 642.

patient satisfaction with pain management because of increased pain and discomfort.<sup>76</sup> Wei et al. conclude by recommending a discussion with patients about oxytocin's benefits and the potential for increased pain and discomfort.<sup>77</sup> This recommendation assumes that there is an existing framework for discussions with patients about oxytocin augmentation, but as I will discuss more in Chapters 2 and 3, this is not an accurate assumption in the case of oxytocin augmentation in many practice environments.

Uterine hyperstimulation is a widely agreed-upon, serious, but rare side effect of oxytocin use. Excessive oxytocin administration, which depends on each patient's unique dose response, can lead to hyperstimulation and morbidity.<sup>78</sup> Like many other drugs used in pregnancy, some of the most serious health risks and unknowns are for the fetus rather than for the mother, reminding us of the complex relationships in pregnancy between providers, fetuses, and the pregnant woman. This is the case with morbidity related to uterine hyperstimulation. Fetal morbidity due to hypoxia and acidemia (both of which compromise fetal oxygenation) is a serious potential side effect of hyperstimulation of the uterus.<sup>79</sup> A large Swedish study (28,486 deliveries) not only links prolonged hyperstimulation of the uterus to fetal morbidity, but also suggests direct negative effects on the fetus due to oxytocin by an as-yet unknown mechanism.<sup>80</sup>

<sup>&</sup>lt;sup>76</sup> Wei et al., p. 646-7.

<sup>&</sup>lt;sup>77</sup> Wei et al., p. 647. This meta-analysis did not use studies with enough power to detect serious maternal or fetal side effects.

<sup>&</sup>lt;sup>78</sup> Clark et al. (2009), p. 35.e2.

<sup>&</sup>lt;sup>79</sup> M. Jonsson et al., "Acidemia at birth, related to obstetric characteristics and to oxytocin use, during the last two hours of labor," *Acta Obstetricia et Gynecologica Scandinavica* (2008) 87:7, 745-50; p. 749.

<sup>&</sup>lt;sup>80</sup> Jonsson, p. 749.

Oxytocin exposure from induction or augmentation has also recently been associated with an increased likelihood of attention deficit hyperactivity disorder for the infant later in life.<sup>81</sup>

For the laboring patient, risks of adverse outcomes specifically due to oxytocin have been largely dismissed in the literature due to rarity. Established, though rare, risks for the mother include hypernatremia and hemorrhage. At high doses (>20U/min infusion), oxytocin can cause hypernatremia, or excessive retention of sodium, due to mimicry of another natural hormone in the body.<sup>82</sup> While this effect is dose dependent it is also more likely when the drug is rapidly infused with large volumes of normal saline.<sup>83</sup> This effect is extremely dangerous for the patient and can lead to "confusion, cramps, coma, heart failure."<sup>84</sup> Even though oxytocin is a powerful and widely used treatment for post-partum hemorrhage (PPH), a recent study suggests that large doses and prolonged duration of oxytocin exposure during labor actually increases the risk of serious PPH, defined as the patient requiring a blood transfusion, secondary to uterine atony.<sup>85</sup> On average, among the 54 PPH patients and the 54 controls, PPH patients had received significantly larger total doses of oxytocin, more than double the duration of exposure, and their maximum oxytocin doses were more than double those of the control group.<sup>86</sup> The authors suggest that the uterine atony observed is likely related to oxytocin receptor desensitization due to prolonged exposure to oxytocin.<sup>87</sup>

<sup>&</sup>lt;sup>81</sup> L. Kurth and R. Haussmann, "Perinatal Pitocin as an Early ADHD Biomarker: Neurodevelopmental Risk?" *Journal of Attention Disorders* (2011) 15:5, 423-431.

<sup>&</sup>lt;sup>82</sup> Winkler and Rath, p. 340.

<sup>&</sup>lt;sup>83</sup> Winkler and Rath, p. 340.

<sup>&</sup>lt;sup>84</sup> Winkler and Rath, p. 340.

 <sup>&</sup>lt;sup>85</sup> C. A. Grotegut et al., "Oxytocin exposure during labor among women with postpartum hemorrhage secondary to uterine atony," *Am J Obstet Gynecol* (Jan 2011) 204, 56.e1-e6.
 <sup>86</sup> Grotegut, p. 56.e4.

<sup>&</sup>lt;sup>87</sup> Grotegut, p. 56.e5.
As discussed above, many of the risks associated with oxytocin infusion are dose dependent and therefore theoretically largely preventable. Thus many of the problems that arise are due to medication error. According to a 2008 study on medication errors, 4.8% of voluntarily submitted medication errors over a three-year period involved obstetric care.<sup>88</sup> Of these obstetric medication errors, 48% occurred during labor and delivery<sup>89</sup> and over 70% of these labor and delivery errors occurred during medication administration.<sup>90</sup> Reporters named oxytocin specifically in 22% of all reports of harm-causing medication errors in obstetric care.<sup>91</sup> According to another study, oxytocin infusion errors most often involved a lack of appropriate treatment of excessive doses of oxytocin as evidenced by unacceptably high frequency of contractions and/or fetal distress per fetal heart rate patterns, accidental infusion of oxytocin with normal saline, and inappropriately early use of oxytocin for induction of labor.<sup>92</sup>

There are also risks inherent to any medication dependent upon the way it is delivered. Intravenous infusion of medication has well known potential complications that all nurses are trained to recognize that include local or systemic infection, infiltration (delivery of the infusion into soft tissue instead of into the blood stream, often because the catheter in the vessel has become dislodged), and phlebitis (inflammation of a vein due to chemical/mechanical irritation of the vascular tissue).

The ambiguities enumerated here with regard to oxytocin's indications and benefits as well as the largely preventable, though serious and sometimes fatal, risks have led to two

<sup>&</sup>lt;sup>88</sup> T. A. Kfuri et al., "Medication Errors in Obstetrics," *Clinics in Perinatology* (2008) 35, 101-117; p. 108.

<sup>&</sup>lt;sup>89</sup> Kfuri et al., p. 108.

<sup>&</sup>lt;sup>90</sup> Kfuri et al., p. 109.

<sup>&</sup>lt;sup>91</sup> Kfuri et al., p. 113.

<sup>&</sup>lt;sup>92</sup> K. R. Simpson and G. E. Knox, "Oxytocin as a high-alert medication: implications for perinatal patient safety," *American Journal of Maternal/Child Nursing* (Jan-Feb 2009) 34:1, 8-15; p. 8-9.

initiatives in the last five years: a safety warning and an initiative to make dosaging and monitoring more uniform. The Institute for Safe Medication Practices is a federally certified, non-profit patient safety organization that functions through donations. The Institute recently brought some negative attention to oxytocin by putting it on their high-alert list of medications. The medications and drug classes on the list can cause serious injury if used incorrectly, more so than drugs that are not high alert.<sup>93</sup> As of 2007, there were eighteen classes of medications considered high alert, and twelve medications specifically discussed, IV oxytocin among them. The Institute bases its recommendations on survey results from medical providers across the country.<sup>94</sup> Seven hundred seventy health care providers, primarily nurses and pharmacists, answered the survey in 2007. A substantial majority of the nurses, those actually administering the drugs, indicated that oxytocin should be considered a high-alert medication while pharmacists, who are more removed from the drug's application, expressed less concern: 73% of nurses surveyed voted to put oxytocin on the list versus 38% of pharmacists.<sup>95</sup>

As a result of ambiguous efficacy and safety findings regarding oxytocin, much attention has been brought over the last few years to the need for uniform dosing.<sup>96</sup> According to these studies, the lack of standardization of oxytocin dosaging poses the largest risk to patients, due to

<sup>&</sup>lt;sup>93</sup> Simpson and Knox, p. 8.

<sup>&</sup>lt;sup>94</sup> For more information see: Institute for Safe Medication Practices, "About ISMP," (2012) Last accessed on 21 Jan 2012, <u>http://www.ismp.org/about/default.asp</u>.

<sup>&</sup>lt;sup>95</sup> Institute for Safe Medication Practices, "ISMP 2007 survey on HIGH-ALERT medications: Differences between nursing and pharmacy perspectives still prevalent," (May 17, 2007) Last accessed 21 Jan 2012, <u>http://www.ismp.org/newsletters/acutecare/articles/20070517.asp</u>.

<sup>&</sup>lt;sup>96</sup> Clark et al. (2009); Clark et al. (2007); E. J. Hayes and L. Weinstein, "Improving patient safety and uniformity of care by a standardized regimen for the use of oxytocin," *Am J Obstet Gynecol* (June 2008) 198:6, 622.e1-e7; Jonsson et al.; L. R. Mahlmeister, "Best practices in perinatal care: evidence-based management of oxytocin induction and augmentation of labor," *Journal of Perinatal and Neonatal Nursing* (Oct-Dec 2008) 22:4, 259-63; L. A. Miller, "Oxytocin, excessive uterine activity, and patient safety: time for a collaborative approach," *J Perinat Neonatal Nurs* (Jan-Mar 2009) 23:1, 52-8; Simpson and Knox.

its dose-dependent side effects. However, as previously mentioned, a "standard" dose may not be an achievable goal due to individual variations in physiological response to oxytocin, so the focus has been mainly on the formation of protocols for incremental, lowest need dose oxytocin administration with close monitoring of maternal and fetal indicators of morbidity.<sup>97</sup> An article from 2008 called for much more cautious use of oxytocin augmentation, not just in terms of dosage, but concerning overall usage. The authors, Romano and Lothian argue, as I have hinted in this chapter, that oxytocin augmentation is a symptom of a larger issue in our healthcare system of overlooking ambiguity of evidence and privileging existing high-intervention practices without questioning them, under the assumption that technology and synthetic hormones are safe and beneficial entities with minimal risk/harm.<sup>98</sup>

In this chapter, I have discussed the medical and scientific communities' evolving and continuing efforts to more fully understand childbirth and the resulting ambiguous nature of the indications for an oxytocin augmentation for "slow" labor. The benefits of hastening labor and therefore decreasing duration of labor are largely subjective both for providers and for patients due to its impact on the *experience* of labor, leaving a great deal of room in decisionmaking for preference distinct from medical "need." While it is often assumed to be "safe" by providers utilizing it, as the physician in the anecdote assumed, this is not accurate for either fetal or laboring patients due to the direct effects of the synthetic hormone and risks of medication error, in particular.

As I will explore in Chapter 2, oxytocin augmentation is a decision made almost solely by providers. Authors like Romano and Lothian note that oxytocin augmentation is often used

<sup>&</sup>lt;sup>97</sup> For an example of a recent protocol initiative see Clark et al. (2007) and Clark et al. (2009).
<sup>98</sup> A. M. Romano and J. A. Lothian, "Promoting, Protecting, and Supporting Normal Birth: A Look at the Evidence," *Journal of Obstetric, Gynecologic, and Neonatal Nursing* (2008) 37, 94-105; p. 99.

because of "arbitrary time restrictions," both personal and professional, influencing provider decisionmaking.<sup>99</sup> Professional pressures, personal timing considerations and other factors that impact decisionmaking will be the focus of Chapter 2. There, I will evaluate the interactions that occur between providers and patients and the influences on the major parties involved, setting the stage for an exploration in Chapter 3 of possible approaches to informed consent regarding oxytocin augmentation that take into account the biases and generalization of expertise identified in Chapter 2.

<sup>99</sup> Romano and Lothian, p.99.

# III. CHAPTER 2: DECISIONMAKING AND PATIENT-PROVIDER INTERACTION

In Chapter 1, I established that oxytocin is an intervention with highly subjective indications dependent upon inconsistent, ambiguous, and, in one instance, meaningless diagnostic criteria for normal and abnormal labor. In this second chapter, I will discuss the interests of, and influences on, the major stakeholders involved in the decision to augment with oxytocin, with particular attention to the relationships and pressures of relative power. My analysis is informed by my observation of, and participation in, patient care as a medical student. Giving birth tonight instead of tomorrow is advantageous for many stakeholders, providers and patients alike, and is an advantage that can be hard to balance against other considerations within an environment of hierarchical power.

# A. A LOOK AT THE STAKEHOLDERS, INFORMED, WHERE APPLICABLE, BY DIRECT OBSERVATIONS

Providers, including physicians, midwives, and nurses, pregnant women and their fetuses are all stakeholders involved in childbirth and oxytocin augmentation.<sup>100</sup> All share an interest in health and safety for laboring patients and their fetuses, but each party brings a framework for decisions

<sup>&</sup>lt;sup>100</sup> Hospitals and payers as representatives of system-based influences were explored, but little data was available so they will not be discussed in this work.

made and actions undertaken during labor and delivery. Each individual involved brings his or her own training, experiences, professional pressures, and personal interests that form his or her practices and preferences. Any of them may have personal values and fears regarding the intervention based on their own or their significant other's laboring experience, if they have had children, which might also affect his/her professional choices. Larger entities like hospitals and payers bring previous experience and self-interest, including financial interests, to bear on their policies. A few small studies even suggest that a combination of such subjective factors, particularly those influencing physicians, may be playing a role in higher rates of intervention and more numerous operative delivery outcomes, independent of individual patient factors.<sup>101</sup> One study's authors observed higher rates of caesarean section, oxytocin use, and epidural use among women randomly assigned to be admitted to the hospital during the latent phase of labor, compared to women sent home during latent labor who returned and were admitted for active labor.<sup>102</sup>

Providers are under complex pressures and influences when deciding whether or not to augment labor with oxytocin. As established in the introduction, providers often assume that the decision is theirs to make and do not include patients in the decision-making process. I argue that informed consent is ethically required for oxytocin augmentation of labor *and* that it can be achieved consistently and in a way that privileges patient preference through re-structuring the patient-provider interaction to acknowledge difference in relative power and to begin to alter the existing power dynamics regarding oxytocin augmentation. There is one part of the decision to augment, however, that the provider makes alone: specifically, the determination of medical

<sup>&</sup>lt;sup>101</sup> L. J. Bailit et al., "Outcomes of Women Presenting in Active Versus Latent Phase of Spontaneous Labor," *Obstetrics and Gynecology* (Jan 2005) 105:1, 77-79; p. 79.

<sup>&</sup>lt;sup>102</sup> P. S. McNiven et al., "An early labor assessment program: a randomized, controlled trial," *Birth* (1998) 25, 5-10.

need for oxytocin augmentation informed by training and expertise. If a patient has a contraindication to oxytocin augmentation, for instance, oxytocin augmentation would not be appropriate and would not be offered. Thus whether or not the intervention is even an option is the provider's decision. Ideally, the provider would then seek informed consent to interventions from among the options available, and the patient could express her preferences. In my observation, however, the typical physician extends his/her power over the *entire* decision-making process regarding oxytocin augmentation, not just the determination of medically appropriate options. It is important to note that providers, particularly physicians and midwives, also control how and when to convey those options to patients. Admittedly, however, the timing of a patient's presentation to the clinic for prenatal care or the hospital for labor can also very much impact the degree to which each patient can realistically be involved in a decision. For instance, a provider can choose to talk about augmentation during prenatal care, upon admission to labor and delivery, or right before ordering the hormone for administration.

Provider control of decisionmaking power constitutes a generalization of expertise, conceptualized by Robert Veatch as occurring "when, consciously or unconsciously, it is assumed that an individual with scientific expertise in a particular area also has expertise in the value judgments [...] simply because he has scientific expertise."<sup>103</sup> According to Veatch, generalization of medical expertise to judgments involving values is never appropriate because training in the one area does not instill knowledge or expertise in the other, and because the values involved are frequently personal ones for those impacted by the decision. The practice of providers deciding about oxytocin augmentation for patients, involves the assumption that the provider knows what patients would want for themselves, specifically what treatment plan

<sup>&</sup>lt;sup>103</sup> Veatch, p. 29.

fulfills their vision of a good or acceptable childbirth or promotes their well-being. This constitutes an example of generalization of expertise. In addition to being subject to imperfections in understanding of patient perspectives, moreover, providers' medical expertise is not independent of external and internal factors such as their own localized cultures and their personal practice experiences. These factors may very inappropriately fill the gap in provider understanding of patient perspectives, values, and preferences and would also be a generalization of expertise. The following subsections explore factors that impact the ways that physicians make decisions and interact not only with patients but also with other providers.

#### 1. Providers: Physicians

#### a. Training, experience, practice culture, and professional pressures

Training, experience and practice culture inevitably influence physician decisions. There are a few specific situations in which oxytocin augmentation is contraindicated and therefore recommendations are straightforward. The contraindications described are rare, so relatively few cases that physicians manage will meet definitive criteria. The indications in the absence of contraindications, as discussed in Chapter 1, are ambiguous. The rate of labor progression should be the major factor weighed when evaluating a patient's medical need for oxytocin. As mentioned in the introduction, however, personal observations and discussions with providers in a few different practice types and locations suggest that rate of labor is not always the main criterion for oxytocin augmentation. In addition, as discussed in Chapter 1, the medical and scientific communities imperfectly understand the progression of labor, and "slow" is a relative and subjective term. In this clinical setting of scientific ambiguity, an individual physician's

interpretation of the evidence regarding abnormal and normal labor will certainly be affected by the interpretations of those with whom s/he trained and practices and her/his own personal experiences.

In my observation and informal discussions, the influence of using an epidural on the need for oxytocin is largely training-based, rather than evidence-based. For example, I witnessed some providers order nurses to start a continuous intravenous infusion of oxytocin right after the epidural had been started, without any confirmation that the contractions had actually changed in any way. Such an order suggests that these providers consider oxytocin a "necessary" countermeasure to an epidural, without evidence of medical need. In fact, the effects of epidurals on labor duration depend on when in labor the epidural is initiated, and study results are often inconsistent. In a systematic review comparing 7 different studies, epidural analgesia did not have a statistically significant effect on the duration of the first stage of labor and only slowed the second stage of labor by 15 minutes, on average.<sup>104</sup>

Experience with oxytocin augmentation, personally and professionally, is another factor that might influence a physician's decision for or against augmentation. Frequency and severity of side effects in a physician's previous patients may have a large impact, for instance. Number of labors overseen with and without augmentation may also influence a physician in either direction. Each provider's practice pattern, his or her training, as well as the predominant practice culture at each institution are likely to affect whether or not oxytocin augmentation is used.

<sup>&</sup>lt;sup>104</sup> B. L. Leighton and S. H. Halpern, "The effects of epidural analgesia on labor, maternal, and neonatal outcomes: A systematic review," *Am J Obstet Gynecol* (May 2002) 186:5, S69-S77; p. S75, Table III.

Based on observations and discussions, I found that patient load at any given moment may strongly influence a physician's decisions about oxytocin augmentation. A scheduled cesarean section later in the day or the number of labors anticipated to be in the second stage at a given time under the supervision of the same provider may encourage a provider to augment labor in order to have some "control" over the timing of the labors with which s/he must assist. There may be pressure on a provider from his/her hospital to keep labor rooms turning over. Patient load and system-based distinctions between nurse and physician responsibilities are the major reason physicians are not in the room as much as nurses and also maybe a reason physicians are ordering oxytocin in ways that nurses deem "unsafe," thereby creating conflict between nurse and physician. According to Simpson, James, and Knox, oxytocin is reportedly often cited as a source of disagreement between the labor nurse, who is present in the room for most of the patient's labor, and the attending physician or resident, who is in the room only intermittently.<sup>105</sup> In this study, nurses were most often resistant to starting or increasing oxytocin doses while physicians consistently wanted "aggressive" augmentation, with the difference of perspective leading to failures in communication and tension in the workplace.<sup>106</sup> There could also be situations where the reverse is true, in which the nurse is pressuring the physician to use oxytocin and the physician is resistant.

#### b. Personal interests, values, and fears

Personal interests, values, and fears may also play a role in a physician's decision to augment. For instance, if a physician trained where 90% of births were augmented, one could speculate

<sup>&</sup>lt;sup>105</sup> K. R. Simpson, P. C. James, and G. E. Knox, "Nurse-physician communication during labor and birth: Implications for patient safety," *J Obstet Gynecol Neonatal Nurs* (2006) 35, 547-50. <sup>106</sup> Simpson, James, and Knox, p. 549.

that s/he may simply be impatient with a slower-paced labor. Anxiety or fear about *not* having "control" as one does with oxytocin could be related to this impatience. For instance, one family-practice-trained physician reported that she prefers to use oxytocin in all labors she manages because it is a low-risk way to keep a labor progressing, and it is easy to change the dosage if there is too much or too little of an effect. For this physician, oxytocin was a tool to keep things at a pace acceptable to her according to her personal and professional preference. Essentially, she used oxytocin because the use of oxytocin reassured *her*, the physician. She reported telling patients that it would keep labor on track.

A physician could have also mistakenly ordered oxytocin when there was a relative or absolute contraindication for a patient or been sued about oxytocin use in the past. These could easily make him/her reluctant or anxious about using it again. On the other hand, a physician could have had a bad outcome in the absence of oxytocin in a patient, herself, spouse, or a family member, been sued over not ordering oxytocin, or been reprimanded for not ordering oxytocin soon enough or at all. In this case, the physician might overuse oxytocin augmentation out of fear when put in a similar position to make a decision about augmentation. Making decisions based primarily on these personal factors on the part of physicians would not be in patients' best interest and would constitute an inappropriate generalization of expertise.

#### 2. Providers: Midwives

### a. Training, experience, practice culture, and professional pressures

In my observation, attitudes and interactions about oxytocin augmentation in the course of a normal labor generally differed based on the type of institution and, therefore, environment in

which the providers worked and trained, particularly for midwives. Generally speaking, it is the case that midwives use oxytocin infrequently for augmentation. Much of the midwifery literature is insistently opposed to oxytocin augmentation, and the training focuses on low intervention in normal births. Though I did not directly observe oxytocin's use by midwives, some of the midwives with whom I spoke said they had noted their own practice patterns, or those of fellow midwives, changing. The biggest factor seemed to be the practice environment. For example, the midwife I observed working out of a free-standing birth clinic stated that the clinic's policy was to use oxytocin only in the third stage of labor to prevent post-partum hemorrhage. There might have been a rare occasion during her training elsewhere when she or another midwife might have used it to augment labor, but she could not recall a specific instance of this.

In contrast, the hospital-based midwife I observed stated that she had recognized and lamented her practice patterns changing to become more like those of the physicians around her since she had started working in a hospital. In the hospital where she worked, the midwives were responsible for teaching the residents in low-risk, normal deliveries, thereby empowering the midwifery view in this particular hospital setting. Indeed, the labors and deliveries I observed were quite low intervention, and oxytocin was used much less and with more conscious reflection on the part of providers than in the other hospital in which I spent time. The midwives have to have physician oversight throughout the labor, however, and a physician has to be in the room at the time of birth. The loss of important privileges as independent care providers for birthing mothers, determined by hospital policy and state law, make it extremely hard for these midwives to maintain the practice patterns of their initial training, despite the potential to gain respect and good rapport with their physician colleagues through teaching. The increased use of oxytocin is one aspect of the erosion of their training-inculcated practices.

#### b. Personal interests, values, and fears

Midwives' values likely influence their choice of profession; in this respect the choice of the low intervention approach of midwifery likely reflects midwives' personal values against interventions like oxytocin augmentation. On the other hand, however, there may also be personal factors involved in changing practice patterns toward using more oxytocin for augmentation based on the practice environment. For instance, if midwives are practicing in a high intervention setting like a hospital, the patient population may have expectations that more intervention equals better care, particularly if the patient did not specifically choose a midwife for her care. This may, in turn, become a matter of personal interest for the midwife in an effort to build a patient base in a community that values more intervention. In addition, midwives might also come to use oxytocin or continue to avoid it for some of the same personal reasons as physicians, or out of fear of repeating prior outcomes or litigation concerns.

#### 3. Providers: Nurses

Nurses and physicians have very distinct roles in today's labor and delivery suites. Nurses are present in the room with one or two patients for a significant amount of the labor, whereas physicians are more often out of the room than in it, at least until the second stage begins. It is the nurses who most directly support these patients who are in pain, exhausted, and sometimes overwhelmed with all that is happening. Due to their extended time with patients, which is not necessarily unique to labor and delivery units, nurses might make management suggestions,

depending on their training and experience, but it is the physician who usually has the final decision and who must order the drug or intervention.

Based on my observations and informal discussions, I found that nurses can have a significant impact on a laboring patient's experience, and may directly affect which interventions a patient "needs" or wants. At a few institutions on the West coast, for instance, family medicine residents and attendings alike touted that the reason for their low oxytocin augmentation and epidural rates is focused, supportive nursing care for each laboring patient. A systematic review of studies regarding pain control and patient satisfaction found that, in 16 studies, perceived caregiver support had a large impact on patient satisfaction.<sup>107</sup> For instance, "[i]n one US-Canadian study, 44% of the variance in satisfaction was explained by women's ratings of the quality of intrapartum nursing support." In a randomized controlled trial of one-on-one nursing support for laboring women, those patients with one-on-one support showed a small trend of reduced requests for epidural analgesia that was not statistically significant, and a large and statistically significant decrease in oxytocin requirement, compared to the usual nursing technique group.<sup>108</sup>

The power dynamics with physicians regarding oxytocin augmentation in other places, however, seem to be particularly inflexible,<sup>109</sup> and nurses may have to work in a system that denies them the agency to advocate for their laboring patients regarding oxytocin augmentation. During my labor and delivery rotation at an East Coast/Midwest institution, for example, I

<sup>&</sup>lt;sup>107</sup> E. D. Hodnett., "Pain and women's satisfaction with the experience of childbirth: A systematic review," *Am J Obstet Gynecol* (May 2002) 186:5, S160-S172; p. S167.

<sup>&</sup>lt;sup>108</sup> A. J. Gagnon, K. Waghorn, and C. Covell, "A randomized trial of one to one nurse support of women in labor," *Birth* (1997) 24, 71-77; p. 75, Table 2.

<sup>&</sup>lt;sup>109</sup> The inflexibility of power structure between nurse and physician regarding initiation of oxytocin administration was indicated in Simpson, James, and Knox's article about nurse and physician disagreements over oxytocin augmentation as mentioned in section 1. a. above.

witnessed one disagreement in which a nurse refused to start an oxytocin infusion the physician had ordered. She was an experienced nurse who was well acquainted with the physician involved, which likely gave her confidence to voice her own opinion about the intervention. The physician had taken the nurse's advice about other concerns regarding this particular patient, but on augmentation he held firm. Observations by Clark et al. (2009) echo this type of disagreement between nurse and physician over oxytocin augmentation:

Our experience in assessing and improving obstetric practices in many hundreds of different institutions has led all the authors to 1 identical conclusion: the most common cause of discord between obstetrician and labor nurse is the tendency of a physician not at the patient's bedside to urge the use of oxytocin in a manner deemed unsafe by the bedside labor nurse.<sup>110</sup>

Clark et al., a group of three physicians and one nurse, go on to argue that the party with more experience, usually the bedside labor nurse, is often correct.<sup>111</sup> In my experience, the ultimate decisionmaking power in such a disagreement typically, however, goes to the physician. Theoretically then, such a rigid hierarchy and inappropriate generalization of expertise by physicians in such cases could actually be a safety risk for patients if Clark et al. are correct in their conclusion that the more experienced labor nurse is usually in the right regarding oxytocin augmentation.

A nurse may have little control over whether a physician starts oxytocin once that physician determines "need," but s/he does have power over the titration of the hormone after it has been started. Once the infusion is on, it is the nurse's responsibility to ensure the patient's safety in relation to the effects of oxytocin and the efficacy of the intervention: if a patient is not progressing, the nurse must increase the dose according to the protocol established by the hospital where s/he practices; on the other hand if a patient develops uterine hyperstimulation,

<sup>&</sup>lt;sup>110</sup> p. 35e3. <sup>111</sup> p. 35.e4.

the nurse must either decrease or stop the oxytocin infusion, depending on her clinical judgment and training, *before* involving the physician who ordered the oxytocin.<sup>112</sup> So while nurses may not control the initial use of oxytocin, they have a great deal of responsibility for and control over the way it is used once it is started. Thus, they are personally invested in oxytocin's safe use just as much, if not more than, physicians are invested, at least in terms of personal liability.

### a. Training, experience, practice culture, and professional pressures

The use of oxytocin for augmentation directly affects the way nurses interact with laboring patients. A physician must order the oxytocin, but it is the nurse who must set up the drip, and it is *the nurse*, not the physician, who must increase the frequency of patient exams and watch closely for fetal heart rate changes and contractions getting too close together. Thus, oxytocin may make just two patients challenging to manage simultaneously. Due to the hierarchy often present between nurses and physicians, nurses often have little recourse to contest a recommendation for oxytocin augmentation with which they disagree. Nurses may also be concerned about physicians' limited discussion, or complete lack of discussion, with patients regarding oxytocin. Furthermore, the increased pain levels of oxytocin-augmented labors for patients, as compared to labors without oxytocin, may be seen more clearly by nurses than physicians, in part because nurses spend more time with patients during labor. These additional oxytocin-associated factors—increased patient management pressures, patients' increased pain, and patients' lack of understanding of their experience with or need for oxytocin—may increase tension between nurses and physicians, and may affect nurses' interactions with their patients.

<sup>&</sup>lt;sup>112</sup> S. Clayworth, "The Nurse's Role During Oxytocin Administration," *Am J Mat/Child Nurs* (March/April 2000) 25:2, 80-85.

Nursing training plays into how comfortable each nurse is with this supportive role of the laboring patient as well as comfort with oxytocin administration and monitoring. Even though nurses are often intentionally assigned to patients experiencing alternate stages of labor (i.e. one in early labor and one in late labor) when possible, labor rarely follows a predictable course. When it does, as might be said for oxytocin-augmented labors, the nurses are not often able to take advantage of the "predictability" of labor progression to check on another patient because oxytocin has increased the nurse's monitoring requirements. According to one study about communication between nurses and physicians during labor, the majority of nurses interviewed were resistant to keeping a patient's labor on a predetermined timeline, which the nurses often felt was the physician's personal timeframe rather than one devised for the patient's best interest.<sup>113</sup> In this qualitative research project, a large patient burden on the unit was another reason cited by nurses to delay or disagree with a physician-requested initiation of, or change in, oxytocin management, because these nurses felt that they could not monitor these patients frequently enough at a busy time to keep the patient and the fetus safe.<sup>114</sup>

#### b. Personal interests, values, and fears

Nurses' professional experiences may influence fear or favor of oxytocin augmentation, depending on the outcomes of patients they worked with in the past. Perhaps a previous patient experienced a rare or serious side effect, or the nurse him/herself made a mistake with administration or missed important problems in the fetal heart tracing or contraction pattern. On the other hand, a nurse might have witnessed numerous positive labor experiences and outcomes

<sup>&</sup>lt;sup>113</sup> Simpson, James, and Knox, p. 549.

<sup>&</sup>lt;sup>114</sup> Simpson, James, and Knox, p. 549.

with oxytocin augmentation. On the level of personal interests, a nurse, like a physician, might prefer oxytocin augmentation because of the shorter labor time. Alternatively, a nurse might have a preference against augmentation due to the increased monitoring required. A nurse may or may not support a decision to augment for fear of litigation as well. Acting on these interests, values, and fears on the part of nurses is not necessarily in the patient's best interest, and awareness of them brings insight to nurses' interactions with patients.

#### 4. Obstetrical Patients

#### a. Considerations in the decision-making process

Unless the patient is informed and educated about the birth process and the interventions that can be provided, through books, websites, articles, friends, or family, the patient derives much, if not all, of her information about treatment options from her provider. As I have observed, some patients may not have any information on which to base a decision regarding oxytocin augmentation because informed consent has not been attempted.

If a laboring patient is informed, however, and is facing oxytocin augmentation or any intervention, she has a range of factors to consider. Her health and safety and those of her fetus are major concerns, though it is impossible to predict whether these concerns alone would support a positive or negative patient preference regarding oxytocin augmentation, because even the "objective" evidence on safety for patient and fetus is ambiguous. A patient may desire a low intervention birth, and therefore, on principle, wish to avoid oxytocin augmentation. A different laboring patient may want to manage and "control" her vaginal birth as much as possible and therefore desire oxytocin augmentation and probably an epidural as well. Physicians and other

providers certainly cannot definitively predict the ways in which such preferences might affect a patient's ultimate decision about oxytocin augmentation, when these preferences are weighed among other factors. Thus it is important to involve patients in the actual decision-making process.

#### b. Conditions influencing decisionmaking

Pain, hunger, and exhaustion impact decisions. Fear of pain or wish to avoid pain may, quite understandably, drive a patient to plan an early epidural, or intense experience of pain during labor may lead a patient to request an epidural she wasn't planning to have. A preference for oxytocin augmentation may also be related to a preference for shortening the duration of a patient's pain. For a patient without an epidural, however, avoidance or fear of pain may mean a preference against oxytocin augmentation, given the increase in frequency and strength of contractions, and therefore in pain, it causes. In another patient, hunger and exhaustion may influence her to desire a shorter labor, and oxytocin augmentation, whatever the change in pain level. For patients without insurance or without full coverage of labor costs, the higher cost of the labor room may also be a factor influencing patients to request or accept oxytocin augmentation to shorten labor.

As in the case of all the stakeholders already discussed, previous experience may also have a significant impact on a patient's preference. A laboring patient may have had a previous birth experience in which oxytocin was used with increased pain, or serious side effects for herself or her fetus, and the patient may fear a repetition of the prior experience and therefore want to resist or refuse augmentation. There may also be an association from a prior birth experience between oxytocin and a bad outcome like stillbirth, in which oxytocin would be given

to induce labor after fetal death is confirmed so that the fetus could be delivered in the absence of spontaneous labor. On the other hand, a patient may have been pleased with an actively managed labor in the past and may wish to repeat it by accepting or even requesting oxytocin augmentation.

Given all of the factors that influence the patients, providers, and nurses involved with oxytocin augmentation, navigating patient-provider interactions and discussions is unquestionably complicated, and ensuring that conditions are created to enable informed consent could be challenging. Interactions with patients about oxytocin augmentation may even be personally challenging because many of the factors, pressures, and influences mentioned here require serious self-reflection for both patient and provider. How then should we think about these interactions, what they need to achieve, and how they should be conducted? Informed by the exploration of bias, power, and influence in this chapter, the following chapter will suggest a method for re-structuring the patient-provider, particularly the patient-physician, interaction in ways that provide meaningful choice for patients while specifically avoiding providers' generalization of expertise as now occurs in oxytocin augmentation decisions.

# IV. CHAPTER 3: INVOLVING THE OBSTETRICAL PATIENT IN DECISIONS REGARDING OXYTOCIN AUGMENTATION

In this thesis, I have discussed the goals and requirements of informed consent, highlighted the absence of informed consent for oxytocin augmentation, and explored two of the three clinical norms that are violated through the absence of informed consent. Informed consent is needed for oxytocin augmentation due to its risks and unclear indications, as well as the many influences and pressures on, and unequal power dynamics amongst, the stakeholders. Informed consent is also necessary because of the personal experiential nature of the process of childbirth, about which patients have preferences and expectations. This chapter involves articulating different conceptions of informed consent in practice and then considers how to incorporate preferences through a method that empowers patients to take an active part in the decision-making process. In this chapter, I discuss an approach to the patient-physician interaction that empowers pregnant patients to participate in decisions regarding oxytocin augmentation. This method could allow informed consent's goals of patient well-being and autonomy to be achieved in a way that privileges patient preference and encourages awareness, if not removal of, the biases that reinforce the current unilateral power dynamic and generalizations of expertise that hamper decisionmaking about oxytocin augmentation.

### A. INFORMED CONSENT IN PRACTICE

The need for greater patient involvement in birth decisions is highlighted by a 2002 study in which 40% of US patients who did not initially want an epidural received one, compared with a UK study which found that only 10% of patients who did not plan an epidural eventually received one.<sup>115</sup> The comparison suggests that US providers and UK providers could be educating patients differently: prenatally, US providers may not be adequately educating patients about the birthing process and their options, so that patient preferences are unrealistic, or such education is not accessible to the same percentages of patients as in the UK; perinatally, US providers may be encouraging intervention more than necessary and/or patients may not be adequately empowered to defend their preferences.

There are myriad factors involved in the patient-physician interaction in the context of medical decisionmaking that can impede or encourage the substantial understanding about a given medical intervention that informed consent ideally achieves and depends upon. An examination of the interaction will elucidate the ways in which informed consent can be achieved to more fully address the social, institutional, and personal factors for the individuals involved. Authors Jessica W. Berg, Paul S. Appelbaum, Charles W. Lidz, and Lisa S. Parker describe typical formats of informed consent attempts in *Informed Consent: Legal Theory and Clinical Practice*.<sup>116</sup> Berg et al. argue that sense<sub>2</sub> informed consent typically occurs in practice in two dominant ways, a "process model" and an "event model." A "process model" of informed consent occurs slowly over time, often in the context of a long-term patient-physician

<sup>&</sup>lt;sup>115</sup> T. R. Marmor and D. M. Krol, "Labor Pain Management in the United States: Understanding Patterns and the Issue of Choice," *Am J Obstet Gynecol* (2002) 186:5, S173-S180; p. S176. <sup>116</sup> J. W. Berg et al., *Informed Consent: Legal Theory and Clinical Practice*, 2<sup>nd</sup> ed. (Oxford: Oxford University Press, 2001).

relationship, and may even achieve both senses of informed consent articulated by Faden and

Beauchamp:

The advantages of a process model are substantial. The process model promotes the objectives of the underlying idea of informed consent and, at the same time, is equally in conformance with the requirements of the legal doctrine of informed consent as the event-oriented approach. Patients are brought actively into the decisionmaking process, in a manner that encourages their knowing participation. They receive information, over time, in a fashion that allows it to be contemplated, shared, and assimilated. Further, by participating in the stream of decisions as they are made, patients are not excluded from the "ultimate" decision, by virtue of being excluded from the many preliminary decisions that may, in effect, predetermine the outcome.

[...Also, it] should serve to make the idea of informed consent meaningful to physicians. No longer is the disclosure and decision-making process divorced from the real decisions that need to be made.<sup>117</sup>

Berg et al. contrast this process model of informed consent, with its emphasis on

disclosure of information and subsequent shared decisionmaking, with an "event model." An

"event model" of informed consent is one in which patients are given a minimal amount of

information to make a decision and are encouraged or expected to make a decision at the time of

disclosure, without time to consider the information, form additional questions, or seek

additional counsel. Berg et al. argue

[T]he event model appears to be structured in the worst possible way as far as facilitating patients' informed participation is concerned. Educators have long known that provision of information repetitively, over a sustained period, results in better understanding and better retention than exposure at a single point. Information provided when patients are at relative ease is more effectively assimilated than information offered at times of stress. The event model encourages "one-shot" education of patients, with little opportunity for reflection and integration of the information obtained into the patients' underlying scheme of values, and at a time, given that a decision must be made imminently, when patients' anxiety is likely to be at a peak.<sup>118</sup>

<sup>&</sup>lt;sup>117</sup> Berg et al., p. 172-73.

<sup>&</sup>lt;sup>118</sup> Berg et al., p. 170.

The "event model," then, specifically precludes the understanding and much of the participation described above as being at the core of sense<sub>1</sub> informed consent. The "event model" is heavily provider and institution-driven as a result. This "event model" is the most accurate description of informed consent in the setting of oxytocin augmentation in current practice, if any attempt at informed consent occurs at all.

A great deal of a patient's education goes on in birthing classes and prenatal visits, but oxytocin augmentation is rarely specifically addressed, thus the only women becoming well informed about it are women who have already done their own reading or are asking questions. Even women who take advantage of structured childbirth education time prenatally can have limited access to information from providers regarding oxytocin augmentation specifically. When they do get information it is sometimes from nurses or midwives with views regarding oxytocin augmentation that contradict their labor provider's views. There are structures in place to pursue informed consent according to the "process model" approach taken with other childbirth topics during prenatal care, but it cannot be achieved unless advantage is taken of that structure and time. Even more widespread use of an "event model" of informed consent for patients who go into labor early or do not receive prenatal care would be an improvement from the absence of disclosure or dialogue with most patients' augmentations.

Patient-physician interaction during the medical decision-making process has important implications for informed consent. The method discussed next seeks to empower the patient, provide information, satisfy informed consent requirements, and provide space in the discussion for clarifying and exploring the patients' preferences. Janet Farrell Smith's application of the communicative ethics model to medicine attempts to achieve these goals through acknowledging

and making more visible underlying power structures so that both parties' values can be represented and respected.<sup>119</sup>

# B. COMMUNICATIVE ETHICS: A PARADIGM FOR INFORMED CONSENT INTERACTIONS BETWEEN PATIENTS AND PHYSICIANS

Smith's account of communicative ethics involves revising existing clinical practice and changing the nature of the encounter in question. Communicative ethics occurs when speakers in an open forum "critically analyze existing norms, explore new ones, and come to mutual understanding or consensus."<sup>120</sup> According to Smith, conceptualizing communication as just a transfer of information, as too often occurs in current interactions, is "too limited even to account for the normative importance of information in physician-patient discourse."<sup>121</sup> Moreover, most existing patient-physician interactions are not a free exchange of speech acts in a medical context, but a "highly structured discourse in which the physician is usually very much in control."<sup>122</sup> The information transfer approach to communication, which Manson and O'Neill also criticize, fails in four ways: it allows for a conflation of factual and prescriptive statements which can be influenced by the perceived role and status of the doctor, <sup>123</sup> does not highlight the

<sup>&</sup>lt;sup>119</sup> J. F. Smith, "Communicative Ethics in Medicine: The Physician – Patient Relationship," in *Feminism & Bioethics: Beyond Reproduction*, S. M. Wolf, ed. (New York: Oxford University Press, 1996) 184-215.

<sup>&</sup>lt;sup>120</sup> Smith, p. 184.

<sup>&</sup>lt;sup>121</sup> Smith, p. 185.

<sup>&</sup>lt;sup>122</sup> Smith, p. 187.

<sup>&</sup>lt;sup>123</sup> This observation bears significant resemblance to Veatch's concept of the "generalization of expertise" discussed in Chapter 2.

importance of facts and information in contrast to opinion and provider preference, does not encourage dialogue, and does not acknowledge differential access to power.

The patient-provider form of communication she envisions is more than the simple and inadequate transfer of information because it must conform to ethical principles of respect and moral equality, which the transfer of information does not do. Importantly, the communicative ethics approach both allows for disagreement to occur without a failure of the interaction and acknowledges "differential power and access to technical knowledge" between patient and physician.<sup>124</sup>In order for this to occur, the approach encourages a step back from the encounter to allow analysis of how speech acts guide, coordinate, and interpret action, with eventual consensual action being the central goal. It is unclear from Smith's account exactly how or when this stepping back is to occur and who is to undertake it. By stressing that the medical encounter should resemble a conversation more closely than an interview, Smith implies that both parties must step back: the party with more power, typically the provider, must evaluate the way s/he presents "fact" versus opinion or recommendation and must identify where patients, without the same knowledge base, may require more detailed explanation of common medical assumptions, terms or processes. The party with less power, typically the patient, must reflect on what s/he does and does not understand in a conversation with a provider, as well as on his/her own personal values that might bear on the decision. S/he must also evaluate the way the provider represents fact and opinion, determine what the alternative options are, and try to reflect upon whether s/he has freedom from outside control or influence to form a preference independent of the provider's.

<sup>&</sup>lt;sup>124</sup> Smith, p. 185.

This may sound like a lot to ask of providers and patients, and it realistically may not be done in every interaction, particularly in situations where the event model of informed consent is the best that can be achieved. Informed consent regarding oxytocin augmentation in most cases, however, can be pursued over time, and even across multiple sessions, as the process model of informed consent describes. Applying a communicative ethics method of interaction would require a few initial encounters for providers to get practice in identifying their own biases and become familiar with the approach. This is much of the work of the method. Providers must still work to individualize the approach to each patient, but, once practiced, it is likely realistic to use the communicative ethics method on a regular basis, with every interaction. In fact, it is not dissimilar to what is taught in intensive interviewing classes at the University of Pittsburgh, through which medical students learn about interacting with patients through practice sessions with "standardized patients," actors who take on a number of different personalities to teach students how to approach various interpersonal, disease-specific, or general interviewing challenges. It can be done, and many outpatient practitioners routinely take similar approaches to a variety of medical topics.<sup>125</sup>

<sup>&</sup>lt;sup>125</sup> Some providers may be more comfortable with applying this approach than others: for instance, midwives, trained to be "with women" and focused on the support of the laboring patient may be more likely to embrace this approach since their training presupposes extensive knowledge of a patient's preferences. In contrast, OB/GYNs may struggle more with this approach because their childbirth training, by and large, is about managing unforeseen complications of birth where they have, in practice, almost sole decision-making responsibility. Family physicians are likely to fall somewhere in between because they often receive their obstetrics training from a combination of OB/GYNs, other family physicians, and midwives. They may also have more time to employ this approach because they manage low-risk births (typically, at least) and are largely not responsible in the current practice climate for managing serious unforeseen complications (they hand off such cases to OB/GYN back-up physicians). Moreover, they come from generalist training that emphasizes the family unit, personal context, and treating all systems of the patient and not just one organ system.

Smith argues that power is accessible to patients through the implementation of ethical principles of respect and equal worth.<sup>126</sup> If this is a reasonable argument or assumption, there has to be part of Smith's approach that implements these principles. I would argue that her step back approach relies on these principles. In order to conscientiously evaluate her/his personal approach to medical decisionmaking as outlined in the step back approach, a provider or patient must have respect for the other as an independent human being, even if, in one extreme, s/he does not approve of, or like, that other as an individual. Equal worth has to do with the nature of each entity: equal worth is something individuals must believe they and others have in order to embody it, and, in turn, respect self and others. A belief in the equal worth of all persons is a significant foundation for one's respect of those persons. Respect is directed toward noncontingent aspects of the other, i.e., not the coincidence of the other's preferences and values with one's own, but the other's equal worth or underlying dignity. Sarah Buss argues that the fundamental purpose of manners is to show respect for the dignity of others.<sup>127</sup> One aspect of informed consent, particularly as achieved through communicative speech acts such as those Smith describes, might be considered a professional version of displaying good manners, as Buss describes them. Seeking informed consent and providing information necessary to enable it has moral import, as doing so recognizes that "persons are ends in themselves- and must be acknowledged as such."<sup>128</sup> Similarly, reciprocal listening and critical self-reflection/evaluation evidence recognition of equivalent valuing of the other, even if only within the context of the patient-provider relationship. Showing respect allows those shown such respect access to power. The demand for respect and recognition of equal worth affords power to those materially,

<sup>&</sup>lt;sup>126</sup> Smith, p. 204.

<sup>&</sup>lt;sup>127</sup> S. Buss, "Appearing Respectful: The Moral Significance of Manners," *Ethics* (July 1999) 109, 795-826; p. 795.

<sup>&</sup>lt;sup>128</sup> This is Buss's interpretation of the moral import of treating others respectfully, p. 795.

socially, or "informationally" less powerful by influencing those with greater power to relinquish, or at least share, some of that power. Belief in equal worth encourages respect and encourages those with less power to seek out and accept greater power.

With oxytocin augmentation as it currently occurs, there is typically no communicative action or interaction between patient and provider, particularly between patients and physicians. If any communication about oxytocin occurs between physicians and patients, information is often simply transferred. Sometimes physicians do not even witness the transfer because they have delegated this task to nurses, physician assistants, or even medical students with an order/request to "get the patient to sign the form." The information is transferred as content only, such that an explanation of what the intervention will accomplish and the risks it might entail are conveyed, using medical jargon, often without discussion of alternatives or values that might impact the decision. Saying "we're starting a 'pit drip'<sup>129</sup>" implies that there is no alternative and that the provider is recommending the intervention, and assumes that the patient hearing this statement knows what oxytocin is, what it is used for, what to expect after it has been started, and how it can affect the total course of the labor. Such cursory communication assumes and, in turn, implies to the patient that the patient's preference is not equal in worth to the provider's preference, and that the patient has relinquished whatever power she had over such decisions.

A more open, communicative approach might be the following. After an hour and a half without any progression of cervical dilation in the active phase of labor, a provider might say "I am considering starting a drug that will increase the strength of your contractions and how often they occur because the progression of this birth is not what I would expect given my experience

<sup>&</sup>lt;sup>129</sup> Pitocin is the pharmaceutical name for oxytocin; oxytocin is often referred to as a "pit drip," slang for continuous intravenous pitocin in the clinical setting.

and what we know about the way labor usually progresses. The alternative is to continue evaluating you and the fetus without the drug, with a plan to reevaluate in 30 minutes. Do you have questions or concerns? How would you like me to proceed?" This approach provides the possibility for dialogue; indeed it requests it. The provider allows for multiple options and acknowledges the power of speech acts to guide the patient by providing multiple pieces of information regarding the indications. At the same time, the provider leaves open the space for questions about the indications, the way labor usually progresses and how the patient's labor differs. This approach assumes that the patient has a preference of equal value as the provider's, such that the provider should and does show respect for it by trying to elicit it.

There are scenarios, however, in which communicative ethics might fail or a participant might undermine the intentions behind the approach. This could occur if one party is not being genuine and superficially elicits a conversation with all the requisite components and then uses the information gathered to manipulate the decision according to his/her preference. For instance, a provider may learn that what a patient fears most is injury to her fetus. While focusing on this value when interpreting options for this patient as encouraged by communicative ethics, over-emphasizing risk, even if minimal, to the fetus at points of decisionmaking to turn the patient's "preference" toward the provider's preference would undermine the goals behind the concept. Next I will discuss more directly the incorporation of patient preference into obstetrical decisions and the particular challenges with autonomy in the obstetrical patient.

## C. AUTONOMY AND THE OBSTETRICAL PATIENT

The Obstetrics and Gynecology Risk Research Group offers another consideration in the search for informed consent through shared decisionmaking, arguing that it is nearly impossible for a provider not to be directive while providing high quality patient care and that it is actually desirable for providers to be somewhat directive while getting as accurate a picture as possible of the patient's values. <sup>130</sup> The OG Risk Research Group essentially outlines the hierarchy of knowledge in childbirth in an attempt to describe, and help women find, autonomy in the obstetrical environment. The group's particular emphasis is on elective cesarean section, but the analysis and recommendations about elective cesarean section have relevance for provider-patient discussions of oxytocin augmentation. One of the most important aspects of the patient-provider interaction is the relationship between choice, autonomy, and a provider's value-laden and directive filtering of relevant information to share with the patient facing a medical decision. The OG Risk Research Group addresses the intersections of choice, autonomy and directive filtering. They begin by discussing autonomy and choice as they are commonly understood:

There is an obvious sense in which expanding women's voluntary access to cesarean deliveries would represent an increase in the options available to women. To the extent that we understand patient autonomy as equivalent to informed choice, and expanding autonomy as a matter of expanding available choices, it may seem that any move in the direction of allowing women more delivery options is a move in the direction of enhancing women's autonomy during birth.<sup>131</sup>

They go on to state, however, that a large number of choices can sometimes reduce a patient's sense of involvement in, and understanding of, the decision-making process. Even if many choices were available, "the physician determines the space of reasonable medical options in

<sup>&</sup>lt;sup>130</sup> Obstetrics and Gynecology Risk Research Group, "Finding Autonomy in Birth," *Bioethics* (2009) 23:1, 1-8.

<sup>&</sup>lt;sup>131</sup> OG Risk Research Group, p. 2.

advance, and patient preferences then play a role within this frame.<sup>132</sup> Marmor and Krol delineate the prominent aspects of provider authority in decisionmaking when they write:

Providers are at an advantage in the patient/provider relationship, the asymmetry of information being obvious to both parties. Providers have access to information that most women do not, have been trained to respond to situations in certain ways, and have been socialized into professional specialties that have a dominant philosophy about the labor process. All of that means they can significantly shape the context of choice facing women. Through this route, providers can influence the final decision about how pain is managed. So, there are some tensions between the realities of provider influence and the normative ideal of patient autonomy and the "helping" medical professional.<sup>133</sup>

The filtering of options by providers is a communicative act that, the OG Risk Research Group

argues, is particularly problematic in the context of childbirth. In this medical scenario, personal

preferences of the patient typically can and should play a large role, cultural and familial

influences carry great weight, and even the determination of appropriate and acceptable risk is an

intimate matter.

[T]he domain of birth and delivery decisions is one where the size of different risks will vary greatly depending on the meaning of the various outcomes for a particular patient, as these outcomes will be situated within the context of her larger narrative, needs, and projects, her family and community responsibilities and relationships, and her cultural values. In short, there is just no answer to how risky an approach to delivery is on the basis of statistics alone; women's perspectives necessarily play a role in measuring risk in the first place. [...] Substantively incorporating a patient's values into decision-making about delivery is not a matter of allowing a 'subjective' element into an otherwise rationalized, evidence-based set of practices. Since *any* assessment of the size of a risk is a normative judgment that relies on a set of values, whether explicitly or implicitly, guidelines and practices that do not interrogate these underlying values are prone to a number of distortions. Careful inclusion of patients' perspectives in determining the riskiness and reasonability of different medical options will likely help correct for these distortions and add evidence-based objectivity to the process, rather than the reverse.<sup>134</sup>

<sup>&</sup>lt;sup>132</sup> OG Risk Research Group, p. 3.

<sup>&</sup>lt;sup>133</sup> Marmor and Krol, p. S177.

<sup>&</sup>lt;sup>134</sup> OG Risk Research Group, p. 4-5.

This perspective again helps to emphasize the importance of conscientiousness regarding what choices are offered, how, when, and by whom options are offered, and how they are represented to the patient in terms of risk and benefit profile in the context of their personal value structure.

The decision-making process, shared out of necessity, particularly in obstetrical settings, is *not* all about the number and nature of the choices available; rather it is about listening and talking to the patient about how those choices fit into her life. Conversations "ought to proceed via respectful probes and receptivity to emerging concerns, questions, and values, including receptivity to a desire not to continue the conversation at all."<sup>135</sup> The existing structure of regular and frequent prenatal visits provides an opportunity often used in just such a manner for other birth interventions, but rarely for oxytocin augmentation. Oxytocin augmentation can and should be discussed just like other birth interventions. Because provider training, pressures, and preferences realistically play a role in oxytocin's use due to inconsistent guidelines for its use, discussions about oxytocin may have to remain somewhat different from discussions about interventions like epidurals. Even in today's practice environment of groups of providers sharing responsibility for laboring patients, a given group of providers could decide what they consider medical indications for oxytocin augmentation. They could then decide how and when to pursue the type of informed consent process described here with their labor and delivery partners, such as the providers with whom they share call, residents, the nurses with whom they work, and students. Providers can learn about patient's preferences about oxytocin augmentation when they discuss other childbirth topics, typically in the third trimester. They might also try to represent the major differences in provider approaches to decisions regarding oxytocin amongst the

<sup>&</sup>lt;sup>135</sup> OG Risk Research Group, p. 7.

providers likely to deliver their patients, particularly if they work with specific colleagues about whom they can speak knowledgeably.

Once patient preference is identified by applying a communicative ethics approach outlined above, it should be honored as long as the laboring patient and fetus remain safe. Preference's role in medical decisionmaking, however, can be complex, especially in situations like oxytocin augmentation. There are real risks for patient safety and fetal safety, but very little consistency in evidence-based guidelines to balance out subjective factors playing into these decisions. Therefore patient preference should have that much more of a place in the decisionmaking process. Preference can, of course, change at any moment during care. The weight appropriately accorded to either the patient's or the provider's preference, or even to the fetus's best interests, often depends upon specific factors including the patient's medical status and the range of medical interventions possible at any moment in the continuum of an illness or process like birth. In other words, there are often values that come to override others as medical status and available options change. Health of self and/or infant may well trump the patient's expectations for the childbirth experience. This may ultimately result in a treatment plan that goes against initial patient preference. For example, if I, the patient, am tolerating labor well and my fetus is tolerating labor well, I don't want oxytocin augmentation because it would increase the intensity and frequency of my pain and put my fetus at risk for oxygen deprivation among other risks. If my labor significantly slows, however, or I feel weaker and become unsure of my ability to endure a long labor and value any intervention that might increase my chances of a vaginal birth over a cesarean birth, I may be willing to entertain the notion of oxytocin augmentation, if my physician thinks it will help to achieve my legitimate medical goals,

including comfort. The provider would only know this by discussing possible outcomes of an evolving situation with the patient.

#### **D. CONCLUSION**

In light of current understandings of labor progression and ideals for patient-physician interactions and informed consent, the current approach to oxytocin augmentation needs to be reevaluated. Care to achieve informed consent for oxytocin through communicative speech acts as described would indicate a commitment to transparency and patient agency in the decision to augment with oxytocin. The key strength of thinking about patient-provider communication as action and interaction, rather than disclosure and mere transfer of information, is that the focus on interaction seeks to address existing structures of power specifically. The greater power and control providers have over oxytocin use is built into the system to some degree, however there are existing clinical practices surrounding epidurals that show change is possible and that there is time and space within the patient-provider interaction for more conscientious consideration of oxytocin augmentation and for incorporation of patient preference.

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