

RECOGNIZED RISK OR COMPLICATION?

by **Richard M. Soderstrom, MD, FACOG**

Medmal attorneys frequently use the “recognized risk defense”, asserting that the undesirable outcome or injury in question is nothing more than an acceptable risk of properly provided treatment considering its potential benefit, its recognition by the medical literature as inherent to the procedure and its rare occurrence rate. Articles reporting similar complications are waved about to demonstrate to the jury that bad things occasionally happen to good people for no good reason. A typical example is iatrogenic ureteral injury during hysterectomy. Every gynecologic surgery text has a chapter on such injuries including etiology, prevention, diagnosis, management and prognosis, but this doesn’t mean that just because it *can* happen there is automatically no negligence.

Careful, prudent, well-trained, experienced surgeons can get unavoidable complications despite the best medical care possible, and these are the recognized risks of any treatment. The extensive pelvic adhesions and distorted anatomy found in endometriosis or cancer greatly increase the risk of intraoperative iatrogenic ureteral compromise, but in the absence of additional factors such injuries may reflect negligence. I reviewed one case in which a surgeon performing a Laparoscopic Assisted Vaginal Hysterectomy (LAVH) dictated in his operative note that “both ureters were dissected out of harms way”, yet both were found to be completely obstructed and transected by the GIA stapler when his patient was diagnosed with postoperative anuria and reexplored.

Just because there is a great deal of literature on ureteral injuries complicating LAVH doesn’t mean they are per se a recognized risk. It’s like the cabin attendant on your flight to Boston announcing, “Previously a pilot landing at Logan International Airport ran off the runway and into the bay, so remember your seat cushion can be used as an emergency flotation device.” Reasonably prudent patients expect and are entitled to the same attention to detail and safety by their LAVH surgeon as you expect and are entitled to by your United Airlines captain piloting a 747 to Boston, the main difference being that the pilot must on a regular basis demonstrate to critical evaluators his professional skill and competence in an aircraft simulator.

The burden of proving negligence, injury and causation falls on the medmal plaintiff, but the burden of proving the alleged injury was unavoidable falls on the defense. Iatrogenic laparoscopy injuries usually involve both. Published studies have shown that bowel injuries can occur in patients without increased risks when either closed or open techniques of primary trochar insertion are used. Even the most careful surgeon may create such injuries and be unaware of them until the postoperative period. These are accepted to be a recognized risk of laparoscopy since they can occur even when care and standard surgical technique are employed.

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THE PRESIDENTIAL BOX

Ray Cestero, President

This will be my final column from the *Newsletter's* soapbox with my good friend and respected colleague Paul Sinkhorn taking office as our President on January 1, the first day of the New Millennium. He is extremely capable, articulate and committed to the Society's objectives so I know we will have a capable captain at the helm next year. I congratulate Paul on his election to office and wish him the best knowing he will do a superb job. And while I'm on that subject, I really want to thank Doug Daniel for his guidance, perseverance and assistance during the past year. I could not have done it without him.

From the land of managed care comes news that the California Assembly and Senate have passed legislation allowing patients who suffer "substantial harm" after HMO denial, delay or modification of appropriate treatment to sue their managed care organization. The bill has been signed by the Governor and becomes effective in 2001. Expect more states to follow suit with some of us inevitably called as witnesses to fact or medical expert witnesses for both sides. This will present a problem for those with a largely managed care practice who may thereby risk retaliation if they testify for plaintiffs. We may even have to become litigants to defend ourselves against the consequences of testifying for our patients. Something to think about.

This issue of the *Newsletter* gives you a preview of what we intend to provide the membership during the coming year. As you know it will now be published every two months instead of quarterly. The lead article by Richard Soderstrom is outstanding. He's not only one of the world's best endoscopists but also a very credible, highly respected medical expert witness. We look forward to future contributions, guaranteed to be full of great practical advice, and thank him for his generosity in sharing his experience and expertise with us.

If the world does not come to an end on December 31 and we survive the Y2K worldwide computer meltdown doomsayers predict, life will go on and we will continue to render our opinions on the appropriateness of care rendered by some of our colleagues or lack of same. It has been a tremendous honor to serve as your President. I wish all our members and their families a very happy and safe New Year as we enter the twenty-first century.

THE WITNESS BOX

Doug Daniel, Editor

"Sacred cows make the tastiest hamburger."

Abbie Hoffman (1936-1989)

YOUR 2000 DUES NOTICE FOR \$100.00 IS ENCLOSED WITH A STAMPED, SELF-ADDRESSED ENVELOPE IN THIS NEWSLETTER. THERE WILL BE NO SEPARATE BILLS OR INVOICES!

Ray Cestero's term as our President is coming to a close, and it's been a great one. He has given unselfishly of his time and expertise in addition to extraordinary efforts building our membership and arranging programs for meetings. He still has a term to serve on the Board and after a few years relief we could do worse than re-electing him. Thanks for everything, Ray.

This month's lead article is the second by Dick Soderstrom, exposing the traditional defense myth of the "recognized" complication. Just because textbooks say a complication can happen doesn't automatically refute negligence. When acting as medical expert witnesses we are more akin to Sherlock Holmes than Dr. Watson, and subsequently must remember to carefully observe the smallest detail, investigate every possibility and assume nothing. There's one more piece to come on life after litigation, but Dick can write in our *Newsletter* any time he wants.

Ray Cestero's Presidential swan song addresses California's response to patient complaints about mismanaged care organizations. I'm sure Paul and Dick would agree it always feels good when someone says nice things about you, more especially someone whose opinion you respect.

This issue's Book Box reviews one of our member's work, There is a Bomb in Gilead: Tales From an Uncivil War by Bill Harrison. He's written for us before and I hope soon will again. The review and book both speak for themselves and anything more I might say here would waste your time, my effort and the *Newsletter's* space. Thanks, Bill.

The Suggestion Box contains some thoughts on the recent interest in folic acid supplementation to prevent neural tube defects. The feds, national medical organizations and charities are making this a cause celebre and we should be aware of it with advice ready for our patients when they ask.

The Litter Box is filled to overflowing this month with a piece trying to make determination of liability in VBACs and other extreme obstetric emergencies more equitable and consistent. It's fairly good even though I'm the author, perhaps even able to clear someone's thinking by explaining how we got into this mess and suggesting a way out of it. One thing should be made perfectly clear; it is not an indictment of the College or its committees, staff, educational programs, or publications. It's only an opinion that the system has failed to accomplish its stated purpose despite the best efforts and intentions of all concerned.

Jim Bofill, currently Assistant Professor, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, University of Mississippi (Jeeze but it feels good to type Mississippi) Medical Center in Jackson, has a special interest clinical, academic and medicolegal in labor induction and operative vaginal delivery. Jim was born in Havana, Cuba, 30 years ago, became a US citizen in 1955, graduated with an MD degree from the University of Tennessee College of Medicine in Memphis, completed his internship and residency at Parkland Memorial in Dallas (WOW!) followed by a fellowship in maternal-fetal medicine at the University of Mississippi Medical Center, then served on the faculties of Wright State University School of Medicine in Dayton, Ohio, and East Carolina University School of Medicine in Greenville. He received a four year United States Air Force Health Profession Scholarship to attend UT and subsequently served four more years active duty with the Air Force as Chief of Obstetrics and Gynecology at Dyess Air Force Base in Abilene, Texas.

This month Jim blows the whistle on one of our best kept secrets, elective induction of labor. He's not opposed to these inductions but feels we should be honest about what we're doing instead of covering it up by cooking the medical record with all kinds of bogus smoke-and-mirror justifications for term inductions. He is opposed to elective induction of primiparas but I've done more than a few myself, always with an excellent Bishop's score and started with amniotomy. My experience has been that if I could safely "snag the bag", immediately placing a scalp electrode and intrauterine pressure catheter, I could safely give the patient a trial of adequate labor with oxytocin begun two hours later if spontaneous labor had not ensued. Not all delivered vaginally but better than 90% did, without serious maternal or fetal complication related to the induction.

There's also a reprint of a very interesting article from *Unique Opportunities: The Physician's Resource* written by Jeff Atkinson, Esq., on the organization of physicians into labor unions for the purpose of collective bargaining. This is an especially hot topic now what with the AMA recently forming their paper tiger "doctor's union" and other more activist physician unions both independent and AFL/CIO affiliated springing up like crocus in the spring. We also have a commitment from the Federation of Physicians and Dentists for a future article on their efforts and results in labor organization.

Jeff is a summa cum laude graduate of DePaul University College of Law in Chicago, now on their faculty. He is an expert on healthcare and family law, representing the State Department in treaty negotiations with foreign countries. *Unique Opportunities* is a national, bimonthly magazine self-described as "an innovative career development guide for physicians" and their article was intended to educate physicians about evaluating career opportunities, negotiating contracts, planning career moves and various other aspects of running a medical practice. Their reader service program enables physicians to request information on advertised opportunities. They may be reached at Unique Opportunities, 455 South Avenue, Louisville, Kentucky 40202, phone 502-589-8250, fax 502-587-0848, or www.uoworks.com. Physicians may request a free subscription by calling 1-800-888-2047.

Once again Catherine Canning, Editor of *Physician's Practice Digest*, has graciously allowed us to reprint one of her excellent articles. This time it's an interview with Gigi Hirsch, a young (43) physician who had trouble finding herself professionally until she started her own consulting firm which advises other disgruntled physicians how to successfully make career changes. While focusing on burn-out as a major cause of physician dissatisfaction, there is a more subtle message at the end of the interview which seems to place a major portion of the blame on managed care's increasing economic and professional pressures on physicians while simultaneously decreasing the quality of care they can deliver. All I can say is "Amen, sister."

As usual we encourage submission of letters to the editor, articles and guest editorials for publication consideration. Letters and editorials are subject to editing only for space requirements with articles and editorials typewritten and double-spaced. Free reprints of individual past *Newsletter* articles are available to members at no cost upon submission of a SASE, back issues for \$10.00 each or \$20.00 per volume of four issues.

All opinions expressed in *The Medicolegal OB/GYN Newsletter* are strictly those of the bylined authors and do not necessarily represent policies, opinions or recommendations of the American Society of Forensic Obstetricians and Gynecologists, its members, Board of Directors, Editorial Board, etc.

THE BOOK BOX

by Doug Daniel

IT'S LIKE DEJA VU ALL OVER AGAIN

There is a Bomb in Gilead: Tales From an Uncivil War
William F. Harrison
Unillustrated. 196 Pages. Fayetteville, Arkansas: 1999
m&m Press
Paperback, \$9.95

The title of this review is a famous quote attributed to Yogi Bera, uncontested malaprop master along with Sam Goldwyn and Casey Stengel. Yogi once told an interviewer, "I never said most of the things I said." Bill Harrison's book kept bringing Yogi to mind because I felt like I had been there, done that, got the T-shirt. And I kept remembering parts of John Irving's 1985 critically acclaimed best-selling novel Cider House Rules.

Like all of Irving's work Cider House boasts multiple, masterfully written and intertwined oddball characters, relationships and plots. Almost all his novels except Cider House have been made into commercially successful films. I've always thought it was not because Cider House was less than magnificent but because one of the protagonists was kindly old Dr. Wilbur Larch, a veteran medical officer of W.W.I who worked the rest of his life "trying to be of use" in the hospital of St. Cloud, Maine's, large orphanage cum home for unwed mothers where he delivered the mothers, cared for their unwanted babies and unadoptable children, and performed illegal elective abortions for the never-ending procession of those desiring same.

Dr. Larch teaches Irving's hero, Homer Wells, how to do safe abortions before the young man leaves the institution. Homer later graduates from medical school and after Larch's death returns to St. Cloud to carry on his work. Hollywood definitely tilts to the left but it knows better than to spend truckloads of money on an entertainment project favorably portraying such a divisive issue as abortion, offensive to the tender sensibilities of far religious right conservatives/Moral Majority minorities. If you don't believe me, rent a copy of Martin Scorsese's masterful film interpretation of Nikos Kazantzakis's "The Last Temptation of Christ". Thought-provoking, stellar cast, tons of non-studio media coverage and controversy, long lines of both picketers and ticketers at the few theaters in mostly large cities which screened it, never seen on cable, critical success and financial failure. No, the movie moguls aren't stupid enough to try that again.

When Bill sent the review copy to the Society office he enclosed a personal letter describing how two literary agents were representing him in negotiations with major publishers in New York and L.A. until last fall's Slepian assassination in Buffalo scared everyone into the woodwork. Everyone except Bill. He finally found a small local publisher who shared his commitment to personal freedom of choice to be or not to be pregnant, and now literally sells Bomb out of his car's trunk.

Plus I've been there myself. I used to think no one else could have ever had a "shadetree" preacher's wife come to them for elective abortion. One even personally brought his pregnant teenaged daughter, paid with a check drawn on his "church's" checking account, and loudly boasted on leaving the office that his Sunday evening sermon was going to be on the evils of abortion. Ditto the patient who one day was marching on the picket line outside the office and later had an elective abortion only to return to the picket line.

Most of you will recognize Bill as a member of the Society. He is an enlisted veteran of the United States Navy, Pacific Fleet, afterward graduating from the University of Arkansas and University of Arkansas Medical School. He completed his residency at University Hospital, Little Rock, and has a solo private practice in Fayetteville, Arkansas. Bill has been a prominent voice defending the constitutionally recognized and guaranteed right of pregnant women to chose between elective abortion or pregnancy and delivery both in his community, state and across the nation since 1984 via multiple presentations, debates, lectures, interviews and articles in various publications including *Vogue Magazine* (January 1998). His home and public appearances have been picketed. His office has been picketed, blockaded and invaded by protesters on multiple occasions in addition to being vandalized twice and firebombed. He has received so many death threats that he no longer keeps count. Bill has been a member of the National Abortion Federation since 1997.

His not-so-subtle style appeared in the *Newsletter's* Suggestion Box, Volume 6, Number 4, October 1998 recalling volunteering for frontline duty in the abortion wars. Bomb is an explosion of that piece, anecdotal with a touch of dramatic license blended into personal experience. And like all of us, I'm sure Bill's stories of people, places and events are an amalgam of 30 years' personal and clinical experience.

It's been said that the hardest parts of creative writing are picking a title, naming your characters and making them appear real to the reader. Bill's title is a play on words substituting "bomb" for "balm". There is reference to the balm in Gilead in Jeremiah 8:21- 23:

"The wound of the daughter of my people wounds me too, all looks dark to me, terror grips me. Is there no balm in Gilead* anymore? Is no doctor there? Then why is there no progress in the cure of the daughter of my people? Who will turn my head into a fountain and my eyes into a spring of tears, that I can weep day and night over the slain of the daughter of my people?"

**Gilead: East of the River Jordan and north of the River Jabbok, an area producing (medicinal) balm and aromatic herbs. (The New Jerusalem Bible, Doubleday and Company, Incorporated. 1985.)*

Bill's title choice is more than clever. It cries out his concern that at the rate things are going there soon won't be competent, caring, trained and experienced physicians willing to provide, at the cost to them and their families of social and professional ostracism, destruction of property and even threats or the reality of violent death, a vitally needed service to desperate women who otherwise will risk disease and even death to avoid an unwanted pregnancy.

The events portrayed are mostly true but Bill really shines in naming his characters. Like his abortionist Dr. T.J. Hobson, as in *Hobson's Choice* (def.: to choose between the least undesirable of two loathed choices). There's also Shadetree Preacher Rev. John C. (J.C.) Calhoun, his wife Elizabeth (cousin of Mary, mother of Jesus Christ in the New Testament), and their troubled young son Joshua (Old Testament prophet of doom). And of course the young, innocent female protagonist named Mary.

As you can tell by now Bill is no Biblically ignorant heathen atheist, and his selections of Old and New Testament scripture prefacing chapters brand him a deeply committed follower of Jesus Christ who has struggled with the question which should plague all us Christians everyday, "What would Jesus do?" Even if you don't sit in a pew every Sunday morning and sing from the Broadman Hymnal you probably try to live by some religious or philosophical credo, and Bomb will be just as relevant. For the majority who are still trying to define their position on elective abortion, reading Bill's morality tale will help in understanding the relevant issues and alternatives if safe, medical elective abortion should ever again become unavailable to rich and poor alike. On the other hand if you are a hardcore antiabortion militant advocating death to all abortionists with no justification for any termination of pregnancy for any reason, don't bother; it will only make you more furiously frustrated than you already are.

I only have one problem with Bill's style. Portions could be described as a bit on the steamy side, similar to what one would expect in a bodice-ripping romance novel with a shirtless Fabio posing on the cover. Of course today it may be necessary to rip a few bodices to get people to read a book, but it just seemed out of place. Other passages graphically describe gory self-mutilation, violent suicide, incest, sexual assault, and Gilead's equivalent of the Oklahoma City Bombing. Not the sort of stuff you'd want to read to your junior high Sunday School class but powerful, gripping and real for those who can handle it. And finally there's a denouement packing the emotional wallop of an overloaded semi doing a swan dive off Stone Mountain.

For your own copy you can reach Bill at:

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THE SUGGESTION BOX

by Doug Daniel

There's been a lot of interest recently in preconceptional folic acid supplementation as a neural tube defect (NTD) preventative. Ralph Hale dedicated an editorial and a news article in *ACOG Today* (August 1999) plus a lead article in the latest *ACOG Clinical Review* (SEPTEMBER/OCTOBER 1999) to it. The known incidence of NTDs is relatively low, 1-9/1000 births or about 4000/year here in the US, and worldwide probably many more cases of asymptomatic spina bifida occulta, geographically isolated patients with symptomatic NTDs, or perinatal/childhood deaths due to NTDs occur. Prevention on the other hand is a no brainer.

Folic acid tablets are cheap and until recently were available without a prescription in 1 mg to 2 mg doses. Higher doses such as 4 mg were available on prescription. Now all folic acid medicinals are available by prescription only due to someone's concern that they might "mask" pernicious anemia. Well, yeah! They actually treat it! The good news is that no deleterious effects have been found from less than megadoses of folic acid; it's relatively safe with a therapeutic window bigger than the screen at your nearest Imax® theater.

The College has addressed this before in Tech Bulletins No. 205 (1995) and 229 (1996). In 1998 the feds required the addition of minuscule amounts of folic acid to our food supply's "enriched" flour, pasta, rice and cornmeal products, specifically a dietary intake of an estimated 0.3 mg/day under the best of circumstances. But in their wisdom the feds also decreed that supplementation to the tune of 0.4 mg/day, 4.0 mg/day if a prior pregnancy was complicated by NTD, from preconception through 28 days after conception in addition to a diet unusually rich in naturally occurring folate was necessary to effectively prevent NTDs. Yes, there does seem to be a gap there.

Starting back when I was an intern and since I have routinely given all pregnant patients at their first prenatal visit a prescription for prenatal multivitamins with folic acid, a prescription for ferrous sulfate tablets and a prescription for folic acid tablets, encouraging them at each subsequent visit to take their pills. I decided back in the 80's that anyone consulting me for preconceptional care would be started on the same regimen, but nobody has. I probably "masked" untold cases of iron and folate deficiency by treating everyone for common pregnancy-related problems but so what?. It was cheap, efficacious, and the patients did fine with relatively few anemias and almost no known NTDs.

Women in their childbearing years and especially those in their teens and twentys are notorious for poor nutritional habits, yet they account for most pregnancies and nearly all of the unexpected ones. So how do we handle this? First of all the incidence of significant NTDs is relatively rare although their treatment is always expensive and usually produces less than optimal results. Secondly they can apparently be relatively easily, cheaply and safely prevented by either early second trimester chemical and ultrasound screening with subsequent elective abortion or, even better, folic acid supplements. The problem with supplements is their preconceptional requirement.

So if anybody asks, I will recommend my patients of childbearing age take a 1 mg folic acid tablet daily unless using effective contraception (BCPs or sterilization). If they've had a prior affected pregnancy either effective contraception or 4 1.0 mg folic acid tablets daily will be advised until the second trimester when the dose will be decreased to one a day. Considering the federal mandates for dietary supplementation, I personally don't think it's worth the effort to try to get everybody taking folic acid pills everyday. If you do, write me.

THE LITTER BOX

Doug Daniel, Editor

DANCING IN THE DARK ON THE HEAD OF A PIN

Christian philosophers during the time of St. Thomas Aquinas spent years arguing tête-à-tête or from pulpits and pages about how many of God's angels could dance on the head of a pin, their aim being to define in earthly terms the size of your average angel. Modern obstetricians have more or less done the same with endless debates over emergency Caesarean section response times and VBACs. Needless to say neither we nor St. Thomas and his contemporaries ever reached consensus. The range of opinion in both instances has been infinite as were and still are God's angels, in spite of Roma and Della's stellar performances.

Obstetrician medical expert witnesses have always argued about our specialty's equivalent of basketball's shot clock, i.e. what constitutes the national minimum acceptable standard of care for decision to incision in emergency Caesarean sections, albeit within more easily defined limits than St. Thomas and his contemporaries. The basis for our arguments has been the College's "30-Minute Rule" and its caveats which have been around for years. This is frequently referred to as "decision to incision", even though the more important consideration from a clinical and liability standpoint is decision to delivery. Negligent delay in diagnosis translates into clinical (physician or nurse) liability while delay from decision to delivery involves administrative (hospital) and clinical liability.

Years ago when to great applause VBACs first swept onto the stage we were told there was no need to hold them to a higher level of care and services than routine uncomplicated labor and vaginal delivery, ergo any facility currently providing obstetrical services could safely provide VBACs. Even the small rural Level I hospital. Some obstetricians bought this hook, line and sinker but those older, wiser, and more experienced refused to do VBACs without continuous in-house anesthesia and OR crew during the labors, much to the dismay of untold administrators of small hospitals already fighting a losing battle to keep their ever-sinking ship afloat with an ever-shrinking cash flow.

Any three-year-old could have told you what the result would be: a relatively small number of "recognized" complications of VBAC (read iatrogenic intrapartum uterine ruptures) which on occasion would result in unnecessary maternal and/or infant permanent disability or death and almost always cause the attending obstetrician acute, severe voluntary and involuntary sphincter disorders not to mention coronary artery insufficiency. I'm not aware of any obstetricians dying as a result but I know several who feared they might. Fortunately most of us were spared that experience and only had to cringe when others related their horror stories. Over the intervening years the larger teaching hospitals duly noted, researched and reported these cases in the evidenced-based peer-reviewed medical literature but we will never know for sure how many went unreported in the smaller hospitals without litigation or settlement.

When litigation was involved, plaintiff's medical expert witness would without effective opposition wave the 30-minute rule before the jury unless obstetrician, anesthesia and OR crew were all in-house with the rupture promptly diagnosed and surgically treated via emergency Caesarean section and repair or Caesarean hysterectomy. In my experience it requires everything going smoothly even in the well-staffed Level II hospital to beat the clock on an emergency Caesarean section unless you're willing to pull out the lidocaine and patient restraints.

The 30-minute rule is not the Eleventh Commandment in spite of what those of you younger than I may think. Although in reality quite specific, the College has always tried to allow variances to fall within the recognized minimum acceptable standard of care by adding two caveats. The first allows hospitals to establish their own local standards regarding acceptable decision to incision time, but I've never worked in one that actually did. This advocacy for recognizing varying local minimum acceptable standards of care also runs counter to the national standard of care rule almost universally accepted now by both federal and state tort systems. The second offers the argument that small rural hospitals can't be held to the same standards as big city hospitals and we should consider "...the needs and resources particular to the locality, the institution, or type of practice".⁵

The College first addressed the maximum acceptable time necessary to accomplish emergency Cesarean delivery in 1982.¹ The publication had a caveat on the authors page as follows (all emphases mine):

“...the standards set down here are presented as recommendations and general guidelines rather than as a body of rigid rules. They are intended to be adapted to many different situations, taking into account the needs and resources particular to the locality, the institution or type of practice. ***Variation and innovation which demonstrably improve the quality of patient care are to be encouraged rather than restricted. The purpose of these guidelines will be well served if they provide a firm basis upon which local norms may be built.***”

This same publication established the first “standard” for decision to incision with the statement “Obstetric services generally caring for high-risk patients should be able to begin a cesarean delivery within 15 minutes.” Perhaps this was primarily aimed at Level II and III facilities but in reality Level I hospitals cared for more than the rare high-risk obstetrical patient. Some of these “standards” were very specific, even going so far as to classify by expected number of yearly deliveries the minimum number, size, square footage and equipment/furnishings of obstetric inpatient facilities including physician-on-call quarters. The other thing to remember is that at this point in time standardization and regionalization of inpatient healthcare was a hot topic nationally and many eminent prognosticators saw most Level I hospitals soon closing or else surviving as very basic dispensaries and clinics. Only Level II and III hospitals (“regional medical centers”) would provide obstetric services in this brave new world of the future.

The next year a list of “additions, corrections, and revisions” dated 14 SEPTEMBER 1983 was mailed stating “Obstetric services should be able to begin a cesarean delivery within 30 minutes.” This was the birth of the 30-minute rule which was to apply to all obstetrical services regardless of size, location or level of obstetrical care offered, thereby making it nationally applicable.

In 1988 the issue was addressed in joint ACOG/AAP (American Academy of Pediatrics) “guidelines”² which had essentially the same caveat as the 1982 ACOG “standards”. It recommended:

“Any hospital that provides labor and delivery services should be equipped to perform an emergency cesarean delivery. ***The nursing, anesthesia, neonatal resuscitation, and obstetric personnel required must be either in the hospital or readily available.*** It should be possible to begin the operation within 30 minutes of the time that the decision is made to operate.”

This apparently was the College’s first use of the term “readily available”, seemingly defined as “in the hospital” or its equivalent. The next section covered VBACs but made no additional recommendations regarding decision to incision, reflecting the College’s position that any facility capable of meeting the recommendations for conducting uncomplicated labor and routine vaginal delivery could safely do VBACs.

The issue next arose late in 1988³ with the College invoking the 30-minute rule by proposing:

“Professional and institutional resources must have the capacity to respond to acute intrapartum obstetric emergencies, such as performing cesarean delivery within 30 minutes from the time the decision is made until the surgical procedure is begun, ***as is standard for any obstetric patient in labor...***A physician who is ***capable*** of evaluating labor and performing a cesarean delivery should be ***readily available.***”

The only caveat here was, “The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.”

In 1989 the next edition of “standards” was published⁴ with the caveat almost verbatim from its predecessor except for the deletion of “The purpose of these guidelines will be well served if they provide a firm basis upon which local norms may be built.” It had this to say regarding decision to incision:

“In ***any hospital*** with an obstetric service, a person qualified to administer anesthesia should be ***readily available*** so that an emergency cesarean delivery can begin within 30 minutes of the time that the decision is made to perform the procedure...Nursing, neonatal resuscitation, and obstetric personnel must also be available to function within this time frame...In larger facilities where care is provided for high-risk patients, 24-hour in-hospital obstetric anesthesia coverage is strongly recommended.”

This publication was much less specific than its predecessors, i.e. the architectural “standards” for labor and delivery suites were gone, “readily available” was no longer equivalent to in-hospital, and there was no mention at all of VBACs which implied they were the same as routine uncomplicated labors and vaginal deliveries. The cheese became quite binding however when obstetricians in Level II hospitals began waving these “standards” around and demanding 24/7 in-house anesthesia

availability while they took call and managed labor patients from multiple hospitals, operating rooms, clinics, offices, homes or country club golf courses.

In 1992 the next edition of joint ACOG/AAP “guidelines” was published⁵ with the caveat verbatim from its predecessor except for adding “demonstrably” to the phrase “demonstrably improve the quality of patient care”. In an expanded section headed “Cesarean Delivery” instead of the prior edition’s “Emergency Cesarean Delivery”, the recommendation was again verbatim except for the addition of “when indicated” to the sentence “It should be possible, when indicated, to begin the operation within 30 minutes of the time that the decision is made to operate.” The expanded language also added the next two sentences:

“Not all indications for a cesarean delivery will require a 30-minute response time. Examples of those mandating the need for expeditious delivery (assumed 30-minute rule) may include hemorrhage from placenta previa, abruptio placentae, prolapsed umbilical cord, and uterine rupture.”

This again placed VBACs in the same category as routine labors since all these can be unforeseen emergency complications of previously uncomplicated pregnancies.

In October 1994 the College updated and expanded its 1988 Committee Opinion on VBACs⁶ with the most interesting changes relating to decision to incision time and risk of VBAC. Its predecessor’s caveat was unchanged but the Opinion completely sidestepped the issue of decision to incision by stating:

“A trial of labor and delivery should occur in a hospital setting that has the professional resources to respond to acute intrapartum obstetric emergencies...A physician who is *capable* of evaluating labor and performing cesarean delivery should be *readily available*.”

Yes, all references to a specific time period, either 15 or 30 minutes, had now been deleted.

The 1988 Opinion addressed risk with “The data also indicate that maternal and perinatal mortality rates for subsequent attempted vaginal delivery are lower than those for repeat cesarean births.” Using more recent literature citations the 1994 Opinion addressed risk with the following deletions, substitutions and additions to the 1988 Opinion’s language:

“The data ~~also~~ indicate that maternal and perinatal ~~mortality~~ morbidity rates for subsequent ~~attempted~~ successful vaginal delivery are lower than those for repeat cesarean births. No differences are noted in maternal or perinatal mortality rates between the two groups.”

In the summer of 1997 the fourth and current edition of joint ACOG/AAP “guidelines” was published.⁷ The caveat is identical except for variances in the terms referring to the two organizations. The section on Cesarean delivery is about twice as long as before and passages addressing emergency Cesarean section have considerable changes such as:

“Required personnel...~~should be~~ ~~must be~~ in the hospital or *readily available*...Any hospital providing an obstetric service should have the capability of responding to an obstetric emergency. No data correlate the timing of intervention with outcome, and there is little likelihood that any will be obtained. However, consensus has been that hospitals should have the capability of beginning a cesarean delivery within 30 minutes of the decision to operate.”

This again seems to equate “readily available” with “in the hospital” even though the general tone of the statement appears more lenient.

Realizing the runaway VBAC pendulum needed to be nudged back toward dead center the College issued its first clinical Technical, Educational or Practice Bulletin on VBAC in October 1998⁸, somewhat surprising considering the debate began with the increasing acceptance of Cesarean section around the turn of the century and became a hot issue in contemporary obstetrics about 20 years ago with the sea change from “Once a Section, Always a Section”. The caveat read:

“These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.”

A section addressing the relative risk:benefit of elective repeat Caesarean section vs. VBAC for mother and infant read as follows:

“Recent Issues: Despite more than 800 citations in the literature, there are no randomized trials to prove that maternal and neonatal outcomes are better with VBAC than with repeat cesarean delivery. Published evidence suggests that the benefits of VBAC outweigh the risks in most women with a prior low-transverse cesarean delivery. Nevertheless, most studies of VBAC have been conducted in university or tertiary-level centers with in-house staff coverage and anesthesia. The safety of trial of labor is less well documented in smaller community hospitals or facilities where resources may be more limited. It has become apparent that VBAC is associated with a small but significant risk of uterine rupture with poor outcome for both mother and infant. Reports indicate that maternal and infant complications also are associated with an unsuccessful trial of labor. Increasingly, these adverse events during trial of labor have led to malpractice suits. These developments, which have led to a more circumspect approach to trial of labor by even the most ardent supporters of VBAC, illustrate the need to reevaluate VBAC recommendations.”

I don't know about you but I feel an ominous chill every time I read that.

As regards decision to incision, there was essentially nothing. One of the necessary conditions to qualify a patient for VBAC was “Availability of anesthesia and personnel for emergency cesarean delivery”, and one of the contraindications for VBAC was “Inability to perform *immediate* emergency cesarean delivery because of unavailable surgeon, anesthesia, sufficient staff, or facility”.

These new and improved practice bulletins are intended to eventually replace the old “tech bulletins” cum “educational bulletins”, and in today's world of “evidence-based medicine” provide a clear, concise summary of “recommendations” on the last page identified as based “on good and consistent scientific evidence”, “on limited or inconsistent scientific evidence”, or “primarily on consensus and expert opinion”. These recommendations can then be weighed and appropriately applied to one's clinical practice.

Under consensus and opinion we found “Because uterine rupture may be catastrophic, VBAC should be attempted in institutions equipped to respond to emergencies with physicians *readily* available to provide emergency care.” No invocation of the fifteen or 30-minute rule, no mention of in-house coverage. This is no help at all unless immediate and readily are clearly defined and differentiated or the time available on the shot clock is given. If you aren't thoroughly confused by now, keep reading.

In July 1999 the College published its next, latest and current discussion of VBAC as yet another practice bulletin.⁹ It is identical to its October 1998 predecessor except for “Inability to perform ~~immediate~~ emergency cesarean delivery” as a contraindication to VBAC and “...institutions equipped to respond to emergencies with physicians immediately ~~readily~~ available to provide emergency care” as a summary recommendation.

The same month, July 1999, Stanley Zinberg tried to clarify the College's position on VBACs via an editorial in *ACOG Today*. It's reprinted on page 14. I was more confused than ever so I wrote Dr. Zinberg a letter, reprinted on pages 15 and 16. His reply is reprinted on page 17.

Several informal conversations have been held off the record with reliable and highly placed sources at the College. There seems to be agreement that intrapartum uterine rupture can be a catastrophic event demanding a more rapid response than the 30-minute rule requires, yet there is a reluctance to overtly advocate this position. Considering the disastrous effect it would have not only on Level I but also many Level II hospitals and their obstetrician staffs (Fellows) now offering obstetrical services, this reluctance is easily understood. There's also the unavoidable argument that VBACs are entirely elective and the whole issue can be avoided by not offering them in facilities already unable to meet the 30-minute rule, much less a more stringent one.

Level III hospitals already voluntarily subscribe to something closer to the College's first 15-minute rule by utilizing 24/7 in-house L&D staffing by residents and fellows in training, generalist and specialist attendings, and dedicated obstetrical anesthesia personnel plus an adequate number of highly trained and experienced obstetrical nurse specialists/CNMs. These perinatal centers also provide the highest level of intraoperative services available in multiple operating rooms within the L&D suite, dedicated to Caesarean sections and performing an adequate number of procedures to ensure staff competence.

I always assumed the College's retreat from a firm position regarding the maximum allowable elapsed time to accomplish emergency Caesarean delivery was first of all based upon a fear of intense negative reaction from its members who routinely for whatever reason failed to meet that standard. Secondly, there also seemed to be a strong opposition against providing enemy medical plaintiff attorneys possible ammunition for their cannon. Finally, I was sure national hospital organizations would call in all their favors to prevent any possible increase in their members' already sizable medical liability exposure and operating expenses. These are the same arguments one hears in opposition to advocating 24/7 in-house

obstetrician coverage for all labor and delivery suites except that the hospitals would actually decrease their medical liability exposure.

The same informal off the record conversations have implied that while I may have correctly read their tea leaves and entrails in the past, the current situation is quite the opposite. Apparently contemporary wisdom sees the 30-minute rule as flawed by not requiring a more rapid response, possibly the old 15-minute rule, for more serious emergencies such as intrapartum uterine rupture. Unfortunately there is probably an accompanying concern that trying to navigate the dangerous slippery slope of more restrictive standards or "guidelines" than the few actual benchmarks which survive might prove uncontrollable.

It is my opinion that there must be a benchmark. The only logical solution in view of the realities of the situation is to routinely continue utilizing the 30-minute rule in determining standard of care issues for liability purposes, but with certain exceptions. A more stringent universally applied standard is simply impractical since too many hospitals currently delivering babies can't even meet the 30-minute rule.

In those cases of iatrogenic intrapartum uterine rupture and other appropriate emergencies in which both maternal and fetal statuses are stable, the 30-minute rule should apply. In those catastrophic cases posing immediate and overwhelming risk of maternal loss of life such as cardiac arrest or rapidly deteriorating maternal status due to iatrogenic intrapartum uterine rupture, emergency classical Caesarean section as soon as possible under local anesthetic field block if the patient is sensate (ten minutes decision to *delivery*) is not only indicated and justified but also necessary as a potentially lifesaving measure and thereby should constitute the nationwide minimum acceptable standard of care.

In cases of iatrogenic intrapartum uterine rupture and other emergencies in which the maternal status is stable but the fetal status is rapidly deteriorating the 30-minute rule should apply until the mother verbally provides informed consent for emergency classical Caesarean section under local anesthetic field block, at which point the 10-minute shot clock referred to above should start. Like it or not, ten minutes is about all the time you've got to salvage quality of life if you're rapidly losing the mother and/or fetus. Your opinions and criticisms are solicited.

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RECOGNIZED RISK OR COMPLICATION, Continued From Page 1

Perforations of the great vessels are something else. The U.S. medical literature has reported many such injuries since 1977, but a close reading reveals the authors' stressing the importance of strict adherence to standard technique when inserting trochars. As one author states, "For the most part these injuries are preventable."¹ She does not say *all* such injuries are preventable as there are some that are unavoidable, i.e. patients with severe scoliosis altering their vascular anatomy. The defense must clearly explain to the jury why in a particular instance perforation was unavoidable. Simply to say perforations of the great vessels are recognized risks of laparoscopy is not enough.

The following case was settled after discovery was completed. A 29 year-old patient requested elective laparoscopic sterilization. She was mesomorphic and physically fit. At surgery a Verres needle produced adequate insufflation, the primary trochar was inserted, and immediately blood began leaking between the trochar and sleeve followed shortly by hemorrhagic shock. Emergency laparotomy revealed a through-and-through perforation of the abdominal aorta at L₁, two centimeters above its bifurcation. A replacement aortic graft was used to successfully repair the perforation but afterwards the patient was paraplegic. The defendant surgeon was experienced, credentialed for laparoscopic surgery, and testified that consistent with standard surgical technique he had inserted the primary trochar at a 45° angle to the spine. The defense expert, author of a widely-read gynecologic surgery text, could not explain how such an injury could have occurred under these circumstances, but stated it was a recognized risk of laparoscopy and therefore was not below the minimum acceptable standard of care. The plaintiff expert, author of a widely-read laparoscopic surgery text, used anatomical demonstrations to show that given the plaintiff's known anatomy, the injury could not have occurred if proper insertion technique had been used. The settlement was for several millions of dollars.

Which medical expert witness would the jury have perceived to be honest, credible and objective? Would the lay jury have understood the difference between a published complication and a recognized risk? The insurance carrier was not willing to find out, even though the settlement was huge. Some carriers will risk jury trial of cases involving obvious malpractice in the hope that the jury will find for more reasonable damages if plaintiff's settlement demands are seen as exorbitant.

Each medical case has its strong and weak points for both defense and plaintiff. Early in the process, proper litigation management requires all defendants and medical expert witnesses to objectively consider whether physician error might have caused an avoidable injury. If so, early settlement should be actively pursued. Relying on a recognized risk defense can itself be risky business.

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OUR LITTLE SECRET: ELECTIVE INDUCTION OF LABOR

by James A. Bofill, MD, FACOG

There are always new and constantly changing trends in obstetrical practice here in the United States, and one of the most recent involves elective induction of labor. Induction of labor is indicated for several reasons including postterm pregnancy (≥ 42 completed weeks gestation), medical complications of pregnancy and fetal compromise. Prostaglandin compounds for cervical ripening such as dinoprostone (Prepidil® or Cervidil®) now facilitate labor induction even when the cervix is unfavorable but may have inadvertently encouraged clinicians' complacency.

In a study of 597 indicated inductions of labor, Xenakis and colleagues¹ noted that vaginal delivery was dependent upon whether the patient was nulliparous or parous and cervical Bishop score at admission. Their Caesarean delivery rate was 34% in nulliparous patients with a Bishop score of 0-3 but only 20% with a Bishop score greater than 3, compared to 12% in nulliparous patients who entered labor spontaneously. In parous patients their Caesarean delivery rate was 23% with a Bishop score of 0-3 and 13% with a Bishop score greater than 3, compared to 6% in parous patients who entered labor spontaneously. All women laboring spontaneously had a statistically significant lower risk for Caesarean delivery. These rates are considered acceptable because the justifications for induction were obvious.

The incidence of labor induction is increasing in the United States. Using data from the National Center for Health Statistics Mathews² noted that the induction rate rose steadily from 90 to 160 per 1000 live births between 1989 and 1995, a 77% increase. Olah³ reported in a 1998 oral presentation before the Central Association of Obstetricians and Gynecologists that inductions increased significantly between 1992 and 1996 in West - Central Ohio. This review of nearly 91,000 deliveries found that inductions were increasing in all hospitals. In Level I hospitals labor inductions as a percentage of all deliveries rose from 12.9% in 1989 to 19.8% in 1996, in Level II hospitals from 9.6% to 21.5% and in the Level III hospital from 17.8% to 23%, all statistically significant differences. There were no substantial changes in the demographics of West - Central Ohio or methods of fetal surveillance, therefore many of these inductions were probably elective. We termed this "the culture of obstetric convenience."

Elective induction of labor is our profession's little secret. An induction is considered elective when there is no medical or obstetric indication. Induction for purely social indications can sometimes be justified. ACOG completely ignored elective induction in a relevant 1995 Technical Bulletin⁴. Likewise there is no mention of elective induction in the latest edition of Williams Obstetrics⁵. Other textbook authors such as O'Brien and Cefalo⁶ state outright that elective inductions should not be performed.

Elective induction of labor is common in practice but rarely admitted. The risks of elective induction include iatrogenic prematurity and increased risk of Caesarean delivery. Clearly the physician performing elective induction should be certain his patient is at least at 39 completed weeks' gestation, the same as if she were to undergo a non-emergent repeat Caesarean delivery. He should also inform her that an elective induction may increase her risk for Caesarean delivery and subsequent complications.

How common is elective induction of labor? No one knows for sure because most physicians will not identify an elective induction in the medical record. A disturbing yet fascinating study from Prysak and colleagues⁷ addresses this issue. They retrospectively studied elective inductions in low risk singleton term pregnancies at a community hospital in Michigan. In one year there were 736 inductions; 461 (63%) considered elective by chart review. Not one of these 461 charts documented the absence of medical or obstetric indications for the induction. How's that for "our little secret"? The study was confusing because women who were electively induced had a statistically significant higher rate of Caesarean delivery by simple statistical analysis ($p = .036$) which disappeared with multiple logistic regression. Their logistic model had several flaws but it should be noted that in nulliparas the Caesarean delivery rate was 21.4% when cervical ripening was followed by an elective induction compared to 9.7% with their spontaneous onset of labor ($p = .033$). The authors' final point was that elective induction was safe, efficacious, and commonly practiced but could increase Caesarean delivery rates for nulliparas or those with an unfavorable cervix.

In my opinion there should be justification for any induction of labor. Nulliparas should not be electively induced. Multiparas may be electively induced only if the cervix is ripe. Term patients desiring elective induction due to mild discomfort and/or anxiety should be informed that induction can increase their risk for Caesarean delivery and its subsequent complications, even increase risks in future pregnancies. If physician and patient agree to elective induction it should be honestly noted in the chart. We need good prospective data and it is incumbent upon those physicians who perform elective inductions to maintain honest records in order to effectively counsel future patients. Local statistics are the best statistics and in this age of computers there is no reason why a physician can't honestly and accurately discuss Caesarean delivery rates with his patients. The way to do

this is to identify cases at the time decision for elective induction is made. Useful data may then be collected and honestly reported. Before I became an academic physician it was easy to tell my healthy low-risk Air Force dependent wives that my overall Caesarean delivery rate was 8%. I still think they derived some degree of comfort from that.

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