CASE STUDY

How to promote justice, greater safety and trust between hospitals and patients

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ABSTRACT

In a time when lack of trust has been cited as an increasing problem between patients and the organizations and physicians who care for them, what can hospitals and physicians do to deal with this problem that is not already being done? We discuss herein an actual obstetrical based legal case intended to be an illustrative example of medical-legal issues that could apply to any specialty. If hospitals and physicians will overtly promote safety by learning from errors and support justice for injured patients, the conveyance of these ethically motivated policies to the public can be a powerful message that hospitals and physicians are to be trusted.

Key Words: Trust, Medical civil liability, Patient safety, Accountability, Informed consent

1. INTRODUCTION

Recently, the American Board of Internal Medicine Foundation urged the promotion of greater trust between patients and the organizations and physicians who care for them. Concerns in this regard rise from a heightened rhetoric in politics and social media that may be blurring the distinction between truth and fiction, conflicts of interest and general upheaval in health care.[1] A proposed framework for increasing trust between patients and organizations like hospitals cites among generalized approaches accountability systems, leadership and measurement of trust related issues. Among the seemingly more specific approaches to increase trust are greater transparency with regard to patient outcomes, improved physician training in communication and structuring care so patients make choices that reflect their preferences.[2]

In a landmark publication issued nineteen years ago, the Institute of Medicine stated that unsafe care must now be recognized as a price to be paid for a lack of accountability.[3] When there is a bad outcome for a patient, an objective assessment of each sequential link that moved the process forward toward patient harm is essential[4] so as to promote not only the patient's valid legal interests but also consistent with medical ethics to promote safer care in the future.[5]

We propose to focus on a legal decision by the United Kingdom (UK) Supreme Court[6] that generated a spirited discussion in JAMA concerning the role of patients and physicians for making informed consent decisions.[7–10] Yet, "bad lawyering" by opposing attorneys almost produced a legal injustice. Our premise is that with "good lawyering", an objective analysis by health-care professionals as well as by members of the lay-public of multiple examples of unidentified substandard care would have been exposed, thereby

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ideally leading to meaningful accountability and constructive steps to reduce the likelihood that similar errors not occur in the future.

Our premise is that by using the medical facts of the UK legal case and the JAMA informed consent debate as a microcosm of reference, we can better illustrate a framework for improving ethical communication. Our premise is that the UK legal case was a worst-case scenario that cried out for civil justice and greater safety. If physicians, administrators, risk managers and attorneys can constructively work together by discussing among themselves and with their patient populations specific understandable examples of substandard care, that kind of honest dialogue would be a step toward promoting solutions for trust related problems.

2. THE FACTS OF THE UNITED KINGDOM CASE

Mrs. Smith, pregnant for the first time and only slightly above 5 feet tall, was an insulin dependent diabetic understood to be at "greater risk" for complications due to mechanical problems during labor and delivery such as cephalopelvic disproportion (CPD) (If the fetal head is disproportionately large in relationship to the maternal birth canal, that can cause or contribute to complications such as excessive fetal head compression and a failure of the labor to progress.), and/or shoulder dystocia (SD) (A shoulder dystocia is an obstetrical complication that arises during a vaginal delivery when the child's anterior shoulder has become impacted behind the maternal pubic bone. Complications are related to forces that may be applied during extraction attempts and due to a delayed extraction.). Mrs. Smith was assigned to Dr. Jones, an obstetrician/gynecologist, employed by the hospital, who never previously delivered a child where a shoulder dystocia arose.

The high-risk pregnancy requiring "intense monitoring" included a series of 10 ultrasounds, the last of which was done on September 15, 1999 at 36 weeks gestation with an estimated fetal weight (EFW) at the 95th percentile (Fetal hyperglycemia due to maternal diabetes may trigger increased growth of the fetal body in relationship to the fetal head. Thus, even if the child's head can be brought through the birth canal with forceps and emerge [as would occur], the increased size of the fetal body predictably can cause or contribute to the anterior shoulder becoming impacted behind the pubic bone [as would occur].). Thus, Mrs. Smith, whose body size was less than the 10th percentile, was carrying a baby who was very likely disproportionately large for safe passage through her pelvic birth canal. Dr. Jones maintained she decided to order no further ultrasounds for EFW, anticipating continued large fetal size because disclosing such EFW might create in Mrs. Smith a "sense of anxiety". Dr. Jones maintained she anticipated that at 38 weeks, the EFW would be 3.9 kg (The ultrasound can be used to accurately estimate fetal weight (EFW) plus/minus about 10% error up or down. The EFW, especially in a high-risk diabetic pregnancy, is part of a process to anticipate a difficult labor (due to CPD) and delivery (including S.D.) in a context of maternal size. 4 kg equals about 8 lbs., 13 oz. The actual birth weight would be 4.25 kg or 9 lbs. 5 oz.) but would not offer cesarean delivery (CD) as an option unless the EFW would be 4.0 kg. Dr. Jones planned to induce labor on October 1, 1999 at 38 weeks and 5 days (Dr. Jones maintained her plan was to offer cesarean delivery as an option if the EFW was 4.0 kg, yet inconsistently maintained she anticipated an EFW greater than 4.0 kg on the day she planned to induce and still cesarean delivery was not offered as an option.) yet according to Dr. Jones, she did not raise with Mrs. Smith the potential for shoulder dystocia or the likelihood that at labor induction, the EFW would be greater than 4.0 kg because Dr. Jones claimed that if she did so, "...everyone would ask for C-section and it's not in maternal interests for women to have C-sections" and "most women would say 'I'd rather have C-section'".

On 10/1/19, a drug (Syntocinon) was used to induce labor contractions; at 0930, there was a "secondary arrest of labor"; at 1300, Syntocinon restarted labor so that at 1600, Mrs. Smith was fully dilated but the unborn child's head was 1 cm above the ischial spines. In other words, the drug stimulated contractions that fully opened the cervix could not move the baby due to CPD (1 cm above the ischial spines meant the head was unengaged representing a lack of labor progress explained in this case by the existence of CPD.). At 1700, Dr. Jones took Mrs. Smith to a delivery room and proceeded to do a high forceps extraction that produced at 1745 the emergence of the newborn's head with his shoulder stuck and impacted behind the pubic bone. High forceps is the application of forceps prior to engagement – is an extremely difficult operation, often entailing brutal trauma of the maternal tissues and killing a large proportion of the babies. High forceps is mentioned only to condemn it.[11]

Dr. Jones ordered general anesthesia to try a Zavanelli procedure (push the baby back up into the uterus) and then abandoned this idea and pulled on the head with "significant traction". When that failed, Dr. Jones tried a "symphysiotomy" (attempting to surgically open the pubic bone) and finally, when all else failed, with a "huge adrenaline surge", delivered the newborn at 1757. During the 12 minutes (1745 – 1757), the child sustained a brachial plexus injury (A brachial plexus injury would be due to forces stretching the nerves

between the spine and shoulder at a point when the shoulder remains impacted. Thus, pushing and/or pulling will not free the shoulder but will stretch and injure the nerve plexus.), but far worse, a catastrophically disabling hypoxic brain injury. (The emergence of the fetal head has brought the umbilical cord into the birth canal, creating hypoxia and acidosis [asphyxia] in the child. The time delay of 12 minutes from SD to delivery produced within the child compensation [a window of opportunity to delivery before brain injury] evolving into decompensation [loss of adequate cerebral blood flow, producing disabling hypoxic-ischemic brain injury].)

The Zavanelli maneuver is associated with a high incidence of fetal death and neonatal brain injury.[12] Symphysiotomy, which is "cutting" to widen the outlet, has been associated with neonatal deaths and significant maternal injury. (Ibid 11)

3. Expert medical testimony

What was raised and rejected by the trial judge who presided without a jury, was a claim of negligence based on an alleged failure to obtain fetal blood (scalp pH) and then do a cesarean because the fetal heart rate (FHR) monitor data during labor showed persistent late fetal heart decelerations. Defense obstetrical experts opined that the FHR data showed no significant hypoxia. The trial judge accepted the defense expert opinions.

Actual labor issues that could have and should have been raised were the failure to assess the prospects for a safe vaginal delivery; the failure to accept that, in this case, the induced labor producing an "arrest" still allowed for a safe cesarean; the failure to accept that the FHR decelerations were ominous in a context of head compression with CPD; the failure to accept that if significant hypoxia related to late fetal heart decelerations had not yet occurred, that such would be expected to occur with a SD; the failure to establish that the incomprehensible attempt at a high forceps extraction created the "nightmare emergency"; and the failure to establish that neither Dr. Jones or her delivery team were prepared for or did implement a standard SD algorithm without including the Zavanelli and symphysiotomy.

By presenting each medical point sequentially, starting with the prenatal errors, there would then be a complete record for all providers to learn from. Through accountability, providers could become safer and through the judicial process, full and fair compensation to the child and his mother could be achieved.

The Hospital Corporation of America (HCA),[13] using data learned from closed medical liability claims, implemented safety protocols that urged and encouraged a use of cesarean delivery liberally for individual cases of labor arrest and abnormal fetal tracing on the premise that a "…difficult vaginal delivery is not appropriate when an easy cesarean delivery is an option…" The HCA reported fewer injuries to mother and baby and fewer cesarean deliveries. How? This can be achieved by liberally performing cesarean deliveries which can be done safely for mother and baby, but only when an informed obstetrical team has a valid indication (e.g., Mrs. Smith's "circumstance") and by not doing cesarean delivery when not indicated. Thus, there would be fewer (not more) cesarean deliveries.

Of additional striking interest is the fact that the HCA study using closed liability claims data to design safer care demonstrated that the liability claims payments mostly were the result of substandard care resulting in preventable injury.[14]

Undiscussed during the UK trial was the use of simulation training so that prompt recognition of SD and skillful use of an orderly sequence of steps can prevent maternal and infant injury.[15] Neither the obstetric organizations in the UK or in the USA require such simulation drills. Why not? If simulations are not required or not available, why has the potential for shoulder dystocia "nightmares" not been anticipated and avoided with a more liberal use of cesarean delivery? There has been an expanding role of simulation in obstetrics and gynecology education that has improved confidence, knowledge, skills, workplace behaviors with translation to better patient care.[16]

4. UK legal decision

The law, as applied by the trial judge was that the physician's duty to disclose risks related to SD, was only to follow the practice of a responsible body of medical practitioners. Further, the reasoning by the trial judge was that since Dr. Jones would have told Mrs. Smith that the risk from shoulder dystocia would be minimal and since Mrs. Smith would not have been so arrogant as to demand cesarean delivery, causation was not established. The factual medical issues were not fully developed. Yet, informed individuals could be perplexed that any legal trier of fact (judge or jury) would not grasp the idea that no medical body of professional opinion could ethically authorize its professional members to intentionally withhold information about potential grievous harm. Further, no professional body would wish to condone such conduct.

The UK Supreme Court judges, to their credit, noted that patients are not passive recipients of care and are capable of understanding and taking responsibility for care decisions. The ultimate responsibility for determining a patient's right must lie with the court system and not with the medical pro-

fession or any divergent attitudes among physicians. As to the degree of respect physicians give their patients, the legal test of materiality is whether a reasonable person under the circumstances would attach significance to the risk and the assessment of risk significance is not subject to percentages but is fact specific. For example, the extremely small risk to the mother and the virtually non-existent risk to the baby from cesarean delivery in comparison to the mounting specific risks for Mrs. Smith due in part to Dr. Jones' disconnect from the issues.

5. Informed consent controversy

The Journal of the American Medical Association (JAMA) published a discussion of "The New Era of Informed Consent: Getting to a Reasonable-Patient Standard through Shared Decision Making" authored by Drs. Spatz, et al.[17] That discussion prompted two more medical discussions[8,9] and a reply by Drs. Spatz, et al.[18] Some medical providers object to a "reasonable patient" being a standard for informed consent disclosure urging instead that medical professional bodies should lay down the disclosure guidance to be used in the courtroom and in actual practice because, patients, during actual care, and jurors, in the legal setting, allegedly may be unable to interpret the medical data leading to confusion and patient anxiety.

True consent is an informed exercise of choice. It is the prerogative of the patient, not the physician, to determine care and the physician's duty to inform is not dependent upon the patient's request for disclosure. Respect for the patient's right of self-determination is set by law for physicians and not by what physicians may or may not wish to impose on themselves. Non-disclosure by a surgeon of a one percent possibility of paralysis from laminectomy is risk information creating an issue of fact for reasonable-minded people. See: Canterbury v Spence, 464 F 2d 772 (1972) (U.S.CT. Appeals, District of Columbia wherein the defendant who failed to disclose risk claimed he did so intentionally because disclosure might deter needed surgery and might produce adverse psychological reactions. See also Johnson v. Kokemoor, 545 N.W. 2d 495 [Wis. 1996] where the patient like in the Montgomery case was unaware of the physician's lack of experience.).

If a reasonable patient would not proceed with a treatment (e.g., the vaginal delivery under the circumstances of the UK case), then logic would suggest a reasonable physician would not offer the treatment. Linked to neglect (i.e., unreasonable conduct) the informed consent legal case becomes important as it emphasizes that the physician never should have proposed the risky treatment.

6. Good lawyering

Medical expert witness testimony is allowed if it results in a truthful and valid conclusion. Validity means that the testimony will assist the trier of fact (judge or jury) to understand and determine a fact in issue.[19] Ethics have been promulgated for medical expert witness.[20] Yet in the UK Smith case the plaintiffs' lawyering aided and abetted by inadequate expert support allowed what could be characterized as almost a legal travesty. Of course, pursuit of a meritless case is a costly and wasteful endeavor. However, non-pursuit or the inept pursuit of a meritorious case is a worse travesty.

7. Motivating physicians

It has been maintained that physicians can be emotionally devasted by serious mistakes that harm or kill patients. It is thought that typically there is a mixture of fear, guilt, anger, embarrassment and humiliation. This in turn can cause a physician to hesitate to reveal error or expose a colleague to similar devastation for a single mistake.[21]

If we postulate that Dr. Jones' errors were a single "mistake" the goal would not be to "devastate" her but to constructively make Dr. Jones and all her colleagues safer.

Professional competence is the habitual and judicious use of knowledge and skills for the benefit of individuals and the community being served.[22]

If we accept the premise that Dr. Jones and her other obstetrical colleagues at the hospital could be motivated to learn and thereafter habitually plan and implement safe child birth, then justice can be done for Mrs. Smith, who would have a vested interest in learning that similar tragedies will in the future be avoided.

8. Conclusion

The medical profession is capable of doing so much good and then shoots itself in the foot with stories of conflicts of interest and proposals for greater leadership which proposals may be viewed by the public as lacking sincerity. Our premise is that errors like those in the United Kingdom case are understandable by members of the lay public and can arise in any area of medicine with similar results.

If hospitals can accept responsibility, demonstrate accountability and motivate providers to be safer by embracing civil justice, that can promote the kind of trust that always will be of mutual benefit to the public and healthcare providers.

Conflicts of Interest Disclosure

The authors declare they have no conflicts of interest.

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