

Maternity Care and Liability: Pressing Problems, Substantive Solutions



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Acknowledgments

Childbirth Connection launched its *Transforming Maternity Care* project in 2007 and engaged more than 100 leaders from across the health care system in deliberative processes to develop two direction-setting consensus reports: “2020 Vision for a High-Quality, High-Value Maternity Care System” and “A Blueprint for Action” to chart the path to such a system (see [http://www.whijournal.com/issues?issue_key=S1049-3867\(09\)X0008-3](http://www.whijournal.com/issues?issue_key=S1049-3867(09)X0008-3)). Key informant interviewees, steering committee members, and other participants during the planning phase of this work identified improving the functioning of the liability system as a core priority strategy for moving toward the envisioned maternity care system and put forth major Blueprint recommendations and action steps for improvement in this area. We are grateful to these leaders and the many partners who are working with us through the *Transforming Maternity Care* Partnership to implement priority Blueprint strategies and recommendations, and look forward to addressing lessons from this report.

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To complement existing investigations of defensive avoidance practices among physicians, former Childbirth Connection Deputy Director Bernadette Brown, JD, investigated the reasons for closure of a series of midwifery practices and birth centers. Her work fills out our report on this important topic.

We are grateful for the opportunity to work with *Women’s Health Issues* Editor Anne Markus, PhD, JD, and her team on a “Maternity Care and Liability” Policy Matters focus within the January-February 2013 issue of the journal. To increase access to results of this report, the journal is publishing three articles that are derived from the report and are freely available at <http://www.whijournal.com/issues/>. In addition to an overview of Part I and Part II with selected priority references, the articles examine, respectively, least promising and most promising strategies for better meeting needs of the relevant stakeholders.

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Executive Summary

Synopsis

This report summarizes the best available research about the impact of the health care liability system on maternity care, and policy strategies for improved functioning of the liability system in maternity care. It draws on maternity-related empirical legal studies and health services research when available and other studies when unavailable. Improved understanding of these matters can help transcend polarized discourse, guide policy intervention, and address persistent shortcomings.

The best available research does not support a series of widely held beliefs about the impact of the liability system on maternity care, including the economic impact of liability insurance premiums on maternity care clinicians, the existence of extensive defensive maternity practice, and the impact of limiting the size of awards for non-economic damages in a malpractice lawsuit. In the practice of an average maternity caregiver, negligent injury (meeting legal criteria for malpractice) of women and newborns appears to occur more frequently than any claim and far more frequently than a payout or trial. Women may be more likely to sustain negligent injury than newborns, while newborn injuries overall are more severe and are more likely to be handled by the legal system.

Recognition that the liability system is not serving well childbearing women and families and providers and payers of maternity care services led us to identify seven aims for a high-performing liability system in this clinical context. We held 25 improvement strategies that have been proposed and/or implemented up to these criteria and found that 15 strategies have not been found to be effective in addressing needs of diverse stakeholders and/or are unlikely to do so. A series of maternity-specific studies found that the effectiveness of tort reforms is at best modest and limited in scope. Ten strategies appear to have promise to improve liability matters across multiple aims. These health care, tort alternative, and liability insurance reforms are stronger candidates for demonstration, evaluation, and refinement to prevent injury or assist women, babies, and families when it occurs. They also hold promise for reducing liability-associated stressors of health professionals and improving the value of maternity care to payers. An appendix summarizes many important gaps in knowledge relating to maternity care and liability, and another provides summary fact sheets on key questions of interest to diverse stakeholders.

Introduction

This report assesses both the impact of the liability environment on maternity care in the United States and strategies for improving this environment. Traditional aims of the liability system are to deter harm and compensate those who sustain negligent injury. Maternity care is a major segment of the health care system impacting the entire population at the beginning of life and 85% of women who give birth once or, more typically, multiple times. Combined care of childbearing women and newborns is the nation's

most common reason for hospitalization. It is also the most costly hospital condition for all payers, private payers, and Medicaid, and these payments include costs of liability.

According to measures of claims, payouts for damages, and liability insurance premiums, providers of maternity services are at high liability risk relative to those in most other clinical areas. Professional liability issues are persistent sources of concern among policy makers and discontent among maternity care providers. It is crucial to ensure that the liability system fosters access to and the quality of all vital maternity services, including those of general obstetrician-gynecologists, maternal-fetal medicine subspecialists, family physicians, midwives, and care in hospitals and freestanding birth centers.

A broad investigation of maternity care liability issues has not been carried out since the Institute of Medicine issued a report in 1989, when limited sound quantitative data with few maternity-specific investigations were available to inform liability matters and the health care system differed in many respects from present conditions. This report provides an update of maternity care and liability by summarizing maternity-related research within the growing body of empirical legal studies, health services research, and other relevant data in the context of more recent conditions of the evolving health care, legal, and liability insurance systems. Medical malpractice policy making frequently has not been guided by best evidence, and such focus can help the various stakeholders move beyond polarized adversarial discourse, competing beliefs and ideologies, and gridlocked decision making to better understand the issues and identify and move toward substantive solutions.

Part I. Impact of the Liability Environment on Maternity Care

Background: Liability Insurance Policies Available to Maternity Care Providers

As the traditional medical liability insurance business has contracted and physician, hospital, and health system affiliates have increasingly offered liability insurance policies, obstetrician-gynecologists appear to have ready and relatively stable access to liability insurance coverage. However, liability insurance cycles, characterized by ebbing and flowing of premium levels and potential limits on the availability of insurance, have been volatile and are impacted by broader economic conditions and insurer industry business decisions. Although the extent of interference with clinical decision making is unknown, some policies impose surcharges for or do not cover evidence-based care, such as vaginal birth after cesarean, obstetrician collaborative practice with midwives, and family physician provision of maternity care.

Maternity Care Provider Experience of Liability Insurance

The cost of professional liability insurance premiums to obstetrician-gynecologists varies widely across geographic areas and time. Obstetrician-gynecologists and other health professionals in specialties that are at higher risk for experiencing liability claims can perceive high and fluctuating premiums and rate increases during hard segments of the cycles as capricious and distressing. Although the specialty's premium levels tend to be higher than those of other specialists, their premiums amount to a relatively small and declining portion of overall practice expenses, and their incomes are high and appear to have outpaced inflation up to the onset of the present global economic downturn. The best current evidence suggests that liability insurance premiums do not threaten the economic viability of obstetrician-gynecologists.

As practice expenses have grown and reimbursement has tightened, this specialty — in parallel with broader medical trends — appears to have successfully increased revenue through a procedure- and test-intensive practice style. With the trend of clinician consolidation into larger clinical groups and as employees of hospitals and health systems, it is likely that maternity care clinicians increasingly receive liability insurance premium coverage as a benefit of employment. However, the extent to which this occurs is unknown.

Maternity-Related Claims and Payouts

The specialty of obstetrics and gynecology is an outlier with respect to the large number of closed legal claims of harm (those resolved by being dropped, settled, or adjudicated by courts), the high rate of insurer payouts to compensate for losses among closed claims (with most occurring in the obstetrics area of practice), and the high level of payouts. More claims are for newborn than maternal injury. The best current estimate about the claims experience of obstetrician-gynecologists found that, on average, a physician had a claim after 11 practice-years, a settlement (payment for damages prior to a possible trial award) after nearly 40 practice-years, and an actual trial after 70 practice-years. Maternal-fetal medicine subspecialists may experience higher rates of claims, trials among claims, and trials resolved in favor of parties claiming injury than general obstetrician-gynecologists. The number of claims paid out on behalf of obstetrician-gynecologists, percentage of payouts (settlements or trial awards) to defendants among claims, and total cost of those payouts appears to be declining substantially over time.

Incidence of Negligent Injury, Compensation for Claims, and Maternity Care Patient Safety

A large carefully conducted study with random samples found that about 0.6% of childbearing women and about 0.2% of newborns sustained negligent injury, the legal standard of medical malpractice, while receiving care in U.S. hospitals. That and a replication study found that the negligent injury rate in hospital labor and delivery units was in the range of 0.8% to 1.8%. Childbearing women may be several times as likely to sustain negligent injury as newborns, but the overall severity of newborn injuries appears to be worse and they receive most compensation. Subsequent research has clarified that the initial landmark studies, which covered hospital care generally, greatly underestimated rates of harm, but replications have not occurred in maternity care. Practicing physicians and defense lawyers judge about 75% of paid obstetric claims to involve injury from substandard care.

Available evidence, not separately reported for maternal-newborn populations, suggests that the rate of filing claims by or on behalf of those who experienced negligent injury is low, about 2%, with payments for damages going to less than 1% of those with negligent injury, and most money awarded going to administrative and legal costs rather than plaintiffs.

Defensive Maternity Care Practice

There is widespread concern in maternity care about defensive practice, a deviation from sound practice carried out primarily to reduce the care provider's risk of liability rather than to benefit the patient. Two broad classes of "defensive" maternity care practice are "avoidance" of risk of liability (e.g., limiting or withdrawing services to reduce risk) and "assurance" practices to demonstrate efforts to avoid adverse outcomes (e.g., making a referral or ordering a test primarily to demonstrate care). Surveys and commentaries of maternity professionals raise concerns about the impact of liability pressure (such as high premiums or high rate of claims) on avoidance defensive behavior, but investigations to corroborate those limited reports clarify that decisions about providing maternity services are multi-factorial. Better quality studies have found that various measures of liability pressure are not associated with maternity care avoidance behavior or have a discernable relationship under limited circumstances. Surveys and

commentaries also describe extensive use of assurance behaviors in maternity care. Better quality studies examining the relationship between liability pressure and cesarean section, a widely cited assurance behavior, generally find at most a small positive relationship that can account for a very small portion of the nation's high cesarean rate. Limited studies of other maternity care practices similarly have not found the extensive maternity care assurance behavior that is believed to occur.

Liability, Career Satisfaction of Maternity Caregivers, and Maternity Care Quality

The adverse impact of the liability system on obstetrical care providers is a persistent concern in their professional discourse. Further, studies comparing the career satisfaction of physicians by specialty suggest that obstetrician-gynecologists are more dissatisfied than nearly all others, including gynecologists, family physicians, and perinatologists/neonatologists. A series of reports have documented disruptive behavior (such as outbursts, insults, and eye-rolling) among maternity care providers. Relationships among liability concerns, dissatisfaction, and unprofessional behavior, if any, are unknown.

Liability and Maternal and Newborn Health Outcomes

A successful liability system would deter harm to mothers and newborns. Existing data generally show no relationship between measures of liability pressure and health outcomes, but they are sparse and too limited to clarify the impact of the liability environment on maternal and newborn health.

Appendix I, a companion to Part I, identifies many important questions about liability and maternity care that cannot be answered at present and warrant research. These include, in addition to those noted above, many basic liability questions about effects on maternal-fetal medicine subspecialists, family physicians, midwives, and birth centers, and many basic questions about liability matters, disparity populations, and safety net providers and settings.

Part II. Policy Interventions for Achieving the Aims of the Liability System

Policy Framework for Liability System Improvement

The disappointing record of the liability system in maternity care, as discussed in Part I and emerging in Appendix I, led us to propose seven priority aims for designing, instituting, and evaluating liability-related policy interventions. Such interventions should:

- Promote safe, high-quality maternity care that is consistent with best evidence and minimizes avoidable harm
- Minimize maternity professionals' liability-associated fear and unhappiness
- Avoid incentives for assurance and avoidance defensive maternity practice
- Foster access to high-value liability insurance policies for all maternity caregivers without restriction or surcharge for care supported by best evidence
- Implement effective measures to address immediate concerns when women and newborns sustain injury, and provide rapid, fair, efficient compensation
- Assist families with responsibility for costly care of infants or women with long-term disabilities in a timely manner and with minimal legal expense
- Minimize the costs associated with the liability system.

Policy interventions that have been implemented or proposed fall into four broad categories: conventional malpractice tort reforms, tort alternative reforms, liability insurance reforms, and health care system reforms. Relatively few specific reforms have been well tested in maternity care. This report rates reforms by their demonstrated or plausible contribution to the seven proposed aims. We argue that those with the potential to impact multiple diverse aims are priority candidates for demonstration and evaluation. Many reforms that have received great emphasis in the past have focused narrowly on the aim of keeping professional liability premiums low, and available studies do not lend strong support for their effectiveness even with respect to this limited aim.

Interventions Likely to Offer Limited or No Benefit

Evidence to date suggests that reform of tort law relating to medical negligent injury is unlikely to have any impact on most liability system aims listed above. When measured in the maternity context, such reforms have had limited impact at best. National multi-variable studies have measured the maternity-specific impact of caps on non-economic damages on liability premiums, award sizes, availability of services, use of cesarean section, and health outcomes. While such caps have proven to be the tort reform with the greatest calming effect in medicine generally, their impact in the maternity context has been weak to nonexistent. Empirical support is lacking for further use of this strategy to improve maternity care. A more limited evidence base of national multi-variable studies has evaluated maternity-specific impact of several other tort reforms: collateral source rule, attorney fee limits, periodic payment of awards, expert witness rule, joint and several liability rule, pretrial screening, and multiple tort reforms collectively. This research provides no compelling support for these strategies.

Similarly, liability insurance reforms such as rating and investment regulation and patient compensation funds may be expected to have a limited impact on the range of aims. One program for malpractice premium subsidy to maternity care providers was not effective in increasing the supply of providers. Joint underwriting associations (JUAs) may provide liability coverage and foster access to crucial forms of care with small insurance pools; evaluation of current JUAs would help clarify the potential of this model. Limited evidence for arbitration and mediation found disappointing results, but mediation may have a role in combination with more promising strategies, such as disclosure.

Substantive Interventions with Potential to Address Multiple Aims

Policy interventions are needed both to prevent adverse events and to assist those who experience them. Interventions for averting harm that have demonstrated or plausible impact on multiple liability system aims, in order of ratings against the seven aforementioned criteria, are: quality improvement programs; enterprise liability; leverage of health insurance, accreditation, credentialing, and other health care system mechanisms; shared decision making; alignment of legal standards with best evidence; and liability insurance coverage regulation. A series of recent reports suggest that rigorous maternity care quality improvement programs can sharply and quickly reduce liability claims, payouts, and premiums. Interventions to assist those who experience adverse events that have demonstrated or plausible impact on multiple liability system aims, in order of ratings, are: disclosure/empathy/apology programs, health courts, administrative compensation systems, and high-low agreements. Administrative compensation programs have a demonstrated favorable impact in maternity care. All of these strategies are good candidates for demonstration and evaluation, with the potential to alleviate maternity care provider stressors, improve care of childbearing women and newborns, and improve value for those who pay for maternity services.

Conclusion

This investigation has found that that more reliable research does not corroborate many widely held beliefs about these matters:

- We did not find evidence of the severe adverse impact that this system is believed to have on premium affordability.
- We did not find evidence about extensive avoidance defensive practice or, with respect to mode of birth, assurance defensive practice.
- Despite widespread concern about vulnerability of maternity professionals to legal action and non-meritorious suits, in the practice of an average obstetrician-gynecologist, negligent injury of mothers and newborns appears to occur more frequently than any claim (warranted or not, obstetric or gynecologic), and far more frequently than any payout or trial.
- Although liability attention is particularly focused on newborn harm and newborn harm may be more severe, mothers may be several times more likely than newborns to experience negligent injury.
- While maternity-specific data are not available, just about 2% of the overall population that experiences negligent injury appears to make a claim, about half of those receive any compensation for damages, and most of the payouts appear to go to legal expenses rather than plaintiffs.
- Despite professional support for caps on non-economic damages, empirical maternity care studies find that they have at best minimal impact of limited scope.

Other notable maternity-specific concerns include the following:

- Some liability insurance policies restrict access to essential maternity services through exclusions (e.g., vaginal birth after cesarean) or surcharges (e.g., for physician collaborative practice with midwives or family physician maternity care), but the extent and implications have not been measured at the national level.
- An abundance of systematic reviews are available to guide maternity practice, but legal standards for clinical care and for admission of evidence frequently provide incentives *not* to provide and uphold care consistent with best evidence.
- Ambiguity about the legal roles and responsibilities of clinicians and childbearing women impedes optimal decision making.
- The legal system compensates some seriously injured newborns facing long-term, high-cost care when their care did not meet the malpractice negligence standard.
- Liability matters are distressing to many caregivers who experience the liability claims, the fluctuation of liability insurance premiums, and other liability matters as capricious; may be singled out as individuals when systems have failed; and are poorly supported in the face of adverse events.
- Studies do not support the effectiveness of reforms that maternity care providers have most strongly advocated and policy makers have frequently implemented.
- Maternity care payers, purchasers, credentials, and other stakeholders with an interest in a high-functioning liability system have often failed to leverage opportunities to improve liability matters.
- Relatively few studies characterize the impact of the liability system on maternal-fetal medicine subspecialists, family physicians, midwives, and birth centers. These provider groups appear to experience less liability-related discontent and greater professional satisfaction than general obstetrician-gynecologists. There are concerns but no strong data about access to affordable insurance products for groups with small risk pools that may be greatly impacted by one or a few claims.

Various remedies for deficiencies in the current liability system have been proposed, and many have been implemented, with some evidence from application in the maternity context. A number of strategies, both to avoid adverse events and to assist those who experience them, have the potential to address multiple aims and improve persistent problems. These approaches have potential to alleviate professional stressors, improve care of women and newborns, and achieve better value for those who pay for maternity services. It would be optimal for states, health systems, and other entities to pilot and evaluate these potentially substantive strategies. Similarly, it would be appropriate to abandon efforts to advance policy strategies that lack empirical support and/or have potential for narrow impact at best.

Appendix II provides summary fact sheets on priority topics for policy makers and other stakeholders. Wide distribution of these is encouraged.

Introduction

This report assesses the impact of the liability environment on maternity care in the United States and strategies for better achieving aims of the liability system. Maternity care is a unique clinical area that impacts the entire population during the crucial period of earliest and most rapid development, and about 85% of U.S. women receive maternity services when they give birth to one or, more commonly, multiple children (Martinez et al. 2012). Such care affects the women, newborns, and families who experience about four million births annually in the nation. It is a major sector of the health care system: combining maternal and newborn populations, childbirth is the nation's leading reason for hospitalization and most expensive hospital condition, overall and for private insurers and Medicaid (Agency for Healthcare Research and Quality 2012). It is also a leading reason for ambulatory visits (Sakala and Corry 2008).

Maternity liability issues are persistent sources of concern among policy makers, women and families, and providers of maternity services. In response to our Milbank Report, *Evidence-Based Maternity Care: What It Is and What It Can Achieve* (Sakala and Corry 2008), many have responded that maternity care providers will not be able to consistently practice according to the best evidence until the liability system is repaired. To achieve the high-performing maternity care system that stakeholders need, we cannot continue to allow these matters to fester and rankle. Discourse and response must rise above affect, anecdote, belief, ideology, and entrenched stakeholder positions to prioritize guidance from the best available evidence about pressing problems and substantive solutions.

This report is relevant to many stakeholder groups. It is a priority to support state and federal policy makers and staffs who have legislative, executive, regulatory, delivery system, and purchasing responsibilities in their efforts to improve the functioning of the liability system and the quality of maternity care. The report is also intended to inform health professionals and health professions educators, hospital and health plan administrators, insurers, employers, researchers, childbearing women and their families, consumer advocates, and journalists about these matters. To make results about key questions more accessible, an Appendix provides 10 fact sheets. To foster broad access, three related peer-reviewed open-access journal articles (Sakala et al. 2013a, 2013b, 2013c) and an invited commentary (Rosenbaum and Sage 2013) are being published simultaneously in *Women's Health Issues* (available at whijournal.com/issues/).

A broad investigation of maternity liability matters has not occurred since the Institute of Medicine's two-volume report on *Medical Professional Liability and the Delivery of Obstetrical Care* (1989a, 1989b), which was preceded by *Proceedings of the Forum on Malpractice Issues in Childbirth: 1985* (Casselberry 1985; Young 1986). At that time, just a small proportion of liability information was derived from sound quantitative empirical research, with few maternity-specific investigations (Zuckerman et al. 1986). This updated overview considers the growing body of empirical legal studies and health services research, including multivariable analyses and other empirical research methods that have been used in the social sciences. It takes into consideration this relatively new empirical focus on legal questions, which supersedes traditional and long-standing legal argumentation or other advocacy (Mello and Zeiler 2008; Struve 2004), as well as other evidence that has appeared since earlier reports, and the evolving liability insurance, legal, and health care systems.

Empirical studies have been used to develop effective health policies in areas such as motor vehicle safety laws, but policy making relating to medical liability often has not been based on best evidence about what has been shown to succeed (Mello and Zeiler 2008). Frequently, polarized, adversarial discourse between trial lawyers and health professionals and their respective allies has often relied heavily on anecdotal evidence and belief. Attention intensifies in “crisis” periods (i.e., when liability insurance premiums escalate and access to such insurance may be reduced); focus has especially been on whether to impose non-economic caps on payments awarded in lawsuits for injury, with the aim of limiting the size of awards and costs of liability. Other well-known systemic liability-associated problems and strategies that might lead to more substantive and far-reaching improvements in the way the liability system functions have not received adequate attention (Mello and Zeiler 2008).

Current Agency for Healthcare Research and Quality funding programs for medical liability reform and patient safety demonstration projects and planning grants and a new series devoted to “new ideas and alternative approaches” to liability challenges in the journal of the American College of Obstetricians and Gynecologists (Scott 2010; see also Lumalcuri and Hale 2010) are among promising signs of a new direction. We hope that this report will complement such efforts and shift the focus in maternity care from responding to pressure to “do something” in an emergency (Mello and Zeiler 2008) to seizing opportunities to better achieve the broader aims of the liability system and improve maternity care quality and value (Chervenak et al. 2010).

Within our civil justice system, medical malpractice law generally aims to deter unsafe professional practice and fairly compensate those who sustain negligent injury. Tort law relating to negligence grants those who are injured through the malpractice of professionals who have obligations to take reasonable care for safe practice the right to make a legal claim to seek compensation for damages in a court of law. It is important to understand how well this system deters unsafe practice, fosters high-quality care, and provides appropriate timely assistance to childbearing women and newborns with negligent injury.

Major liability concerns in this clinical area are the avoidable tragedies of a newborn death or a newborn with lifelong impairment, and of harm in a relatively young and healthy childbearing woman. It is crucial to understand the extent to which women and newborns experience avoidable and negligent injury.

According to many malpractice measures, obstetrical care is an outlier in comparison with other clinical areas. While about 4% of all practicing physicians are obstetrician-gynecologists (Smart 2009), this specialty was associated with 13.75% of all closed claims, or 29,453, over the twenty-year period from 1985 to 2005 in the Data Sharing Project of the Physician Insurers Association of America (PIAA). This positioned it first among 28 specialties in the volume of claims (Carroll and Buddenbaum 2007). A recent updated evaluation of the number of claims closed from 1985 to 2010 in the PIAA database found that this specialty’s rank had fallen to second among 28 specialties (Yates 2012). For both time frames, obstetrics and gynecology ranked second among the 28 specialties in its rate of indemnity (injury compensation) payment to plaintiffs in settlements, at 35%; and for 1985-2005, it ranked third with respect to average expenses paid out and fifth with respect to median expenses (Carroll and Buddenbaum 2007; Yates 2012). A national analysis of 25 specialties from 1991 through 2005 found that obstetrician-gynecologists experienced the greatest number of outlier awards exceeding \$1 million (Jena et al. 2011). Among 25 specialties, just four had higher average defense costs for claims involving payouts in a nationwide liability insurer’s database of claims closed from 1995 through 2005 (Seabury et al. 2012). Public Citizen found that payouts for settlements and awards on behalf of obstetricians (apparently excluding gynecologic payouts) remained steady at about 9.5% of all payouts from 1991 through 2004 (2005b).

Due to frequency and severity (or level of associated costs) of malpractice claims against obstetrician-gynecologists, their malpractice premiums tend to be higher than those of most other physicians. Just a few other specialties are consistently viewed as being at highest risk for liability, including neurosurgery, general surgery, orthopedics, and emergency medicine. In the 2008 Health Tracking Physician Survey of the Center for Studying Health System Change, physicians overall exhibited an elevated level of malpractice concern as indicated by the validated Malpractice Concerns Scale; and obstetrician-gynecologists, surgeons, and emergency physicians scored well above average (Carrier et al. 2010). Feelings of injustice and resentment about liability issues such as the frequency and merit of claims and the size of awards and malpractice insurance premiums appear to be widespread among maternity professionals.

Despite its unfavorable standing among medical specialties, obstetrics and gynecology has experienced several favorable liability trends. First, in comparison with 1986-1991, 44% fewer claims were paid between 2006 and 2011. Second, the percentage involving payments for damages decreased during this time frame from 37% to 32%. Finally, when calculated in 2010 dollars, the total amount paid in the recent period declined by more than \$138 million in comparison with the earlier period (Yates 2012).

Generally, patients have two years to file a malpractice suit after an event that may give rise to a claim; however, statutes of limitations in many states extend this period in cases involving newborns (Hyman and Silver 2006). A recent analysis determined that the national average for newborns was 12 years (versus two years for a 25-year-old), with a maximum of 23 years for newborns (Shea et al. 2008). For liability insurers, this protracted period increases economic uncertainty about the adequacy of underwriting revenues and the potential for volatility in the cost, terms, and availability of insurance due to unanticipated changes in underwriting assumptions (Baker 2005). For maternity care providers, this extended period for filing claims can prolong fear, anxiety, and a sense of vulnerability about perinatal injury claims long after professional services are provided. Periodic spikes in premium levels pose additional challenges to clinicians.

It is important to understand the implications of the liability system for maternity professionals and its impact on maternity care access, quality, and cost. Access may be reduced if professionals limit or refuse to provide certain types of care to reduce their risk of liability or exit the market due to the cost of liability insurance or distaste for related conditions of practice. Quality may be adversely impacted if liability pressure influences clinical decision making. Professionals may practice in ways they believe will reduce their risk of liability or will generate increased revenue to cover insurance premiums by providing care that offers marginal or no benefit to patients and increases risk of harm. The quality of the clinician-patient relationship may be adversely affected if the liability environment contributes to professional fear, demoralization, and wariness in relationships with patients. Costs may increase due to overuse of services to reduce risk or generate revenue; the expense of treating avoidable morbidity associated with defensive practice; or rising liability premiums, settlements, awards, and legal expenses of claims and suits. Care influenced by factors other than best available evidence and the values and preferences of women serves women and families poorly and involves waste and diminished value for payers. Ultimately, everyone pays for such costs through taxes, their impact on employers (e.g., increased costs of goods and services, reduced wages, use of labor from other countries), and direct expenses (Fuchs 2009).

Many strategies involving the legal, liability insurance, or health care systems have been proposed to improve the functioning of the malpractice system, and some have been implemented and evaluated. It is a priority to consider the effects of these strategies, or plausible effects, and to identify the most promising ways to foster high-performing legal, liability insurance, and maternity care systems. Pilots within state or other suitable entities should test and refine the most promising and feasible approaches.

In recent decades, there have been three consecutive cycles with periods of intensified concern about high liability premium levels, reduced access to liability insurance, increased litigation and possible adverse effects on health care access, quality, and costs: from the early to mid-1970s, from the early to mid-1980s, and from the turn of this century well into the first decade (Mello et al. 2003). From the latter part of the first decade to the present has been a soft period in the underwriting cycle (Newman et al. 2011). Due to notable changes in the liability environment, this report gives priority to conditions during the most recent wave of malpractice-related pressure, to the extent that data are available. Data for examining many important questions relating to the liability pressure during this period are sparse. In addition to the usual delay between phenomena and the appearance of reports about them, often-protracted legal liability processes limit what is now known about this third wave. Thus, for example, we include studies of claims resolution at the end of the last century.

The most recent period of liability pressure differs in important respects from earlier ones. In the more cost-constrained health care system of recent years, there are fewer options for absorbing real or perceived increases in liability premium charges and other practice costs. This creates pressure to adjust practice style by accelerating patient throughput for greater time efficiency for clinicians and facilities and/or by providing additional services to increase revenue (Joint Commission on the Accreditation of Healthcare Organizations 2005; Sage 2003; Thorpe 2004).

Consistent with these observations, maternity care practice has changed in important ways since the previous cycles with growing procedure intensity in healthy, low-risk birthing women. For example, prior restraint on use of cesarean section has lessened, and the nation experienced record-level cesarean rates annually from 2000 through 2009. Similarly, intervention-initiated birth — through labor induction and/or planned cesarean section — now predominates, and spontaneous onset of labor initiated by the interplay of maternal-fetal physiology no longer determines gestational age, newborn maturity at birth, and the timing of birth for the majority (Declercq et al. 2002; Declercq, Menacker et al. 2006; Declercq, Sakala et al. 2006; Sakala 2006).

The liability insurance industry is also changing in many important ways, including the entities that offer coverage and their behavior and values, the type of policies that are offered, the terms of the policies, and whether individuals or organizations pay for policies.

While overall claim frequency has been stable, the number of large jury awards associated with maternity care has grown (Chandra et al. 2005). In the context of these and other changes, the most recent period of intensified malpractice pressure, with concern about affordability of and access to liability insurance, was more severe than its predecessors, with harshest effects concentrated in maternity care and a few other areas (Sage 2004a). States have continued to initiate tort reforms, with the aim of moderating some of these effects and varying degrees of success.

Finally, an unprecedented mandate to improve safety and other aspects of health care quality has arisen in recent years, signaled and shaped by two path-breaking Institute of Medicine reports: *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) and *To Err Is Human: Building a Safer Health System* (2000). The safety report concluded that just one component of the problem, deaths resulting from errors in hospitals, involved the loss of from 44,000 to 98,000 lives annually (Institute of Medicine 2000). Subsequently, numerous data sources have suggested that previous estimates substantially underestimated the magnitude of the problem with adverse events and outcomes (Classen et al. 2011;

Leape and Berwick 2005). While safety problems are now widely acknowledged, six years of *National Healthcare Quality Report* monitoring documented an overall net decline in national performance on 38 patient safety measures (Agency for Healthcare Research and Quality 2009). A recent *National Healthcare Quality Report* found that progress on the national priority of patient safety is lagging (Agency for Healthcare Research and Quality 2011), and a hospital survey on patient safety culture identified many areas with trends of marginal progress, no change, or backsliding in obstetrics units (Sorra et al. 2012).

Part I of this report uses available data to describe patterns and trends in liability system performance with respect to maternity services. Subsections focus on the liability insurance market, the experience of maternity providers in securing liability insurance, their experience with claims and lawsuits, the incidence of negligent injury and compensation for it, defensive maternity practice, career satisfaction of maternity caregivers and its relationship to liability and quality, and deterrent effects of the liability system. We end by proposing seven core criteria for a high-functioning liability system: providing safe, high-quality care; reducing professional fear and distress; limiting defensive professional practice; fostering liability insurance that serves the public interest; providing appropriate response to injury; assisting families of infants or women with serious disabilities; and reducing liability costs.

Part II considers options for better achieving aims of the liability system. Opportunities to better achieve aims of the liability system fall in four general areas: tort reform, alternatives to conventional tort solutions, malpractice insurance reform, and health system reform. This section describes various options and their demonstrated or plausible impact in the maternity arena. We hold 25 strategies up to the seven liability system aims.

This report considers the full complement of maternity providers and settings to the extent that data are available. Obstetrician-gynecologists provide most prenatal and intrapartum care in the United States, most births take place in hospitals, and the fullest available picture about liability experiences is for hospital-based obstetrical care. Maternal-fetal medicine (MFM) subspecialists, family physicians (FPs), midwives, and out-of-hospital birth centers play vital roles in the maternity care system. MFM physicians provide specialized care to childbearing women at higher risk, while midwives have expertise in the care of healthier, lower-risk women, and out-of-hospital birth centers offer high-quality, high-value care for those not at high risk (Stapleton et al 2013). FPs who include maternity services in their scope of practice can care for low-risk women and those with many types of health challenges. They offer continuity of care for mothers before, during, and after pregnancy and for babies in the months and years ahead. Midwives and FPs each provide care to an estimated 300,000 to 400,000 childbearing women annually in the United States (Kennedy and Shannon 2004; Reime et al. 2004; Sakala and Corry 2008; Wagner 2001). Many FPs and midwives make crucial contributions to access by practicing in underserved geographic areas, among underserved populations, and through generally high rates of participation in public assistance programs (Declercq et al. 2001; Fryer et al. 2001; Grumbach et al. 2003). Further, these groups have consistently been shown to provide high-quality care and achieve excellent outcomes, including in underserved populations (Hatem et al. 2008; Johantgen et al. 2012; Khan-Neelofur et al. 1998; Klein 1993; Raisler and Kennedy 2005; Sutcliffe et al. 2012; Waldenström and Turnbull 1998; Walsh and Devane 2012; Walsh and Downe 2004).

Support for the full complement of maternity caregivers is crucial in recognition of the aging obstetrician-gynecologist workforce; the trend of this group to work fewer hours, to be less likely to provide obstetrical care, and to spend fewer years attending births than previously; the absence of any obstetrician-gynecologist in about one-half of U.S. counties; the projected increase in the number of childbearing women;

and increasing access to health insurance, which together suggest a severe impending maternity care workforce shortage (Rayburn 2011). Thus, it is important to understand how the liability system impacts all of these groups and settings and to ensure that it enhances and does not compromise access to and the quality of these services.

Appendix I, a companion to Part I, identifies many crucial questions for which data are especially limited or unavailable at this time. In addition to many basic overall questions about how the liability system functions within maternity care, little is known about implications for disparity populations and safety net maternity services and about providers and settings other than general obstetrician-gynecologists and hospitals. Available preliminary maternity-specific or more general data are instructive, and readers are encouraged not to overlook this section. Appendix II provides summary fact sheets on topics of great interest to policy makers and other stakeholders to foster broad access to significant findings. Readers are welcome to reproduce and share these widely.

Note About the Use of Sources

This report gives priority to the weight of the best available evidence. Higher quality studies and stronger conclusions are optimal for guiding policy, practice and education, whereas the larger volume of opinions, commentary, news reports, and anecdotal evidence comprise the least valuable segment of the “information iceberg” (Zuckerman et al. 1986). Despite the growing abundance of systematic reviews and experimental studies about pregnancy and childbirth care (Sakala and Corry 2008), we did not find any systematic reviews or experimental studies about the impact of the liability system on maternity care and the effectiveness of strategies to reduce liability concerns. More trustworthy conclusions about these topics rely on:

- data that are specific to maternity care;
- studies that control for confounding variables or otherwise consider competing factors, as appropriate;
- studies that are national or multistate in scope;
- data collected during the most recent liability cycle (from turn of the century to the present) or, to understand claims resolution, the preceding liability cycle (mid-80s through late 90s);
- results that are consistent across a series of studies.

We briefly summarize results of more recent maternity-specific national, multi-state, and state-level multivariable analyses. We excluded studies from other countries.

Results are much less trustworthy when:

- data are general and not specific to maternity care,
- designs do not consider competing explanations,
- evidence is limited to a specific U.S. geographic setting and may not apply elsewhere,
- data come from a single study or small number of studies without robust representative samples,
- there are puzzlingly inconsistent results across better quality studies,
- data were collected during the first liability cycle in the 1970s and early 80s.

Where studies are unavailable, out of date, of poorer quality, or do not provide strong support for a firmer conclusion, further research is especially needed to improve understanding and guide policy. Appendix I summarizes many important gaps and research priorities and points to available less trustworthy research relating to the matters addressed in part I.

We considered factual survey data (e.g., insurer charges for a specific level of coverage or caregiver experience of claims) to be of higher quality, and survey data about behavioral issues such as motivation, intention, or basis for decision making to be of lower quality. In the latter case, surveys generally do not identify or attempt to measure the effect of competing non-liability factors that potentially impact the behavior or decision of interest. When stronger conclusions from higher quality empirical studies contradict limited survey data, opinion, assertion, or unsubstantiated belief, there are good grounds for concluding that the less rigorous sources are flawed.

Where maternity-specific data were not available, we provide information about medical liability more generally. However, we caution that the general findings cannot be assumed to apply to this area, and maternity-specific investigations are needed. We found a discrepancy between general results and maternity-specific results for two topics in this report that have a rich maternity-specific evidence base and are of great interest to stakeholders: the impact of liability pressure on assurance defensive practice and the impact of caps on non-economic damages on maternity care.

Part I. Impact of the Liability Environment on Maternity Care



Background: Liability Insurance Policies Available to Maternity Care Providers

Changes in the liability insurance market, including increasing provision of insurance by groups affiliated with physicians and hospitals and self-insurance of health care organizations that employ physicians, foster access to liability insurance and create opportunities to improve health care quality and value. Some vulnerability to the impact of external economic conditions remains, and implications for midwives and birth centers are unknown. Liability insurance policies that impose restrictions on professional practice pose concerns.

Note: Although this brief discussion of liability insurance trends is not based on the more rigorous studies described in the introduction, it is included in the body of this report as a background to subsequent sections, as liability concerns that trouble health professionals are first and foremost insurance matters. With the exception of the relative impact on premium levels of such factors as insurance company practices, external economic conditions, and liability payouts, the information here is widely accepted and not controversial.

At least seven states require physicians to carry liability insurance. Such insurance is a precondition for benefitting from certain liability reforms in at least seven other states. Such insurance is also a precondition for staff privileges in most hospitals and of participation in many health plans (American Medical Association Advocacy Resource Center 2012). Many physicians buy insurance from a commercial or a physician-owned mutual company, either individually or through a group practice. The number of insurers offering liability policies to midwives has diminished in recent decades, as these policies have become less profitable. Hospitals and other health care entities purchase their own insurance or self-insure, and those that employ physicians and midwives typically cover both the hospital and its clinical staff (Jevitt and Johnson 2007; Mello 2006b).

Each of the three periods of intensified malpractice pressure since the 1970s generated concern about the affordability and availability of liability insurance coverage, which some viewed as crises. In the first and third pressure periods, many insurers concluded that other lines of insurance would be more profitable and/or involve less risk (Lei and Browne 2008) and exited from medical malpractice or reduced their vulnerability to risk (Mello et al. 2003). Reduced capacity fostered increased premiums.

Some states have assumed some responsibility as liability insurers or as organizers of insurance pools, such as joint underwriting associations and patient compensation funds, which complement commercial insurance. These are discussed in Part II.

Several important recent shifts in the liability insurance market have affected the availability and cost of liability insurance to health care providers and their exposure to liability risk. The impact on maternity care providers may be disproportionate due to their relatively high risk of liability. Notable trends include the following:

- Companies with strong ties to physicians and hospitals have replaced many commercial carriers. Affiliated companies generally have greater staying power, are more responsive to interests of policyholders, and do not cover midwives or birth centers (American College of Obstetricians and Gynecologists 2006; Danzon et al. 2004; Lee 1991; Mello 2006b).
- Many health care organizations are forming insurance companies that are wholly owned by a single facility or hospital system for the purpose of self-insurance; this approach exerts greater control over rates, avoids a risk pool with higher-risk facilities, and provides stable, relatively low-cost coverage to affiliated physicians (Berenson et al. 2003; Mello 2006b). Most practicing U.S. physicians are now employed by hospitals and integrated delivery systems (Kocher and Sahni 2011), giving these systems incentives and capacity to carry out quality improvement programs to reduce liability. While this poses special opportunities for maternity care practice due to its disproportionate risk of liability, we could not determine the extent to which maternity care providers practice within such arrangements.
- Insurers purchase reinsurance policies from other insurers to cover larger losses and reduce the capital they need on hand to cover losses. These policies became more expensive for both self-insured hospitals and medical malpractice insurers during the most recent period of malpractice volatility (Mello 2006b), in part impacted by catastrophic losses that reinsurers suffered on September 11, 2001, and by numerous weather-related events. To remain profitable, reinsurance premium rates increased.
- In markets with more severe liability insurance pressure, a form of experience rating is emerging. Traditionally, all physicians performing certain procedures have been community rated and assigned to a particular risk group with a fixed premium, with maternity specialists in a higher-priced tier due to their relatively high risk of claims. Individual physicians may now face higher premiums or even coverage rejection due to their malpractice judgment or settlement experience, and premium levels of groups may now be influenced by the liability experiences of member physicians (Berenson et al. 2003).
- There is a shift from occurrence policies, which cover all incidents during the policy period, even if a claim is filed afterward, to more meager claims-made policies, which cover only claims filed in the policy period and leave a long tail of exposure for incidents that could become claims thereafter. This shift enables carriers to better predict their costs but creates concerns about claims involving newborns, which often fall under an extended statute of limitations. The most recent professional liability survey of the American College of Obstetricians and Gynecologists (response rate 18%) found that 63% of respondents had claims-made policies, while 30% had occurrence coverage, and 8% had some other coverage or self-insurance (Klagholz and Strunk 2009). Most physicians with a claims-made policy also purchase a tail policy to cover claims filed after the policy period (Mello 2006b). A 2009 survey of members of the American College of Nurse-Midwives (response rate 23%) found that 31% had occurrence coverage, 16% had claims-made coverage alone, 26% had claims-made with tail coverage, and 26% did not know their type of coverage (Guidera et al. 2012). →

- To explain premium levels, physician, hospital, and insurer groups often point to the impact of rising litigation costs, and attorney and consumer groups point to insurer practices. Both factors played a role in the most recent hardening of the insurance market with attendant price increases (Mello 2006b). The economic downturn reduced insurers' return on investments, as did large increases in payouts and the frequency of claims in some states. Unwise business decisions in the 1990s (e.g., under pricing premiums and overextending subscriber bases) also appear to have contributed to steep premium increases (Studdert, Mello et al. 2004; Thorpe 2004). Some analysts sharply criticize insurer business practices for generating liability pressure (Americans for Insurance Reform 2005; Angoff 2005; Hunter and Doroshov 2002). Due to the lengthy period between liability insurance premium payments and either settlements or trial award payouts, insurers' return on investments is a major component of revenue, and loss expenses are uncertain, with potential for wide swings (Baker 2005; Weiler 2005). The U.S. General Accounting Office (now General Accountability Office) found that insurers' losses on paid claims were likely to be the primary cause of premium increases, with insurance cycle volatility and decreased investment portfolio income as secondary causes (2003). In multivariable analysis, Baicker and Chandra, found no relationship between the number and size of payments in each state and the level of premiums of obstetrician-gynecologists in the state between 1993 and 2001, suggesting that other factors (e.g., underwriting cycle, insurance market competitiveness, insurer losses on other investments) play a larger role in premium levels (2005b). Hyman and Silver identified three studies that found that the premium spikes that began in 1999 were largely precipitated by factors outside the medical malpractice system (2006).
- Insurers may be placing more limits on professional practice rather than leaving decisions to maternity care providers and women (Benedetti et al. 2006, Hale 2006). Some policies have exclusions and surcharges that constrain access to core services. For example, among the roughly 13% of women who give birth every year in the United States with a history of cesarean section, a large proportion desire the option of vaginal birth after cesarean (Declercq, Sakala et al. 2006). Further, repeat cesareans increase risks for numerous serious conditions in women and fetuses/newborns (Guise et al 2010). However, some policies exclude coverage for vaginal birth after cesarean, effectively forcing healthy women and newborns to undergo major surgery at increased cost to payers. Similarly, premium surcharges can pose barriers to choice of care provider and optimal use of the maternity care workforce. Surcharges have been imposed, for example, for inclusion of maternity care in the scope of family physician practice and for providing physician backup to midwives. Yet, exemplary research results clarify the quality of maternity care provided by these caregiver groups, as noted above, and vicarious liability is limited to employer/employee relationships (Booth 2007; King and Summers 2005).

See Appendix I for gaps in knowledge relating to medical liability underwriting for maternity providers: impact of claims-made policies on care providers; extent, impact, and ethics of liability-insurance-imposed practice restriction; impact of physician- and hospital-sponsored liability insurance products on midwifery and birth center providers; and access to liability insurance coverage of service providers with small risk pools.

The insurance cycle unsettles many health professionals, especially those in specialties with higher liability risks. Alternation between artificially high premium costs in hard markets and artificially low costs in soft markets poses fiscal challenges. Concern with legal liability matters waxes and wanes: hard markets fuel disaffection and create pressure for remedies, which dissipate in soft markets. These cyclical patterns inhibit development of more fundamental solutions to systemic problems (Baker 2005).

Maternity Care Provider Experience of Liability Insurance

Empirical studies find large variation in the cost of liability premiums to obstetrician-gynecologists across geographic areas and over time. Although their premium levels tend to be higher than those of most other specialists, premium costs amount to a relatively small and declining portion of overall expenses, and the high income of this specialty appears to have outpaced inflation up to the current period of economic dislocation. Large group practices, hospitals, and health systems generally provide liability insurance for the growing number of physicians whom they employ, insulating these clinicians from the responsibility of paying for liability insurance. The best current evidence suggests that liability insurance premiums have not threatened the economic viability of obstetrician-gynecologists. However, a procedure-intensive practice style (e.g., high rates of cesarean section) may contribute to the high income levels. Such care is not in the best interest of the primarily healthy population of childbearing women and babies and of payers and purchasers.

Most maternity care providers are covered by liability insurance. Forgoing liability insurance exposes them to great personal financial risk. Some states and medical facilities require physicians to have a minimum level of coverage (Kern 2011). The high cost of liability insurance has been a persistent concern among maternity care providers, and they have especially advocated for reforms aimed at reducing this expense.

The Medical Liability Monitor, a publisher of news about the medical liability insurance market, surveys U.S. insurers annually about malpractice insurance premium levels of obstetrician-gynecologists (as well as general surgeons and internists) for a single loss of up to \$1 million and total losses up to \$3 million in a policy year. Obstetrician-gynecologist premiums vary considerably across states and markets within states. In the current liability cycle, premiums for this specialty spiked as high as \$299,420 in 2005 and 2006 (Miami-Dade County in Florida, with the next highest rate both years in Cook County in Illinois, at \$266,349). By the 2009 survey, the most expensive premiums for this specialty group were still in Miami-Dade County, but had dropped by about one-third, to \$201,808 (with Nassau and Suffolk Counties in New York the next highest, at \$194,935). In 2012, highest premiums for this specialty were in Nassau and Suffolk Counties (\$204,684), followed by Miami and Dade Counties (\$201,808). By contrast, the lowest premiums for this specialty group have been between \$13,400 and \$20,000 throughout the period 2004–2012 (Albert 2004; Gallegos 2011, 2011b; Krupa 2012; Sorrel 2006, 2007, 2008, 2009). In 2012, the lowest premiums for this specialty were in Nebraska (\$14,286) and 14 California counties (\$15,484). In assessing what many have viewed as malpractice insurance “crises,” it is important to consider the absolute level of premiums, their change from year to year and between hard and soft insurance cycle phases, and inflation (Mello 2006b).

We reviewed Medical Liability Monitor data for the level of coverage noted above for obstetrician-gynecologists from 2000 through 2009. Adjusted for inflation, their premiums rose sharply in the first half of the decade and declined more slowly in the second half. Figure 1 presents state-level average obstetrician-gynecologist premium level for standardized coverage in 2009. We weighted the data by insurers' market shares (National Association of Insurance Commissioners 2009) and distribution of physicians within the state (Smart 2009). The results reveal the broad range in premium levels, variation across states, and some regional correlation, but do not show differences across markets in many states. State averages ranged from below \$25,000 to above \$100,000, with about one-half of states falling in the \$25,000 to \$50,000 range. Overall, this specialty's premium levels have been higher than those of general surgeons and internists in the annual surveys (Albert 2004; Sorrel 2006, 2007, 2008, 2009).

Sources: Medical Liability Monitor 2009
National Association of Insurance Commissioners 2009
Smart 2009

Annual compensation surveys of the Medical Group Management Association found that the *median* obstetrician-gynecologist compensation grew from \$237,191 in 2003 to \$280,629 in 2007. This increase of over 18% exceeded both the 12% overall increase across seventeen medical specialties and inflation during this period (Medical Group Management Association 2008). However, the 2010 median compensation of \$281,190 reflected a leveling off and inflation-adjusted decline of -4.22% over the period 2006-10, (Medical Group Management Association 2011). This loss of ground occurred during a soft phase of the liability cycle with moderating premium levels and broader economic shifts during this period. These comparisons should be viewed in a broader context: physician earnings are among the highest of any occupation in the nation (U.S. Department of Labor, Bureau of Labor Statistics, 2012b).

Other recent comparative reports of physician compensation suggest that obstetrician-gynecologists experience general economic stability and security, and a favorable economic position among medical specialties:

- In a multivariable analysis of physician wages from the nationally representative 2004-05 Community Tracking Study, investigators found obstetrician-gynecologist *mean* wages to be below those of specialty surgeons and specialties deploying sophisticated technologies and drugs, similar to the general surgery reference and many other specialty groups, and above other specialty groups and all primary care physicians (Leigh et al. 2010).
- The U.S. Department of Labor, Bureau of Labor Statistics reported 2011 mean earnings of obstetrician-gynecologists, six other medical specialties, and all other physicians, from the Occupational Employment Statistics survey. At \$218,610, obstetrician-gynecologist incomes were well above general internists (\$189,210), “all others” (\$184,650), family physicians/general practitioners (\$177,330), psychiatrists (\$174,170), and general pediatricians (\$168,650). Only surgeons (\$231,550) and anesthesiologists (\$234,950) had higher incomes (2012a).
- *Modern Healthcare’s* 2010 Physician Survey compiled compensation figures from 15 sources, with average obstetrician-gynecologist salaries ranging from \$247,680 to \$420,000, and 2009-10 change exceeding inflation (Robeznieks 2011).
- An analysis of data from the Faculty Salary Survey of the American Association of Medical Colleges found that over the period 2000-01 to 2008-09, all general obstetrician-gynecologist and maternal-fetal medicine faculty members experienced annual salary growth that kept up with inflation or, in the case of maternal-fetal medicine specialists at associate professor and professor ranks, exceeded inflation. Calculations exclude the value of liability insurance (likely a benefit), other benefits, and outside earnings (Rayburn et al. 2011).

A survey of overhead expenses in 2003 across nine specialty groups placed liability premium expenses in broader perspective (Table 1). The average percentage of all revenues required for malpractice premiums ranged from 1.6% (cardiologists) to 8.1% (obstetrician-gynecologists), a five-fold difference. When looking at the mean portion of revenue required for overhead expenses, obstetrician-gynecologists were near the high end of the range (59.8%), spending nearly fifty percent more of their revenue on overhead than the lowest group, gastroenterologists (41.5%) (Pennachio 2005). Liability expenses were below 14% of this specialty’s overhead costs during a year within the hard phase of the current liability cycle.

Despite their high risk of liability, obstetrician-gynecologists sustain a higher net income than many other types of physicians. *Medical Economics* reported figures from its annual 2009 survey of physician earnings, expenses and productivity for obstetrician-gynecologists, pediatricians, family physicians/general practitioners, and internists. The survey found that although obstetrician-gynecologists had by far the highest malpractice premiums among the four groups in 2008 (\$45,000 versus \$12,500 for the others), they also had a far higher median net income — \$237,500 — than the others, whose incomes ranged from \$162,500 for internists to \$187,500 for pediatricians (Weiss 2009a, 2009b).

Table 1. Physician Expenses for Liability Insurance and Total Overhead by Specialty, United States, 2003

Specialty	Malpractice Amount	Malpractice % of Receipts	Overhead Amount	Overhead % of Receipts
Obstetrician-gynecologists	\$46,157	8.1	\$340,959	59.8
General surgeons	\$31,207	6.1	\$227,111	44.5
Orthopedic surgeons	\$33,247	4.4	\$396,880	52.2
Internists	\$12,682	2.9	\$243,186	55.8
Family physicians (maternity care)	\$12,228	2.7	\$267,221	58.8
Family physicians (no maternity care)	\$11,953	2.7	\$271,547	61.2
Pediatricians	\$10,122	2.2	\$275,164	59.3
Gastroenterologists	\$15,747	2.1	\$310,887	41.5
Cardiologists (invasive)	\$15,514	1.6	\$449,691	45.4

Source: *Statistics: Medical and Dental Income and Expense Averages, 2004 Report Based on 2003 Data*, reported by Pennachio (2005)

Analyzing surveys conducted by the American Medical Association (AMA) from 1970 to 2000, Rodwin and colleagues found that premium increases from 1996 through 2000 had little impact on total practice expenses or net practice income for all physicians and separately for obstetrician-gynecologists (2006). They reported that premiums for obstetrician-gynecologists decreased as a percentage of total expenses from 20% in 1986 to 13% in 2000. Considering those in the top liability premium level quartile in 2000, premiums as a percentage of total expenses were either similar to or less than the overall mean, for all physicians and separately for obstetrician-gynecologists and two other specialties at high liability risk. They reported that malpractice premiums have long been a small part of practice costs, in all regions and for specialties at high liability risk, while non-premium practice expenses have steadily increased in recent decades. Obstetrician-gynecologist premium increases were less than one-twentieth the size of increases in non-premium expenses from 1996 to 2000 (Rodwin et al. 2006).

These investigators provided figures showing that, for all physicians and for each of the three groups at higher risk of liability, inflation-adjusted net income declined from 1996 to 2000, primarily due to increases in non-premium expenses; decreased practice revenue contributed to this net income decline for

physicians overall and surgeons and anesthesiologists in particular. Obstetrician-gynecologists experienced an increase in total inflation-adjusted revenue during this period. The investigators found that increased premiums after 2000 continued to have a “negligible effect” on total practice costs. They concluded that the perceived crisis in liability premium expenses does not reflect a full assessment of changing economic circumstances for physicians, and hypothesized that the emotional nature of medical malpractice issues makes it difficult to place liability premiums in perspective. Although the AMA studies used for this analysis ceased in 2000, the investigators stated that their analysis suggests that even if premiums rose by as high a rate of growth as the 2003 Medical Liability Monitor reported, 2003 premiums remained a small portion of total practice costs (Rodwin et al. 2006).

Lacking a national data source, a follow-up study looked at premium levels from 1975 through 2005 in Massachusetts, a state with high median (ranked fourth among 51 jurisdictions) and mean (ranked sixth) settlement payments (Rodwin et al. 2008). The AMA had designated Massachusetts as a liability Crisis State during the last two years of this analysis (Albert 2005; Tokarsky 2004). With adjustment for inflation, discounts, and surcharges, Rodwin and colleagues found that only tier one physicians (obstetrician-gynecologists, neurosurgeons, and orthopedic spinal surgeons) had notably higher premiums in 2005 than in 1990. In 2005, 29% of Massachusetts obstetrician-gynecologists paid less than 1990 rates, 44% paid \$8,700 to \$18,400 more than 1990 rates, and 24% paid \$28,150 or more than 1990 rates. The mean premium rate for this specialty group in 2005 was \$85,979 (Rodwin et al. 2008). Nationally, 2005 fell within the hard phase of the current liability cycle. To explain the discrepancy between their results and widespread belief that physicians in many areas face a crisis of liability premium affordability, the researchers proposed that many observers fail to adjust for inflation, overlook premium discounts, ignore premium declines in soft market phases and thus modest overall increases, and use unreliable data (Rodwin et al. 2008). For example, a *Medical Economics* physician survey reported an 18% decline in average premiums of obstetrician-gynecologists from 2007 (\$55,000) to 2008 (\$45,000) (Weiss 2009a).

These studies are based on averages, and the impact of liability insurance premium levels may be much greater for safety net providers and organizations, with a high proportion of generally lower Medicaid payments. We did not find data to better understand this matter. We also did not find maternity-specific data taking into account the recent steep growth in professional health information technology expenses (Fellows 2012).

Using national data from many single-specialty physician group practices from 1994 to 2002, Pauly found that higher liability premiums did not lower net physician incomes. Instead, by increasing volume of profitable medical services and sometimes increasing prices, physicians offset the effect of higher premiums on their incomes. Analysis of a subset of surgical specialties — primarily general surgeons and obstetrician-gynecologists — found the same pattern of net income stability despite increasing malpractice premiums. This “forward shifting” transfers money from consumers and payers to insurers to physicians. Although obstetrician-gynecologists devoted a larger percentage of total revenue to malpractice costs, their net income was the highest among the specialties examined (Pauly 2006). A similar capacity of this specialty to pass increased premium costs to patients was found in the 1980s (Mehlman 1994).

Others have found that physician charges for telephone consultations, paperwork, and other services that previously did not incur separate billing defray liability insurance increases (Fleck 2004; Higgins 2005; Rubin 2004). They appear able and willing to pass much of the cost of an adverse financial climate (e.g., both premium and non-premium practice expense increases, tightened reimbursement) to payers via health insurers.

We must interpret with caution widely publicized self-reports in surveys about the impact of liability premiums on maternity providers. For example, many obstetrician-gynecologists in both Missouri and Washington State reported either securing a loan or liquidating assets to cover liability insurance (Amon and Winn 2004; Benedetti et al. 2006). In the most recent American College of Obstetricians and Gynecologists member Survey on Professional Liability, 59% of respondents reported having made one or more changes to their practice due to the affordability and/or availability of liability insurance (Klagholz and Strunk 2009). The surveys do not consider the impact of competing factors on these behaviors. Premium concerns may have been quite salient for respondents, but the studies described above suggest that the size and growth of other practice costs and impact of tightened reimbursement may have been greater actual sources of economic pressure. Response rates, which were 18% in the national survey (Klagholz and Strunk 2009) and 20% (Amon and Winn 2004) and 55% or higher (Benedetti et al. 2006) in the state surveys, also make the results difficult to interpret.

The American Academy of Family Physicians (AAFP) 2011 survey of family physicians found that 19% of respondents attended vaginal births in hospitals. Whereas 14% of urban-based respondents attended vaginal births, 36% of those in rural areas did so. Questions about several possible explanations for not attending vaginal births found that liability issues were not prominent. Most respondents chose “not desired” (72%), 5% indicated that the cost of liability insurance is prohibitive, and 1% cited fear of lawsuits. The survey response rate was 13%, and results were weighted to match the demographic profile of the organization’s membership (AAFP 2011).

Available research suggests that cost shifting may be insulating net incomes of obstetrician-gynecologists from any increases in liability insurance and other practice costs. These analyses are consistent with recent trends in maternity care. Intensified use of childbirth technologies can generate revenue efficiently. For example, national surveys have documented high rates of elective labor induction and induction for reasons that are not supported by best evidence (e.g., the fetus may be large) (Declercq et al. 2002; Declercq, Sakala et al. 2006; Mozurkewich et al. 2009; Sanchez-Ramos et al. 2002). Prenatal caregivers benefit from elective induction by being able to attend the birth and bill for the lucrative labor and birth segment of maternity care — in 2010, payments to maternity care providers for this segment of care involved from 70% to 84% of total maternity care professional fee payments, depending on payer and mode of birth (Truven Health Analytics 2013).

Similarly, the national cesarean rate has increased by 50% over the past decade and reached record levels annually from 2000 through 2009 (Hamilton et al. 2010; Martin et al. 2012), with increases across all population segments including women at low risk and with no possible indication for this procedure on birth certificates (Declercq, Menacker et al. 2006). National analyses identified an almost random pattern of cesarean section in the nation’s largest hospital system (Clark, Belfort, Hankins et al. 2007) and found that higher rates involved increased use of major surgery in healthy women (Baicker et al. 2006). Subjective indications (e.g., non-reassuring fetal status, labor arrest disorders) may account disproportionately for recent increases (Barber et al. 2011). This procedure is associated with greatly increased revenue, with average additional payments of \$1,464 to physicians and \$7,518 to hospitals relative to vaginal births in a national analysis of 2010 employer-sponsored coverage (Truven Health Analytics 2013). When planned and undertaken before labor, cesarean section can be scheduled at a convenient time and carried out quickly.

As reported by the Medical Group Management Association (2008) and the American Medical Group Association (2006), the median incomes of obstetrician-gynecologists in group practice rose steeply in the early to middle years of the initial decade of the century, the most recent period of intensified malpractice pressure. The environment of tightened reimbursement and increased premiums and other practice costs appeared to be driving medical practitioners generally to respond to unintended payment system incentives (Ginsburg and Grossman 2005). As the Medicare Resource-Based Relative Value Scale, which sets a national standard for physician payment in all clinical areas, already includes components for liability premium and other practice expenses that are calibrated by specialty and geographic area and periodically adjusted (see Appendix I), procedure intensification could indeed lead to a rapid increase in net income.

Finally, trends of clinician consolidation into larger clinical groups and clinician employment by often self-insured hospitals and health systems (Berenson et al. 2003; Mello 2006b; Kocher and Sahni 2011) mean that historic concerns of maternity care providers about the fact and size of liability insurance premiums may no longer exist for a growing proportion of these clinicians who receive liability insurance coverage as a benefit of employment.

See Appendix I for gaps in knowledge relating to maternity care provider experience of liability insurance, specifically, the adequacy of liability insurance components built into professional fee schedules; impact of the corporatization of medicine on liability insurance coverage; and impact of liability insurance premiums on the full complement of maternity caregivers and settings, including safety net providers.

Maternity-Related Claims and Payouts

The specialty of obstetrics and gynecology is an outlier with respect to the large number of closed (resolved) claims, the relatively high rate of indemnity payouts to compensate for injury among closed claims (with most occurring in the obstetrics area of practice), and the high level of payments. Claims associated with newborns are more common and costly than maternal injury claims. The number of claims paid out on behalf of obstetrician-gynecologists, percentage of payouts (settlements or trial awards) to defendants among claims, and total cost of those payouts appears to be declining substantially over time.

Maternity-related claims and lawsuits take place within the civil legal system. They begin when a patient or patient's representative believes that injury has resulted from negligence in carrying out a duty of care. The traditional medical malpractice litigation process involves the following key steps and phases, with resolution by settlement possible during any phase and many claims dropped or dismissed before trial:

- Incident, followed by informal investigation, etc. before any filing of a claim
- Filing of claim, followed by pleading phase to define claims and defenses and discovery phase to investigate facts of dispute
- Summary judgment to discourage non-meritorious litigation
- Pre-trial conference or hearing to eliminate non-meritorious claims, facilitate a settlement, plan for a trial, etc.
- Trial phase
- Verdict with jury resolution of dispute, followed by appeal phase (Metzloff 1992).

To win a malpractice case, a plaintiff and legal team must show that the defendant owed a “duty of care,” that the defendant was negligent in meeting the standard of care, that the plaintiff was harmed as a result, and that the plaintiff suffered financial, physical, and/or emotional damages. The standard of proof for such civil cases is the preponderance of evidence, that is, these were more likely than not to have occurred.

Relative to most other specialties, malpractice claims against obstetrician-gynecologists tend to be more frequent and costly. Injury compensation is especially costly for a newborn facing lifelong disabilities. Obstetrician-gynecologists also tend to face high premiums as surgeons, who are at higher risk for malpractice litigation than most other medical specialties. Notable risk exposure exists for many common aspects of childbirth care, including use of synthetic oxytocin, misoprostol, elective labor induction, assisted vaginal birth, cesarean section, and vaginal birth after cesarean; interpreting fetal heart rate patterns; supporting women during the pushing phase of labor; attending multiple gestation births; and resuscitating newborns (Simpson and Knox 2003).

Although about 4% of practicing physicians are obstetrician-gynecologists (Smart 2009), for the period 1985 through 2005, the specialty was involved with 14% (29,453) of closed, or resolved, claims in the database of the Physician Insurers Association of America (PIAA), a trade association of medical liability insurance companies. Among twenty-eight specialties, none had more closed claims. This specialty ranked second in the likelihood that a closed claim involved a payment to the plaintiff (36%) and fifth in median indemnity (injury compensation) payments made directly to plaintiffs (Carroll and Budenbaum 2007). When extended from 1985 to 2010, the number of closed obstetrician-gynecologist claims in the PIAA database fell to second place, exceeded by claims against the much larger specialty of internists, and the single largest payment for damage, \$13 million, was awarded on behalf of an obstetrician-gynecologist (Yates 2012). (These data exclude some groups of physicians, including those employed by self-insured corporations.)

The PIAA database reveals several favorable trends for this specialty. First, the number of claims that were paid in settlements or trial awards declined by 44% between the period 1986-1991 and the period 2006-2011. Second, the percentage of claims that were paid declined from 37% in 1986 to 1990, to 32% from 2006 to 2010. Further, when claims for both periods are standardized to 2010 dollars, the amount paid out more recently declined by \$138 million (Yates 2012).

The National Practitioner Data Bank includes records of malpractice payments on behalf of health care providers (self-insured corporations are not required to report). This Data Bank indicates that 16,764 payments were made for obstetrics-related claims from 1990 to 2003, with a mean of \$377,305 and median of \$200,000. While payment levels have increased over the years, investigators apparently did not adjust for inflation. For the 1,255 obstetrics-related payments made in the United States in 2003, the mean was \$475,880 and the median was \$290,000. From 1990 to 1996, the Data Bank indicates, payments totaling \$2,824,280,036 were made for obstetrics-related claims (Blickstein et al. 2007). Public Citizen found that payouts for settlements and awards on behalf of obstetricians (apparently excluding gynecologic payouts) in the Data Bank remained steady at about 9.5% of all payouts from 1991 through 2004 (2005b).

The 2007-08 Physician Practice Information survey of the American Medical Association found that obstetrician-gynecologists and general surgeons had similar and highest rates of ever being sued, of being sued two or more times, and of the number of claims per 100 physicians, relative to ten other specialties and specialty groupings. The data were weighted to correct for possible non-response bias (Kane 2010).

The American College of Obstetricians and Gynecologists (ACOG) conducted the most recent of an ongoing series of liability surveys among its members in 2009. Results are difficult to interpret, as the 18% response rate may involve selection bias. Most respondents (74%) provided both obstetric and gynecologic care, and 6% solely provided obstetric care. Ninety-one percent of respondents indicated that they had had at least one professional liability claim filed against them during their careers. Of these, 43% had had at least one such claim filed against them for care provided during their residencies. The average number of claims filed against them during their careers was 2.7. From 2006 through 2008, 2,796 claims were filed against 4,334 respondents, with 45% reporting one or more such claims during that period. Of these, 62% involved obstetric care, and 38% involved gynecologic care (Klagholz and Strunk 2009).

In the ACOG survey, hospitals were the most common co-defendants (43%), followed by obstetrician-gynecologists associated with the defendant's practice (30%), residents (16%), nurses (14%), and obstetrician-gynecologists outside of the defendant's practice (12%). Other co-defendants were anesthesiologists (6%), pediatricians or neonatologists (4%), nurse-midwives (4%), family physicians (3%), and nurse practitioners (1%) (Klagholz and Strunk 2009).

In the most recent ACOG professional liability survey, the most likely primary allegation of an obstetric claim was a neurologically impaired infant (31%), followed by stillbirth/neonatal death (16%). Most closed claims (53%) were dropped or settled without a payment on behalf of the physician. Of the closed claims involving payment, 31% settled before a trial or verdict, 3% were closed through dispute resolution procedures, and 13% through a jury or court verdict. The average payout for claims involving a neurologically impaired infant was \$1,055,222 (Klagholz and Strunk 2009).

While not reported for the 2009 survey, the 2003 survey found that of the 9% of closed claims that went to trial, 81% were resolved in favor of the physician (Cohen et al. 2005). An analysis of claims submitted to a nationwide liability insurer and closed between 2002 and 2005 found that 48% of obstetrician-gynecologist claims were dismissed, and 41% were resolved before a trial verdict; of the 11% that went to trial, 90% of verdicts favored the physician (Jena et al. 2012).

The data-sharing project of the Physician Insurers Association of America showed that the median size of payments for injury for obstetrician-gynecologists between 1985 and 2005 was around \$120,000 (using 2005 dollar value). The mean defense-related expenses for an obstetrician-gynecologist claim between 1985 and 2005 were slightly above \$25,000 (using 2005 dollar value) (Carroll and Buddenbaum 2007).

A survey of members of the Central Association of Obstetricians and Gynecologists (CAOG) investigated the association between claims among obstetrician-gynecologists and characteristics of the defendants. The response rate was 73%, and the authors argue that their overall findings are likely to apply to members of the American College of Obstetricians and Gynecologists as the respective memberships are demographically similar. The study identified the five most common causes of claims as newborn brain damage, gastrointestinal or genitourinary injury, fetal death, missed diagnosis of cancer, and maternal death, accounting for 30% of claims. Further data analysis found no strong relationship between 1) physician demographics (age, gender, ethnicity, marital status, location and type of practice, year of residency completion, year of board certification, type of subspecialty) and number of liability claims; 2) type of injury and settlement amount; or 3) payment at settlement or trial verdict and cost of liability insurance. Female physicians were more likely than male physicians to be claim-free, to have cases dismissed or dropped, and to experience fewer claims. However, verdicts at trial were similar for both groups (Chauhan et al. 2005).

On average, CAOG members experienced a claim every 11 practice years, provided a deposition every 15 practice years, had a dropped or dismissed claim every 21 practice years, had a settlement every 39 practice years, had a trial every 70 practice years and had a settlement of at least \$1 million every 588 practice years. Among respondents, 22% had not experienced any litigation, and an additional 23% had not paid to settle. Although 29% of respondents had made a payment, and 26% of respondents had proceeded to a trial, the median settlement was \$100,000, and the vast majority (85% for female and 83% for male respondents) of verdicts at trial favored the physician (Chauhan et al. 2005).

A more recent study of claims from 1991 through 2005 handled by an insurer offering policies in all fifty states and the District of Columbia found that while 74% of obstetrician-gynecologists faced a claim by age 45 and 97% by age 65, 30% faced claims involving payment for injury by age 45, and 71% by age 65. The percentage of obstetrician-gynecologists experiencing claims with indemnity payments by 45 and by 65 were higher than physicians in the other five reported specialties or specialty groupings (Jena et al. 2011).

Two recent studies shed light on the liability experiences of maternal-fetal medicine (MFM) subspecialists. The Society for Maternal-Fetal Medicine adapted the national liability survey of the American College of Obstetricians and Gynecologists for its members, and 50% responded to the survey. The survey found that almost 80% of MFM subspecialists had had at least one claim filed against them (not significantly different from 76% for general obstetrician-gynecologists). Other differences were significant: they had on average experienced 3.9 claims against them (50% greater than general obstetrician-gynecologists), 29% of all MFM claims went to trial (versus the significantly lower 9% for general obstetrician-gynecologists), and 70% of cases that were tried were resolved in favor of the MFM subspecialists, in comparison with 81% of generalist-tried cases (Cohen et al. 2004; Cohen et al. 2005).

Using data from Massachusetts, Barbieri found that for the period 1996–2005, 38.6% of obstetrician-gynecologists made at least one professional liability payment, and the proportion of MFM subspecialists who made a payment was significantly less: 3.7%. However, the average payment per claim for MFM subspecialists (\$1,950,000) was more than four times as great as the average payment per claim for obstetrician-gynecologists (\$447,983) (Barbieri 2006).

A national liability survey of members of the American College of Nurse-Midwives (ACNM) was carried out in 2009, and the response rate was 23%. About one-third (32%) had been named in a lawsuit, and one-third of those had been named in two or more lawsuits. Compared with those who had not been named in a lawsuit, those named were older, had attended more births, were more likely to practice in Region II (DE, NJ, NY, PA, PR, VI), and less likely to practice in Region V (Southwest and Midwest). The hospital was the most common care setting involving the lawsuit (69%), and freestanding birth centers (4%) and homes (2%) were the least common settings. Most suits (90%) involved maternal or newborn care, and 65% of those were related to intrapartum care. Fewer than 5% involved gynecologic care (Guidera et al. 2012).

Among participants in the ACNM 2009 survey who were named in a lawsuit, 25% were dropped individually, 15% had cases dropped without a settlement, and 35% paid settlements. Of the 13% of cases that proceeded to a trial or arbitration, most (59%) involved awards to plaintiffs, and 41% favored the midwife. The remaining 14% were unresolved at the time of the survey (Guidera et al. 2012).

Closed claims analyses reveal that maternity care claims involve many health outcomes and care practices (e.g., Angelini and Greenwald 2005; Clark, Belfort, Dildy et al. 2008; White et al. 2005). The use of many different classification systems in these analyses makes a broader summary of trends difficult.

See Appendix I for gaps in knowledge relating to maternity litigation experience, specifically, experiences of the full complement of maternity caregivers, the extent of non-meritorious claims, including those with serious injury and no negligence; the accuracy of maternity caregivers' understanding of their risk of liability; and claims and lawsuits among safety net providers and disparity populations.

Incidence of Negligent Injury, Compensation for Claims, and Maternity Care Patient Safety

A large, carefully conducted state-level study with random samples found that about 0.6% of childbearing women and about 0.2% of newborns sustained negligent injury while receiving care in U.S. hospitals. That study and a replication study in two additional states found that the negligent injury rate in hospital labor and delivery units was in the range of 0.8% to 1.8%. While childbearing women may be several times as likely to sustain negligent injury as newborns, current evidence suggests that the injuries of newborns are more severe. Subsequent research has clarified that the initial landmark studies, which covered hospital care generally, greatly underestimated rates of harm, but replications in maternity care have not taken place.

Major studies conducted in New York (1984) and in Colorado and Utah (1992) provide the best population estimates of medical injury in the United States. Both examined the extent of adverse events and the proportion that can be attributed to negligence in random samples of hospital records, and as judged by trained clinicians. The path-breaking Harvard Medical Practice Study evaluated 30,121 random records from fifty-one acute hospitals in New York in 1984. Investigators found that 1.5% of maternal hospitalizations involved adverse events, and negligence was associated with 38.3% of those, while 0.6% of newborn hospitalizations involved adverse events, and negligence was associated with 25.8% of those (Table 2) (Brennan et al. 1991). Results were also reported by site of care. The adverse event rate in the labor and delivery room was 2.8%, with 27.7% of those attributed to negligence, and 9.8% of adverse events were associated with serious disability (Table 2) (Leape et al. 1991).

As expected in these primarily healthy populations, both mothers and newborns experienced lower-than-average rates of adverse events. However, the mothers experienced the highest rate of negligence among adverse events across ten clinical areas, with 38.3% of their adverse events deemed negligent (Brennan et al. 1991). Extrapolating these rates of adverse events due to negligence to all U.S. hospital births in 1984, an estimated 23,118 adverse events due to negligence occurred among childbearing women, and 7,262 such events occurred among newborns (National Center for Health Statistics 1986, 1987). While liability concerns around the time of birth have primarily focused on the welfare of fetuses and newborns, this well-conducted study found that adverse events due to negligence occurred more than three times as often in mothers as in babies. However, the overall severity of newborn injuries appears to be worse than the severity of maternal injuries.

Thomas and colleagues replicated this research with random samples from Colorado and Utah in 1992. Despite differences in environments and populations across the three states and measurement at hard versus soft periods in the liability cycle, overall results were remarkably similar. Several maternity statistics from the replication study are comparable to data from the New York study. About one-quarter of the maternal discharges with adverse events were rated as having been caused by negligence. In combined Colorado and Utah data, the labor and delivery area had an adverse event rate of 6.5%, with 27.8% of those events due to negligence, resulting in an overall 1.8% rate of adverse events due to negligence (Table 2) (Thomas et al. 2000).

Table 2. Rate of Adverse Events and of Associated Negligence and Disability in Random Hospital Discharge Samples

	New York 1984	Colorado 1992	Utah 1992
All care			
Discharges	30,121	10,000	5,000
Adverse events	3.7%	2.9%	2.9%
Negligence among adverse events	27.6%	27.5%	32.6%
Adverse events due to negligence	1.0%	0.8%	0.9%
Labor and delivery room/area site of care			
Adverse events	2.8%	6.5%	
Negligence among adverse events	27.7%	27.8%	
Adverse events due to negligence	0.8%	1.8%	
Serious disability among adverse events	9.8%		
Maternal care diagnostic related groups			
Adverse events	1.5%		
Negligence among adverse events	38.3%	25.8%	
Adverse events due to negligence	0.6%		
Newborn care diagnostic related groups			
Adverse events	0.6%		
Negligence among adverse events	25.8%		
Adverse events due to negligence	0.2%		
Postpartum type of adverse events *			
Negligence among adverse events		25.5%	
Permanent disability among adverse events		0%	
Permanent disability among negligent adverse events		0%	
Neonatal type of adverse events †			
Negligence among adverse events		25.3%	
Permanent disability among adverse events		29.8%	
Permanent disability among negligent adverse events		19.3%	

* Postpartum limited to vaginal births.

† With just eighteen postpartum and twenty-nine neonatal adverse events in the sample, New York data are limited for describing rates of negligence and permanent disability among adverse events.

Sources: Brennan et al. 1991; Leape et al. 1991; Thomas et al. 2000

These landmark studies of health care and liability clarified that adverse events, overall and attributable to negligence, occur in mothers, babies, and others in U.S. hospitals on a scale that had not previously been recognized. They played a key role in leading to and framing the Institute of Medicine's landmark report, *To Err Is Human: Building a Safer Health System* (2000) and in fostering the patient safety movement. Subsequent careful prospective studies suggested that the initial landmark studies and others relying on record review greatly underestimated rates of error and injury (Classen 2011; Leape 2000; Leape and Berwick 2005).

The New York State investigators have reported experience with claims and their disposition, and the Utah and Colorado investigators have reported experience with claims, without providing breakdowns by clinical area. Available evidence, not separately reported for maternal and newborn populations (see Appendix I), suggests that claims are filed by or on behalf of just about 2% of those who experience negligent injury, with indemnity payments going to less than 1% of those who sustain negligent injury.

More recent studies of the safety of maternity care are consistent with the earlier studies and evolving understanding of patient safety concerns:

- At the start of a comprehensive quality improvement program, an academic medical center had an Adverse Outcome Index rate above 3%, indicating the proportion of women with one or more index events occurring to herself or her newborn; the team nearly halved this rate over eleven quarters of the quality improvement program (Pettker et al. 2009).
- Another teaching hospital reported that 6% of birthing women experienced at least one adverse event from 1999 through 2000, a figure that was reduced to 5% over the four years of a patient safety program (Nielsen and Mann 2008).
- The National Nosocomial Infections Surveillance System, which tracks hospital-acquired infections, measured three health care-associated infections per 1,000 patient days in hospital well-baby nurseries (19,059 total) and seven such infections per 1,000 patient days in high-risk nurseries (33,269 total) in 2002 (Klevens et al. 2007). The combined samples represented 1% of liveborn babies discharged from U.S. hospitals in the Nationwide Inpatient Sample (Agency for Healthcare Research and Quality 2012).
- A neonatal intensive care unit (NICU) trigger tool for detecting adverse events applied to random charts drawn from 15 NICUs found an adverse event rate of 0.74 per newborn, with the majority considered to be preventable. The hospitals' standard occurrence reporting systems identified just 8% of these events (Sharek et al. 2006).

In maternity care, the present liability system appears to encourage a high degree of risk aversion with respect to the rare but catastrophic outcome of a newborn with serious disabilities or death. However, similar incentives to avoid what appears to be a more extensive problem of adverse events and negligence in childbearing women do not appear to be present. The current system also fails to take many opportunities to avoid lesser adverse events in newborns, for example, by avoiding or delaying elective delivery to increase gestational age (Clark, Miller et al. 2009; Kuehn 2010; Tita et al. 2009). This is consistent with the leading obstetric claims allegations (neurologically impaired infants and stillbirth/neonatal death, which in one typology of injury accounted for 46% of all active obstetric claims during the period

2003 through 2005) and very high payouts for these conditions, noted above (Klagholz and Strunk 2009). Closed claims analyses suggest that maternal allegations may compose 10% or fewer perinatal claims (Angelini and Greenwald 2005; Clark, Belfort, Dildy et al. 2008). We did not find any analyses of the pathway from maternal event to filing of negligence claims and their resolution.

A related question is the extent to which occurrences leading to filed and paid claims deviated from the standard of care. The medical director of Women and Newborn Clinical Services for the nation's largest hospital system summarizes results of work with numerous hospital systems and major malpractice insurers over several decades:

Regardless of carrier, state, or year, one figure has seemed to remain constant: When closed claims are confidentially reviewed by practicing physicians and defense lawyers, about 75% of all paid claims are, in the judgment of these *defense* consultants, the result of violations of the standard of care having caused an injury (Clark 2009b).

He concludes that health systems and professionals can readily impact about three-quarters of filed claims by improving flawed delivery systems (Clark 2009b).

See Appendix I for gaps in knowledge related to rates of negligent injury in maternity care and compensation for it, specifically, current rates of maternal and newborn negligent injury; whether the liability system deters maternity-specific negligent injury; the extent to which maternity-specific negligent injury is litigated and compensated; the proportion of maternity-related claims and costs associated with negligent and avoidable injury; the proportion of payments that goes to legal expenses versus injury compensation; negligent injury claims and damages recovery in disparity populations; and maternal versus newborn patterns in these matters.

Defensive Maternity Care Practice

Defensive clinical practice is a deviation from sound practice that is carried out primarily to reduce the care provider's risk of liability rather than to benefit the patient (Hershey 1972). "Positive" or "assurance" defensive behaviors involve providing additional services of marginal or no clinical value to demonstrate that efforts were made to avoid adverse outcomes. The intent is to discourage malpractice claims or be positioned to withstand them. Practices such as ordering an ultrasound scan, referring to a maternal-fetal medicine subspecialist, or performing a cesarean are "overused" assurance behaviors when done primarily to reduce the risk of liability. They pose quality and cost problems in exposing patients to needless risk and wasting resources. "Negative" or "avoidance" defensive behaviors reflect clinicians' efforts to avoid legal risk (Studdert et al. 2005). Avoidance behaviors — such as discontinuing providing any maternity care or maternity care for higher-risk women due to liability concerns and unwillingness to practice in localities with greater liability pressure — can create access problems. Defensive practice is widely viewed as being particularly worrisome in obstetrics-gynecology, a high liability risk specialty.

Evidence from Professional Self-Reports

Surveys and commentaries of maternity professionals raise concerns about the impact of liability pressure on defensive behavior, but can be of limited value if the diverse drivers of practice decisions are not included and response rates are low. Concerns have been raised about the accuracy of the estimates and about incentives to overstate defensive behavior as justification for tort reform. Considerable gaps have been documented between decisions that health professionals predict and those they actually make.

In the most recent American College of Obstetricians and Gynecologists (ACOG) member Survey on Professional Liability, 63% of respondents reported having made one or more practice changes due to the risk or fear of malpractice claims or litigation. Respondents reported decreasing the number of high-risk obstetric patients (30%), increasing the number of cesarean deliveries (29%), and stopping performing or offering vaginal birth after cesarean (VBAC) (26%). Additionally, 8% of respondents reported that they had stopped practicing obstetrics altogether due to risk of liability. The survey did not pursue the impact of competing factors that might lead to these decisions and behaviors, and had a low response rate of 18% (Klagholz and Strunk 2009). Throughout more than twenty-five years of national ACOG surveys, members have reported practice changes due to malpractice pressures (American College of Obstetricians and Gynecologists 1983, 1985, 1987, 1990, 1992, 1996, 1999, 2003, 2006, 2009).

In its 2011 survey of family physicians, the American Academy of Family Physicians (AAFP) found that 19% of respondents attended vaginal births in hospitals, with a substantial range across regions and in urban versus rural areas. Five percent identified the prohibitive expense of liability insurance as a reason for not attending vaginal births, and one percent identified fear of a liability suit as a reason, a sharp contrast from their obstetrical colleagues. Most (72%) did not attend vaginal births because this was “not desired.” Similar results were reported for performance of vacuum extraction, forceps extraction, labor augmentation, and labor induction. Although fewer attended high-risk births (14%), vaginal birth after cesarean (11%), and cesarean birth (9%), a similarly small proportion continued to cite liability reasons, with most citing “not desired.” The response rate was 13%, and results were weighted to match AAFP’s membership profile (AAFP 2011).

Participants in the most recent liability survey of members of the American College of Nurse-Midwives (23% response rate) described the impact of liability fear on their behavior. Of those no longer attending births, just 3% attributed this to fear of liability or experience with litigation. Among those who had been named in a lawsuit, 66% reported making no change in practice, 8% cared for fewer high-risk women, 6% increased referrals that probably led to cesarean births, and fewer reported reduced confidence, improved documentation, or quicker consultation (Guidera et al. 2012).

In state and local surveys of obstetrician-gynecologists, family physicians, and midwives, notable proportions of respondents stated that they practice with assurance and avoidance defensive behaviors (recent examples include Brooks et al. 2004; Brooks et al. 2005; Donlen and Puro 2003; Dresden et al. 2008; Menachemi et al. 2005; Menachemi et al. 2006; Smits et al. 2004; Xu, Lori et al. 2008; Xu, Siefert et al. 2008a).

These self-reports clarify that liability issues are salient and troubling to many maternity professionals, but they are difficult to interpret with respect to the true impact of liability pressure on professional behavior because response rates are generally low and professional decisions reflect competing pressures and trade-offs. For example, paths to a cesarean after a borderline fetal monitor tracing could reflect a concern about reducing liability risk as well as cautiousness unrelated to liability, adherence to an evolving clinical standard, a medical culture that often favors action and intervention, the prospect of receiving greater reimbursement, pressure to get back to the office, or some combination. With respect to avoidance behavior, many surveys cite fear of litigation and liability insurance cost and access as reasons for not offering or planning to discontinue maternity services, along with having a more balanced lifestyle, fulfilling family duties, needing access to backup, getting adequate reimbursement, being available for ambulatory patients, and carrying out retirement plans (Dresden et al. 2008; Larimore 1993; Smits et al. 2004; Smits et al. 2006; Smits et al. 2009; Xu, Lori et al. 2008).

Such surveys have been criticized for reliance on self-reports, and assertions of health professional trade organizations about defensive practice have similarly been questioned. Concerns include the possibility that maternity professionals may have inaccurate impressions about the severity and impact of malpractice pressure, often do not make accurate predictions about their intention to discontinue clinical practice, and may be tempted to overstate the impact to bolster the argument for tort reforms, which are expected to reduce malpractice premiums (Klingman et al. 1996; Mello, Studdert, Schumi et al. 2007). In support of such caution, one investigation found that just 35% of physicians who stated that they would be exiting practice within three years had actually done so by that point (Rittenhouse et al. 2004). Another found that access to malpractice premium subsidies was not associated with continued provision of maternity services in a multidisciplinary clinician population that had identified liability premium costs as the leading factor in discontinuation of maternity services four years earlier (Smits et al. 2009).

Mothers of infants who participated in the national *Listening to Mothers II* survey also believed that liability issues have a considerable impact on maternity practice, including causing maternity providers to: charge more to cover the cost of liability insurance (68%), take better care of their patients (62%), order unnecessary prenatal tests (53%), perform unneeded cesareans (42%), and stop offering maternity services (40%) (Declercq, Sakala et al. 2006).

Empirical Studies of Avoidance Defensive Behavior in Maternity Care

While surveys and commentaries of maternity professionals raise concerns about the impact of liability pressure on avoidance defensive behavior, investigations to corroborate those reports clarify that decisions about providing maternity services are multi-factorial. The highest-quality studies, at both national and state levels, did not find an association between various measures of liability pressure and avoidance behavior or found a relationship under limited circumstances, such as in decisions about where to establish an initial practice and about provision of maternity care in rural areas.

The impact of liability on defensive practice and health outcomes is best understood through studies that can examine associations with varying degrees of exposure, control for potential confounders, and/or simultaneously test for competing explanations. Studies of defensive avoidance maternity practices have primarily examined whether malpractice pressure drives physicians to relocate or to refrain from providing care or the full scope of needed care. Anecdotal reports of these problems have been plentiful in recent years (Guadagnino and Mello 2003), and the health care community has published surveys and commentaries on practice closures and physician/resident exodus (Mello and Kelly 2005). The strongest studies on this topic have found that the malpractice environment has a small impact or none on the overall supply of physician services (Mello 2006a). Maternity investigations and research are consistent with this conclusion.

Several investigations have attempted to corroborate reports of access problems that have been attributed to liability pressure:

- The U.S. General Accounting Office investigated the impact of liability pressure in the early years of the twenty-first century by comparing five states identified as “crisis” states by the American Medical Association and other professional groups (Florida, Mississippi, Nevada, Pennsylvania, West Virginia) and four states without this designation (California, Colorado, Minnesota, Montana). Investigators attempted to substantiate provider organization reports of potentially acute consumer access problems. They were unable to substantiate liability-associated problems with access to maternity services in Florida, Nevada, and West Virginia. As the number of childbearing women in Pennsylvania had decreased, they did not view relocation of obstetrician-gynecologists from that state as a problem. They found evidence of sporadic concerns about access to maternity services relating to premium increases as well as other longstanding factors for obstetricians and family physicians providing maternity services in rural Mississippi, and problems with access to obstetrical services in two Pennsylvania counties associated with rising liability insurance premiums and other factors (2003). →

- In response to publicity by physicians and their insurers about problems of access to obstetrical care due to rising malpractice premiums, Public Citizen carried out a similar investigation in the District of Columbia. Public Citizen identified considerably more practicing obstetricians, including those who attend births, than medical leaders had reported. The investigation also found that virtually all were accepting new patients and that medical residents at four teaching hospitals further boosted the maternity workforce. Reported levels of relocation, discontinuation of maternity services, and retirement were not substantiated (2005a).
- Similarly, we investigated reports of liability-associated closures of midwifery practices, clinics, and birth centers that have appeared in women's health news services in the present century. While closures were consistently substantiated, and liability issues were often cited as a primary reason and/or the tipping factor in actual closure, liability rarely proved to be the sole factor. Other factors named included inadequate reimbursement, increasing restriction on scope of practice, difficulty finding birth center employees as midwives can earn more in hospital practices, hospital employer dissatisfaction with levels of revenue generated due to less technology-intensive practice styles, and failure of local health care systems to offer collaborative services required by statutes and regulations.

Formal recent national studies are largely consistent with these investigations:

- Baicker and Chandra used four years (1989, 1995, 2000, and 2001) of state-level data on physician supply and found that changes in malpractice premiums did not significantly influence the overall size of the obstetrician-gynecologist workforce. They found that rural physicians were more sensitive than physicians overall to increases in malpractice premiums, and reported that a 10% increase in malpractice premiums was associated with a 1.7% decrease in rural obstetrician-gynecologists per capita. They also found weak evidence that some physicians younger than 35 and older than 55 years make entry and exit decisions partially based on the size and number of payments (2005b).
- In a subsequent multi-variable analysis, Baicker and Chandra, examined the relationship between malpractice premiums in each state and the number of obstetrician-gynecologists per capita in each state between 1993 and 2001. They found no relationship overall, and a small decrease in participation of physicians over age fifty-five in rural areas (2005a).
- Whereas 24% of non-metropolitan counties lacked hospital-based maternity services in 1985, 44% lacked such services in 2002. An investigation of services that closed during this period found that the most frequent reasons for closure were low volume of births, financial vulnerability due to high proportion of Medicaid beneficiaries, and staffing difficulties. The latter included malpractice burdens for obstetrician-gynecologists and family physicians, changing attitudes about balance between work and personal life, and difficulty and costs of recruiting supporting specialists (e.g., anesthesiologists, surgeons). More than 60% of the facilities that closed were within thirty miles and a thirty-minute drive from another hospital providing at least basic maternity services (Zhao 2007).
- In a mixed-effects model with data across fifty-one jurisdictions from 1991 through 2003, adjusting for health care market and socioeconomic factors, Yang and colleagues found that premium levels were not associated with two measures of obstetrician-gynecologist supply. Results suggested that these specialists generally do not respond to liability pressure by relocating out of state or discontinuing practice (Yang et al. 2008). →

- The American Medical Association designates states with highest liability concerns as “crisis” states, and the American College of Obstetricians and Gynecologists uses the designation “red alert” states. While the organizations do not provide specific criteria for these designations, the cost of liability insurance premiums may be an important concern. Robinson and colleagues compared “crisis” and all other states and “red alert” and all other states, and found no significant difference in the percentage changes in births per fellow or births per junior fellow of the American College of Obstetricians and Gynecologists between 1995 and 2003. There was also no difference in births per fellow when comparing the ten states with the highest liability premiums to the ten states with lowest premiums. However, there were significantly more births per junior fellow in the highest than lowest premium states, suggesting that junior fellows may prefer to establish practices in areas with lower premiums (Robinson et al. 2005).
- Polsky and colleagues examined the relationship between liability premium levels and other factors that might impact entrance and exit and actual entrance and exit of obstetricians and family physicians who attended births in Florida, New York, and Pennsylvania, from 1998 to 2004. They concluded that a 10% increase in premium level was associated with an exit rate of 0.28% and a 0.38% decrease in rate of entry. They estimated that the net effect in Florida and Pennsylvania was a 5.3% decline in the maternity care physician workforce during the 2000-04 hard phase of the liability cycle with 20% premium increases annually, but did not analyze changes in the prior period of declining or stable premium levels (2010).

Several recent single-state studies also examine these questions:

- The study of red alert and crisis states is consistent with reports of Pennsylvania obstetrics-gynecology residency directors, that the liability environment dissuaded more residents from locating their own practices in the state in 2003 during the hard phase of the liability cycle in comparison with retention two to three years earlier (Mello and Kelly 2005).
- By contrast, in New York from 1998 to 2003, location of obstetrician-gynecologists beginning their patient care career was not associated with premium levels (Chou and Lo Sasso 2009).
- A database allowed researchers to track behavior among physicians providing maternity care as Pennsylvania moved from a soft market to the most recent hard market, and was widely viewed as a crisis state. Researchers found that shifts of obstetrician-gynecologists from full-scope care to not attending births and from attending low-risk births to none at all did not differ in soft and hard periods, suggesting that factors other than liability influenced their behavior. Further, despite the trend of obstetrician-gynecologist discontinuation of maternity care in both periods, the number of physicians offering maternity services did not significantly decrease due to family/general physician maternity services (Mello, Studdert, Schumi et al. 2007).
- An analysis of maternity practice changes in Florida from the recent soft to hard phases of the insurance cycle focused on obstetricians’ attendance of high-risk births, in 1997, 2000, and 2003, when widely viewed as a crisis state. The analysis found that behavior and trends varied by volume of complicated births attended. From 2000 to 2003, when liability premiums rose quickly, low-volume physicians attended a smaller proportion of high-risk births, medium volume physicians attended a larger proportion, and high- and very high-volume physicians remained relatively

constant. Investigators calculated that women's travel time to the site of delivery did not change across the three time periods, overall and in rural markets, and for births coded as complicated or not (Dranove and Gron 2005).

- Gimm conducted a multi-variable analysis of Florida births from 1992 through 2000 that were attended by obstetricians, maternal-fetal medicine physicians, and family physicians with caseloads of ten or more births per year. He found that on average physicians attended six fewer births three years after closing a claim and fourteen fewer births three years after a high award of more than \$250,000. The latter represented about 11% of the average annual number of births attended. The analysis could not distinguish between such possible explanations as reduced interests of physicians due to legal experience and reduced interests of women due to damaged reputations. Other claims severity measures (low, medium, and very high awards; and minor, major, or grave injury, or death) were unrelated to birth volume (2010).
- Xu and colleagues used multivariable analysis of 2000 survey data from Michigan obstetricians and family physicians with a history of providing maternity care to assess the impact of liability burden (premium levels and claims and payment experience) on discontinuing maternity care in rural and urban areas. They found no relationship between liability burden and discontinuation of maternity practice, overall and in rural areas, but noted that for reasons not measured, rural family physicians had a greater than fourfold likelihood of discontinuing maternity practice, in comparison with urban family physicians (2009).

Empirical Studies of Assurance Defensive Behavior in Maternity Care

Surveys and commentaries describe extensive use of assurance behaviors in maternity care. A series of studies has examined the relationship between malpractice pressure and cesarean section. Malpractice pressure has generally been measured as premium level and/or claims experience. Study results range from no relationship to a modest one, with most finding a small positive relationship. Performing increased cesareans in the face of high premiums could reflect perceived financial pressure to generate increased revenues and/or liability risk aversion given support in the legal system for performing this procedure. At most, the association accounts for a small portion of the substantial increase in the cesarean rate since the mid-1990s.

Summarizing the evidence for medicine in general, a leading medical liability scholar found that defensive assurance behaviors are widespread and increase with increased liability pressure (Mello 2006a). Multivariable studies of defensive assurance maternity practices present a different picture. They have focused primarily on the link between malpractice liability and use of cesarean section. The concern is with overuse because the legal system is far more likely to penalize a professional for not performing a cesarean section that might have contributed to an improved outcome than for performing one that was not needed and might have caused avoidable harm to mother or baby. (Studies assessing the impact of tort reform on use of this procedure are summarized in Part II.)

National multi-variable studies generally provide the firmest understanding of the relationship between malpractice pressure and cesarean section and related mode of birth practices:

- Yang and colleagues, using longitudinal mixed-effects regression models to examine data from fifty-one jurisdictions over twelve years (1991–2003), found that a \$10,000 decrease in malpractice premiums was associated with a 0.35 percentage point increase in the VBAC rate, and 0.15 and 0.16 percentage point drops in the total and primary (initial) cesarean rates, respectively. Nationally, in 2010, this would have meant about 2,000 fewer cesarean births among the more than 1.3 million that occurred. Other significant factors were time trends, medical conditions, multiple births, midwife-attended births, and HMO penetration (Martin et al. 2012; Yang et al. 2009).
- Kim explored whether obstetrician-gynecologist claims resolved over the most recent three-year period from 1990 to 2005 in each state or the amount of those claims was associated with use of cesarean section and other practices, overall and for several at-risk subgroups. The analysis found that use of cesarean section, forceps, and vacuum extraction was not associated with number of claims against this specialty per 1,000 births or other measures of malpractice risk. Results of several supplementary analyses also supported the lack of association between cesarean section and malpractice pressure (2007).
- Baicker and Chandra used state-level data on premiums and closed claims to examine the impact of malpractice premiums and claims on health care delivery. They found no relationship between malpractice premiums and cesarean sections from 1993 to 2001 (2005b). As few control variables were included in the model, their estimates may be subject to omitted variable bias.
- A subsequent study used birth data from 1995 through 1998 across U.S. counties, and found that malpractice pressure (defined as mean liability premium levels and as number and size of settlement and judgment payments per physician for surgery, obstetrics, and internal medicine) helped explain geographic variation in the use of cesarean section. The malpractice variables explained 15% of the variance in performing cesareans with normal birthweight babies and 14% with low- and very low birthweight babies. Other major factors that were unrelated to needs and preferences of childbearing women were practice style variation (41% to 43% of variance) and local health system capacity (9%) (Baicker et al. 2006).
- In an analysis of 2006 births across all 37 states then participating in the Healthcare Cost and Utilization Project, Zwecker and colleagues found that the 10 states with liability premiums above \$100,000 had a higher adjusted odds (1.17) of performing cesarean section and lower odds of vaginal birth after cesarean (0.60) and instrumental birth with vacuum extraction or forceps (0.72) than the 9 states with premiums below \$50,000 (Zwecker et al. 2011).
- Dubay and colleagues examined the relationship between cesarean rates and regional malpractice insurance premiums over the period 1990–1992 and found a small but significant effect of malpractice premiums on cesarean rates: a \$10,000 increase in the annual premium was associated with an increase in risk-adjusted cesarean rates of 0.4% (Dubay, Kaestner, and Waidmann 1999).

Relatively recent single-state studies are generally consistent with the national studies:

- Grant and McInnes found that personal experience of high-indemnity payment claims was associated with an increase of one percentage point in risk-adjusted cesarean rates among Florida obstetricians from 1992 through 1995, whereas there was no relationship between experience of any claim and cesarean section (2004).
- Also in Florida, Gimm found that the cesarean rate of obstetricians, maternal-fetal medicine subspecialists and family physicians who attended ten or more births each year from 1992 through 2000 was unrelated to claim severity as indicated by four levels of awards and three measures of injury severity (2010).
- Also in Florida, Dranove and Watanabe, using multi-variable analysis with 1994–2000 hospital discharge data and 1979–2003 closed claims data, found that obstetricians increased use of cesarean section after an initial suit, but not thereafter, and when other physicians at their hospital were sued; however, both associations were quite small in magnitude and quite short-lived. There was no association between county litigation rates and cesarean section rates (2010).
- Examining the relationship between premium levels and primary cesarean section in single births in Illinois from 1998 through 2003 with multivariable analysis, Murthy and colleagues concluded that each \$10,000 increase in premium levels was associated with an increase in primary cesareans of 1.6% in first-time mothers and 0.5% in experienced mothers (Murthy et al. 2007).
- In multivariable analysis of obstetrical care for women in Florida in 1992, Sloan and colleagues found that malpractice premiums and measures of claims frequency were not associated with mode of birth (Sloan, Entman et al. 1997).
- Glassman and colleagues examined the association between personal malpractice experience and response to clinical scenarios and attitudinal and decision-related items among obstetrician-gynecologists and three other specialty groups in an eastern state. They found no systematic relationship between several measures of obstetrician-gynecologist malpractice experience and resource use, attitudes, estimates of clinical risk, and tolerance of uncertainty. The sole reported marginally significant difference was increased likelihood of use of cesarean section or labor induction, versus VBAC, in one clinical scenario for those in top versus bottom claims rate quartiles (Glassman et al. 1996).
- In logistic regression analysis of the relationship between lawsuit rates against physicians and hospitals in the preceding years and 2002 primary cesarean section rates in Texas, Brown removed the effect of small-area practice variation. While significant, the resulting odds ratio was very small. The author concluded that failure to remove practice variation may overestimate the effect of liability pressure on this procedure, and practice variation would be a more fruitful focus than malpractice pressure in efforts to drive appropriate use of this procedure (Brown 2007).

As more recent studies are available, we excluded studies describing the relationship between liability pressure and cesarean section performed in the 1980s, which were limited to single states, had limited control variables, and were carried out in a different practice environment (Baldwin et al. 1995; Localio et al. 1993; Rock 1988; Tussing and Wojtowycz 1992).

At most, the studies identify modest associations between malpractice pressure and increased use of cesarean section. The U.S. cesarean rate increased by about 50% over the last decade, and other factors appear to be much greater drivers of overuse of this procedure, most notably changes in practice patterns with a decreased threshold for performing this procedure and much variation (Declercq, Menacker et al. 2006).

Despite this limited association, health professionals frequently describe the legal pressure to perform cesareans. However, as the cesarean rate grew, cerebral palsy, preterm birth, and various other adverse outcomes increased (U.S. Centers for Disease Control and Prevention, National Center for Health Statistics 2010), and research has increasingly documented adverse effects of cesareans and repeated cesareans (Cardwell et al. 2008; Guise et al. 2010; Hyde et al. 2012; Mercer et al. 2008; Silver et al. 2006; Thavagnanam et al. 2008) and the association of iatrogenic prematurity with mistimed elective cesarean section and labor induction (Engle and Kominiarek 2008; Fuchs and Wapner 2006; Kuehn 2010). Higher cesarean rates involve increased use in healthy women and associated morbidity and waste (Baicker et al. 2006). This incentive is poorly aligned with best evidence, high-quality care, and avoiding harm and waste.

Relatively few studies examined possible non-cesarean assurance behaviors to demonstrate taking precaution to avoid risk of liability. A recent national study referenced but did not specify fifteen conditions treated by obstetrician-gynecologists with significant associations with malpractice premium levels suggestive of defensive medicine in multivariable analysis. The investigators reported that these clinical conditions accounted for 11% of all care episodes managed by this specialty. They estimated that a \$10,000 reduction in premiums would result in a mere 0.05% decrease in overall medical care costs of these physicians, and did not explore possible clinical implications. In the same study, data for family physicians including maternity services in their practice found a positive and significant relationship with 13 conditions comprising 2.2% of all of their episodes. Investigators estimated that a \$10,000 premium reduction would save 0.16% of the costs incurred by that group of family physicians. They conclude that defensive medicine exists, is widespread, but has a small overall impact on health care costs (Thomas et al. 2010).

A national multivariable study assessed the relationship between liability pressure (represented by claims and claim costs) and use of prenatal visits, ultrasound, amniocentesis, and fetal monitoring, and found a positive relationship solely for amniocentesis, overall and for five of six subgroups (additional study details and lack of association for cesarean for cesarean section and instrumental delivery are reported above) (Kim 2007).

Two state-level studies explored the relationship between liability pressure and maternity practices other than mode of birth. A multivariable analysis of all births in Illinois from 1991 through 2003 found that each \$10,000 increase in county-level insurance premiums was associated with one late preterm labor induction in 1,000 women with at least one prenatal risk factor for induction, which might account for one-half of the increase in late preterm inductions during the study period (Murthy et al. 2009). A multivariable analysis considered possible associations in Florida with two prenatal tests, and found a negative association with amniocentesis and a positive association with alpha-fetoprotein testing (Sloan, Entman, et al. 1997).

See Appendix I for gaps in knowledge relating to impact of liability-induced behavior on maternity care, specifically, whether the full complement of caregivers and settings engage in defensive behavior; factors that may underlie cesarean-related defensive practice; whether defensive behavior impacts practices other than mode of birth; and whether liability pressure adversely affects disparity populations and safety net settings.

Liability, Career Satisfaction of Maternity Caregivers, and Maternity Care Quality

The conventional approach to medical error has been to focus on the “broken part” that is to be fixed or replaced and blame one or more individuals (Dekker 2010; Leape 2010). Wu characterized a caregiver whose patient experiences an adverse event in this context as the “second victim” — in need of sympathy and support, but frequently feeling exposed, having self-doubts, and experiencing the grudging or qualified reassurance of colleagues (Wu 2000). Wu observed that in the absence of healing processes, the caregiver might resort to anger, projection of blame, callousness, substance abuse, and other dysfunctional modes of protection (2000). A systematic review about coping with medical error identified many adverse psychological outcomes, as well as the potential for favorable outcomes (Sirriyeh et al. 2010). Scott and colleagues interviewed second victims and described six predictable stages in their response and resolution (2009).

The experience of a liability claim can result in psychological trauma (McAninch et al. 2008) and be deeply unsettling to obstetrician-gynecologists:

Guilt and shame typically are the primary feelings that should be recognized and addressed during, and following, liability litigation. Deep shame and a reduced sense of self-worth may be felt in response to litigation because of a fear of public exposure. Anxiety is the usual reaction to these threats to one’s integrity, self-confidence, and well-being. Whether consciously experienced or not, depressive reactions and a sense of diminished self-worth commonly follow guilt. When a lawsuit is completely unexpected, its effect may be traumatic, resulting in shock and numbness, alternating with a hyperarousal state, including sleeplessness and tension (American College of Obstetricians and Gynecologists 2011).

When health professionals injure patients and/or become legal defendants, the needed support and healing processes are not routinely provided, and current responses give inadequate attention to the considerable role of systems in medical error (Mello and Studdert 2008). In this context, obstetrical discourse about liability can focus exclusively on injury to professionals rather than to patients and position this as “condition critical” (Lockwood et al. 2004, 2005) or elevate the former and downplay the latter, for example, an article entitled “Obstetric Litigation is Asphyxiating Our Maternity Services” states: “although health care has never been safer for the woman and her fetus, it has never been more dangerous to the physician” (Hankins et al. 2006, p. 1382). To understand discourse about liability, investigators from the Harvard Medical Practice Study interviewed obstetrician-gynecologists, general surgeons, and internists and analyzed fact sheets from the Medical Liability Project of the American Medical Associa-

tion and the Council of Medical Specialty Societies. They found that the liability system as it presently operates threatens medicine's territory and boundaries of authority. The investigators described four recurring modes of discourse — affective lament, rejection of tort law, complaints about the deteriorating culture of clinical practice, and calls for active campaigning (Marjoribanks et al. 1996).

Sage, a leading health law scholar in the United States, described the paradox of clinicians' general capacity to weather liability challenges and their great antipathy to liability issues. For example, protracted disruptive lawsuits are the exception rather than the rule, insurers and not care providers are primary payers of settlements and awards, malpractice premium costs do not impoverish physicians, and periods of stability and prosperity are more common than hard phases of insurance cycles. Sage argues that this deep antipathy and a tendency to overestimate vulnerability are responses to the liability system's challenge to some of medicine's most fundamental values: professional autonomy, peer review, and self-policing. Allegations assault the reputation and dignity of professionals who otherwise experience considerable prestige and control (Sage 2004b). Carrier and colleagues suggested that a malpractice claim may be a "dread risk" for physicians, reflecting the human tendency to overestimate the risk of rare and fearful events that may feel out of control and have severe repercussions (2010). The situation is more extreme for maternity providers than for many others, as premium levels, the number of claims, and the size of payments are higher than most; there is a protracted statute of limitations for newborns; and every birth has the potential, however rare, of perinatal death or lifelong disability. Minkoff observed that obstetricians' views of liability may be subject to "anchoring" and "priming" cognitive biases that intensify perceptions of vulnerability (2012).

Discussions in Part I, Part II, and Appendix I contribute further to the question of liability-associated distress of maternity care providers in identifying many aspects of professional practice that may be confusing, uncertain, ambiguous, misunderstood, and/or anxiety arousing to health professionals and may disproportionately impact maternity care providers. These include tension between practice supported by best evidence and discouraged by terms of liability insurance policies; whether liability insurance costs are onerous to health professionals; the likelihood of experiencing a claim, payout, or trial; the likelihood of being responsible for injuring women and newborns; concerns about the integrity of expert witnesses; prolonged exposure to risk through statutes of limitations applying to newborns; ambiguity about responsibility in clinical decision making; legal clinician standards that are often misaligned with best evidence; whether to voluntarily disclose and address injury; whether juries and judges are qualified to make determinations that involve technical clinical matters; and whether the tort system should be a primary source of support to parents facing long-term expenses of caring for injured newborns. Part II discusses these tensions and uncertainties, identifies many strategies with the potential to lessen them, and clarifies that strategies that clinicians have most strongly advocated and that have been implemented are unlikely to address many chronic sources of tension.

Appendix I summarizes studies of the career satisfaction of maternity caregivers and of disruptive behavior of maternity caregivers. There are suggestions of a relationship between liability pressure and career satisfaction and concerns about spillover into disruptive behavior, poor quality care, and compromised outcomes of care, but we did not find research to further understand any relationship among professional liability, satisfaction, and behavior. That appendix identifies gaps in knowledge about the impact of the liability environment on the career satisfaction of maternity caregivers and possible implications for maternity care quality, including disruptive behavior for the full complement of maternity caregivers and settings.

Liability and Maternal and Newborn Health Outcomes

Conventional tort theory assumes that penalizing health care providers whose negligence injures patients provides economic and non-economic incentives to exercise precaution in providing clinical services. By extension, this system should contribute to improved quality and outcomes of care. While the section on negligent injury above clarifies that the liability system fails to prevent a burden of negligent injury to childbearing women and newborns, the system's deterrent effects in these populations, if any, have not been measured (see Appendix I). It is important to understand a related question, the liability system's specific impact on maternal and newborn health. Possible effects include improving outcomes by fostering high-quality care, causing injury associated with unnecessary tests and treatments, and having no discernible impact.

Several studies have explored the relationship between the liability system and maternity care outcomes, focusing on malpractice pressure and birth outcomes. Researchers used multivariable analysis to analyze the incidence of various adverse outcomes as a function of liability risk, taking into account other factors that could influence results. As there is just one recent well-conducted national study, which relies solely on premium level as an exposure to liability pressure, there is a gap in knowledge about this question. Appendix I summarizes results of existing studies, which are largely consistent in showing no relationship. Data on the related question of impact of tort reform on maternity care outcomes, discussed in Part II, are consistent with these results.

We did not find any studies that explored the impact of the liability system on maternal and newborn health outcomes after injury has occurred, for example, possible effects relating to the degree to which prompt and ongoing care are provided and steps are taken to avoid future harm.

See Appendix I for gaps in knowledge about the impact of the liability environment on health outcomes in childbearing women and newborns.

In Summary: Impact of Liability System on Maternity Caregivers, Care, and Outcomes

Liability issues are deeply salient and distressing for many maternity professionals and are widely viewed as having a deleterious impact on maternity care. Liability pressure is often presented as an intractable barrier to the practice of optimal maternity care and a driver of overuse and access challenges in maternity practice. However, we were unable to find in empirical studies the severe adverse impact that this system is believed to have on maternity professionals from the perspectives of economic viability, assurance and avoidance defensive maternity care practice, and outcomes of care. Widely held views and feelings about this aspect of professional practice likely reflect the lack of control and vulnerability maternity care providers experience in terms of premiums, claims, and legal proceedings and their greater risk than colleagues in most specialties.

Existing evidence suggests that childbearing women and their newborns are far more likely to experience negligent injury in the course of maternity care than they are to involve maternity providers in litigation. For example, with a relatively high response rate of 73%, Chauhan and colleagues found that the participating obstetrician-gynecologists on average experienced a claim every 11 practice years, a settlement almost every 40 practice years, and a trial every 70 practice years (Chauhan et al. 2005), figures that include meritorious and non-meritorious obstetric and gynecologic claims. By contrast, the best source on the frequency of in-hospital negligent injury suggests that 1 in 174 childbearing women and 1 in 646 newborns sustained a negligent injury (Brennan et al. 1991). Using the finding of an eight-year multi-specialty study of an average caseload of 121 births per year (Gimm 2010), we estimate that, on average, a childbearing woman would sustain such an injury every 17 practice months and a newborn about every five and one-third practice years.

Another way of understanding opportunities for improvement is to consider that across records of various major liability insurers and large hospital systems, about 75% of paid obstetric claims are judged by defendant teams to have involved injury due to substandard care, while about 25% are judged not to have involved malpractice (Clark 2009b). Despite the increasing focus on safety and other aspects of health care quality, current discussions about the problem of maternity care liability do not sufficiently recognize and address opportunities for quality improvement (Hickson and Entman 2010).

We use this opportunity to bring together clearer results in Part I and more limited evidence about key questions identified in Appendix I. *Italicized notes in parentheses identify points that are not based on studies meeting criteria for more trustworthy empirical studies described in the Introduction or are among the more important unanswered questions.* A summary of material presented in Part I and in corresponding sections in Appendix I follows:

- The liability cycle fluctuates, with recurring periods of stability and quiescence and of volatility in the level of premiums and access to insurance products. Due to this cycle, as well as wide geographic variation in premium levels and widespread community rating, premium levels of individual maternity care providers are generally unrelated to the safety and quality of the care they provide and are understandably experienced as capricious. *(This reflects consensus observations over three recent liability cycles.)*
- Medical liability insurance carriers and programs affiliated with physicians, hospitals, and health systems (including self-insurance) have to a great extent replaced traditional commercial insurers. *(While these sources of liability insurance aim to provide physicians and hospitals with access to affordable products, implications of this trend for midwives and birth centers and implications of their smaller risk pools for access to affordable insurance products are unclear.)*
- *(Liability policies of many health professionals who do or might provide maternity care impose some constraints on practice. Policies may exclude coverage of core services that are currently supported by best evidence or impose surcharges for such coverage. They may impose surcharges for coverage of any maternity services. We found neither national studies describing the nature, extent, or impact of insurance-induced constraints nor any evidence of regulatory oversight of these industry practices.)*
- Among physicians, obstetricians experience some of the highest liability insurance premiums.
- Liability premiums are a relatively small part of overall practice expenses of obstetricians and other physicians and have risen less sharply than other practice expenses in recent years.
- As practice expenses have increased and reimbursement has tightened in recent years, obstetrician-gynecologists have been able to increase revenue and maintain incomes that may surpass inflation. Simultaneously, the primarily healthy population of childbearing women has experienced unprecedented rates of interventions such as labor induction and cesarean section, with associated health and cost concerns.
- Maternity professionals experience more claims and more costly liability payments than most other health professionals; in recent years, the number of claims has been stable *(with anecdotal references to a decline in the most recent period)*, while payment levels have increased.
- *(The legal and insurance systems appear to deviate from the negligence standard in a willingness to make settlements and awards for newborns with serious impairments. See Appendix I.)*
- *(Maternity professionals appear to substantially overestimate their likelihood of legal challenges. While professional fear and antipathy are widely recognized, few studies have formally compared belief/expectation and reality. See Appendix I.)* →

- A troubling and insufficiently recognized proportion of childbearing women and newborns experience negligent injury; although liability focus has largely been on newborn outcomes, about three times as many mothers as babies may experience negligent injury. *(These were quantified at the population level in the Harvard Medical Practice Study and/or its replication study in Colorado and Utah; smaller less generalizable studies also identify concerns about negligent injury in these populations.)*
- Much professional discourse about maternity care liability focuses on adverse effects on health professionals rather than adverse events and negligent injury in mothers and babies. *(This observation describes many liability-focused commentaries or roundtables in leading obstetric journals in recent years.)*
- Best current estimates suggest that a claim is filed on behalf of just about 2% of all medical patients who sustain negligent injury, and less than 1% of those with negligent injury receive compensation through a settlement or trial award. Very high legal expenses further limit awards for injury. *(Comparable figures specific to maternity care were not identified. See Appendix I.)*
- In survey reports and concerns expressed by clinical leaders, liability pressure has a substantial role in “assurance” (overuse) and “avoidance” (diminished access) defensive behaviors.
- In available empirical studies, liability pressure has at most a modest positive relationship to cesarean rates and, in one recent national study, a modest negative association with rates of vaginal birth after cesarean. *(The studies do not clarify whether this association reflects motivation to provide “assurance,” response to perceived financial pressure of premiums and other expenses, or other factors. Fewer studies examined the relationship between liability pressure and use of other obstetrical tests and procedures, and results were consistent with the cesarean studies.)*
- In available empirical studies (and formal investigations in response to professional claims), liability pressure has a sporadic impact on access to maternity services — in some, especially rural, areas and at hardest points in the liability cycle. Many factors affect decisions to limit or refrain from providing maternity services, and investigations were unable to corroborate many reported liability-associated maternity care access problems.
- Obstetrician-gynecologists report higher levels of dissatisfaction relative to practitioners in nearly all other medical specialties. *(Limited evidence associates the experience of liability issues with this dissatisfaction. Research is needed to clarify the role of liability in this discontent and the impact of discontent on the provision of maternity services. See Appendix I.)*
- While existing studies have not found an association between liability pressure and maternal and newborn health outcomes, further research is needed.
- There are many important gaps in knowledge of these matters, in addition to those noted above. Little is known about the liability experiences of maternal-fetal medicine specialists, family physicians, midwives, and birth centers, as well as safety net providers and settings and disparity populations (see Appendix I).

Part II identifies seven fundamental liability-associated concerns that adversely impact maternity care, as shown in Part I, and discusses the evidence or likelihood that a broad range of strategies would help address these concerns. Gaps in knowledge about applying these strategies present opportunities for states, health systems, health plans, and other entities to carry out and evaluate demonstrations.

Part II. Policy Interventions for Achieving the Aims of the Liability System



Policy Framework for Liability System Improvement

Part I clarifies that the liability system is not serving well childbearing women and families, maternity care providers, and the employers, taxpayers and individuals whose payments for maternity care include costs of liability. Persistent concerns identified in Part I suggest that policy interventions are needed to better achieve the broad liability system aims of preventing injury in women and newborns and responding appropriately to harm or claims of harm when they occur. Effective strategies are needed to better achieve a high-functioning liability system that:

- Promotes safe, high-quality maternity care consistent with best evidence, and minimizes avoidable harm
- Minimizes maternity professionals' liability-associated fear and disaffection
- Avoids incentives for assurance and avoidance defensive maternity practice
- Fosters access to high-value liability insurance policies for all maternity caregivers without restrictions or surcharges for care supported by best evidence
- Implements effective measures to address concerns when women and newborns sustain injury, and provides rapid, fair, efficient compensation
- Assists families with responsibility for costly ongoing care of infants and women with long-term disabilities in a timely manner and with minimal legal expense
- Minimizes legal and administrative costs.

Four major classes or reforms might be used to improve liability matters: tort, tort alternative, liability insurance, and health care system reforms. Each encompasses diverse possible strategies.

Tort reform. The legal framework and rules governing harm resulting from medical malpractice have traditionally been matters for state courts. Over the past four decades, tort reform statutes supplemented this tradition in nearly all states. During each malpractice crisis, physicians exhorted policy makers to modify the medical malpractice legal system, and states responded with various statutory tort reforms (Studdert, Mello et al. 2004). Primary aims of the measures have been to stabilize the size of liability insurance premiums, the frequency of claims, and the cost of claims, and to deter behavior that is believed to accompany malpractice pressure (Mello and Zeiler 2008). Conventional tort reforms generally address the size of awards (with greatest focus on caps on damages awards), modify liability rules (e.g., joint and several liability rule), or limit access to court (e.g., pretrial screening) (Studdert, Mello et al. 2004).

The evidence base for evaluating effects of most traditional tort reforms in medicine generally is large and mature. With the exception of caps on non-economic damages, better-quality studies in medicine generally have found relatively little evidence of desired impact of traditional tort reforms on liability-related concerns (Mello and Kachalia 2010). The effect of caps on non-economic damages has been well studied within maternity care. A smaller number of studies have examined effects of several other traditional tort

reforms within maternity care. Numerous tort reforms have also been evaluated in the context of maternity. This report discusses eight specific tort reforms and the effect of multiple tort reforms.

Tort alternative reform. The national debate about problems with the liability system has been framed largely as a controversy between physicians and attorneys and their divergent views of the merits of conventional tort reform. However, some scholars and policy makers consider “tort alternative” reforms directed at making the malpractice system more efficient and more responsive to patients who are injured. These strategies use alternative mechanisms to resolve disputes (e.g., arbitration), dispense with negligence as the basis for compensation (e.g., administrative compensation systems), and relocate legal responsibility for accidents at the institutional level (e.g., enterprise liability) (Studdert, Mello et al. 2004). None has been widely adopted by states.

Liability insurance market reform and regulation. Reform of liability insurance has attracted less attention than tort and tort alternative reforms (Sage 2004a). Liability crises that trouble health professionals are first and foremost insurance crises with spikes in the cost of liability insurance and/or reductions in the availability of coverage. It is important to lessen the volatile cycle of premiums that rise and fall regardless of risk and to provide insurance that fosters high-quality care (Baker 2005; Sage 2004a). The insurance cycle is not an immutable response to uncontrollable economic forces, but rather is shaped by belief, opinion, strategic interests in profitability, and feelings of “fear and greed” (Baker 2005; Sage 2004a). It is amenable to policy intervention, including better information, altered incentives, and appropriate behavior constraints (Sage 2004a). Liability insurance reforms focus on direct insurance industry regulations, government acting as insurers (e.g., patient compensation funds), government-sponsored pooling arrangements (e.g., joint underwriting associations), and subsidy of premiums. We found no controlled studies that have investigated the effectiveness of liability insurance reform in general or in the context of maternity care.

Health care reform. Finally, there is growing awareness that reform of the organization and delivery of health care can impact liability outcomes, and there is a valuable track record in maternity care for the health care reform strategy of quality improvement.

Tables 3 and 4 summarize current understanding of the degree to which the more limited and more substantive strategies, respectively, do or could achieve the seven aims described above. Table 3 and the following subsection include strategies that have been shown to have little or no impact or may plausibly be expected to have limited impact, in consideration of the breadth of liability system aims. Consequently, these are low policy priorities. The first strategy in Table 3 and topic in the following section considers the combined effect of multiple tort reforms. Following this, we consider eight specific tort reforms, a tort alternative reform, and five liability insurance reforms.

Table 4 and the section below on Substantive Interventions include interventions with the potential to have a positive impact on multiple aims of a high-performing maternity care system. They hold the promise of generating substantive improvement to alleviate chronic maternity and health care malpractice concerns. In the many instances where firm evidence is lacking, overall or with respect to maternity care, demonstrations and evaluations to test the strategy would be an appropriate policy response. In some cases, important pilot efforts *are* under way or established initiatives could be evaluated for their impact on these concerns. Table 4, and the section on Substantive Interventions, present interventions to prevent harm and reduce liability, followed by interventions to improve processes and outcomes after injury has, or is claimed to have, occurred. Within those sections, strategies are ordered according to their ratings.

Table 3. Evidence Summary: Effects of Least Promising Reforms on Diverse Aims of Liability System

AIMS INTERVENTIONS	↑ safe, high-quality care	↓ clinician fear, distress	↓ defensive practice, practice variation	↑ public interest liability insurance	↑ appropriate response to injury	↑ help for infants, women with disabilities	↓ liability and administrative costs
TORT REFORMS							
Collective tort reforms	(-)	?	(-)*	(-)	(-)	(-)	(-)
Attorney fee limits	(-)*	(-)	(-)*	(-)	(-)	?	(-)
Caps on non-economic damages	-*	?	-*■	(-)*	(-)	(-)	(-)*■
Collateral source rule	(-)*	(-)	(-)*	(-)	(-)	(-)	(-)
Expert witness rule	(-)*	(-)	(-)*	(-)	(-)	(-)	(-)
Joint and several liability rule	(-)*	?	(-)*	(-)	(-)	(-)	(-)
Periodic payment of awards	(-)*	(-)	(-)*	(-)	(-)	(-)	(-)
Pretrial screening	(-)*	(-)	(-)*	(-)	(-)	(-)	(-)
Statute of limitations	(-)	(-)	(-)	(-)	(-)	(-)	(-)
TORT ALTERNATIVE REFORM							
Arbitration, mediation	?	(-)	(-)	(-)	?	?	?
LIABILITY INSURANCE REFORMS							
Joint underwriting associations	?	(-)	(-)	?	(-)	(-)	(-)
Liability insurance investment regulation	(-)	?	(-)	?	(-)	(-)	(-)
Liability insurance rate regulation	(-)	?	(-)	?	(-)	(-)	(-)
Liability insurance premium subsidy	(-)	?	(-)*	(-)	(-)	(-)	(-)
Patient compensation funds	(-)	?	(-)	(-)	(-)	(-)	(-)

Key

- + Stronger evidence suggests strategy has this effect
- (+) Plausible that strategy has this effect and/or weaker evidence suggests that it does
- Stronger evidence suggests strategy does not have this effect or has modest effect at best effect
- (-) Weaker evidence suggests that strategy does not have this effect or has modest effect at best; or impact implausible in absence of evidence
- * Support from assessment includes maternity-related data
- ? It is difficult to anticipate actual impact
- Ratings, based on maternity care evidence, differ from those of Mello and Kachalia (2010) who reported a favorable effect in medical system overall.

Table 4. Evidence Summary: Effects of Most Promising Reforms on Diverse Aims of Liability System

AIMS INTERVENTIONS	↑ safe, high-quality care	↓ clinician fear, distress	↓ defensive practice, practice variation	↑ public interest liability insurance	↑ appropriate response to injury	↑ help for infants, women with disabilities	↓ liability and administrative costs
PREVENTION STRATEGIES							
Quality improvement	+	+	+	(+)	(+)	(-)	+
Enterprise liability	(+)	(+)	(+)	(+)	(+)	?	(+)
Leverage of health insurance, accrediting, credentialing, etc.	(+)	(+)	(+)	(+)	(+)	(-)	(+)
Shared decision making	(+)	(+)	(+)	(+)	(+)	(-)	(+)
Align legal standard with best evidence	(+)	(+)	(+)	(+)	(-)	(-)	(+)
Liability insurance coverage regulation	(+)	?	?	(+)	(-)	(-)	(-)
REDRESS STRATEGIES							
Disclosure, empathy, apology	(+)	?	?	(+)	(+)	(+)	(+)
Health courts	(+)	?	?	?	(+)	(+)	(+)
Administrative compensation systems	(-)	?	?	?	+	+	+
High-low agreements	(-)	(-)	(-)	(-)	(+)	(+)	(+)

Key + Stronger evidence suggests strategy has this effect
 (+) Plausible that strategy has this effect and/or weaker evidence suggests that it does
 - Stronger evidence suggests strategy does not have this effect or has modest effect at best
 (-) Weaker evidence suggests that strategy does not have this effect or has modest effect at best; or impact implausible in absence of evidence
 * Support from assessment includes maternity-related data
 ? It is difficult to anticipate actual impact

Interventions Likely to Offer Limited or No Benefit

Of the 25 interventions considered in this report, 15 have very limited demonstrated or plausible effect on the range of pressing liability concerns for maternity care. These fall into three areas: most are traditional tort reforms, one is a tort alternative reform, and five are liability insurance reforms (Table 3).

Tort Reforms

Tort Reforms Collectively

Two studies measured the additive effect of individual tort reforms on the supply of obstetrician-gynecologists, due to concern that liability pressure adversely reduces supply:

- Yang and colleagues evaluated the association between a series of tort reforms and two measures of obstetrician-gynecologist supply (number of obstetrician-gynecologists both per 10,000 births and per 100,000 women of childbearing age) across all states and Washington, DC, from 1991 to 2003. They examined 10 reforms: attorney fee limits, collateral source rule, damages caps (four types), periodic payment, expert witness rule, joint and several liability modification, and pretrial screening. They found no relationship between the collective effect of the tort reforms and obstetrician-gynecologist supply (Yang et al. 2008). Results for individual reforms are summarized below.
- Kessler and colleagues examined the impact of tort reforms on the growth of physicians at the state level from 1985 to 2001. In an adjusted model, they found that obstetrician-gynecologist supply increased by 2% in states that had adopted tort reforms that might directly reduce malpractice awards relative to states with no reforms. Indirect reforms were associated with a 0.5% decrease in supply. The supply was increased by 2% in states with both direct and indirect tort reforms. Comparable increases were much higher when this specialty's results were combined with those of four other specialties: 8% and 10%, respectively, suggesting a more modest impact on supply of obstetrician-gynecologists relative to physicians in other specialties (Kessler et al. 2005).

Existing evidence about the impact of multiple tort reforms in a jurisdiction focuses only on the outcome of obstetrician-gynecologist supply and finds no impact or a modest impact relative to other clinical areas.

Attorney Fee Limits

In medical malpractice, attorneys for the plaintiff usually receive a fee only if their client wins the case. This “contingent fee” arrangement is a fixed percentage of the award (Inselbuch 2001). This provides incentives for attorneys to take a large enough share of the damages when they win to offset lawsuits without compensation when they lose. Often, attorneys charge from 33% to 50% of the total award.

The contingent fee arrangement has the potential to reduce the injured person's monetary recovery below their actual out-of-pocket loss by the amount paid to the representing attorney, especially when damages are strictly limited to actual monetary losses. This has led to legislative changes that target the amount of money paid to the plaintiff attorney. Some states restrict the attorney's contingent fee to no more than a specific percentage of the total award or settlement, sometimes with a decreasing percentage as the size of the award increases (Budetti and Waters 2005).

A recent review found several well-designed studies showing no effect of attorney fee limits on claim frequency, claim payouts, liability premiums, and physician supply, with more limited evidence also suggesting no effect on defensive assurance behavior and quality of care (Mello and Kachalia 2010). We found two recent national maternity-specific studies:

- An analysis from 51 jurisdictions from 1991 to 2003 found that attorney fee limits were neither associated with measures of obstetrician-gynecologist supply (Yang et al. 2008); nor with mode of birth (total cesarean, primary cesarean, and vaginal birth after cesarean [VBAC]) rates (Yang et al. 2009); nor with six health outcome measures (low five-minute Apgar scores, preterm birth, low birthweight, birth injury, infant mortality, and maternal mortality) (Yang et al. 2012).
- In two models assessing the association between attorney fee limits and death of newborns in the first six days of life across states from 1980 to 2001, contingency fee restrictions were associated with a 7% reduction in black newborn mortality, a significant reduction only in models that did not include state-specific trends, and had no relationship to white newborn mortality (Klick and Stratmann 2007).

Caps on Non-Economic Damages

Payments made to individuals to compensate for damages because of medical error are generally divided into economic and non-economic damages. Economic damages usually consist of past and future expenses for medical care and rehabilitation, as well as lost wages or earnings potential. These damages are measured in monetary terms, often using objective or third-party standards such as wage receipts, medical bills, or expert estimates of degree of disability (Levmore 1994). Non-economic damages are more subjective and compensate for such intangible damages as the loss of a family member through "wrongful death," past and future pain and suffering, and mental anguish (Levmore 1994).

The size of damage awards has become a major focus of state legislation. The principal response has been to limit, or "cap," the amount of money that can be awarded in a malpractice suit, versus leaving juries free to determine the size of awards. Legislated caps have restricted the size of awards well below levels otherwise awarded. Several states limit the total recovery available to plaintiffs. More commonly, they limit non-economic damages that an injured party can receive, such as the cap of \$250,000 for non-economic damages enacted by California's landmark Medical Injury Compensation Reform Act of 1975 (MICRA) (Budetti and Waters 2005).

Health professionals have often actively lobbied for caps on non-economic damages, whereas consumer advocates have generally held that such limits, which may be set near the level of a physician's average annual income, are unfair to injured parties and especially create burdens for those with more serious injury. These also can provide a cushion to plaintiffs as legal fees and other "haircuts" (Hyman et al. 2007) often erode any awards that are made (see Appendix I). Further, there are concerns that caps provide a disincentive for lawyers to take clients with meritorious cases and might reduce incentives for deterring harm. About one-fifth of states have struck down caps on non-economic damages as unconstitutional (American Medical Association 2009).

Many consider the limitation on non-economic damages to be the most effective single tort reform that a state can enact (Studdert, Mello et al. 2004). Previous research has established caps as the tort reform with the greatest calming impact on the overall medical liability environment (Danzon 1986; Mello 2006a; Sloan et al. 1989; Thorpe 2004; Viscusi and Born 2005). Summarizing the better studies across all clinical areas, Mello and Kachalia found that non-economic caps substantially reduce claim payments, may increase litigation costs, moderately constrain premium growth, may reduce defensive assurance behaviors, and modestly increase physician supply. They found the evidence to be unclear about any possible impact on the number of claims that plaintiff attorneys accept, health insurance premium levels, and the quality of care (2010). It is important to note that these investigators did not consider most of the criteria included in Tables 3 and 4.

A series of multi-variable studies has assessed the impact of caps on non-economic damages in maternity care. While many continue to endorse this strategy as a solution to maternity liability dilemmas, consistent evidence suggests that the impact of non-economic caps on damages in this context is minimal at best, with a number of studies finding no benefit and one identifying harmful population effects. Any modest benefits must be balanced against questions about justice for injured women and newborns and their families and other potentially more effective ways of achieving desired aims. It is a priority to inform the relevant stakeholders about this body of studies. Where compelling maternity related data are available, the ratings in Table 4 for caps on non-economic damages reflect those data. As noted, evidence for the broader health care system suggests that such caps favorably impact defensive practice and liability costs (Mello and Kachalia 2010).

National multi-variable studies suggest that non-economic damages caps have a less clear and strong impact in the maternity arena than in medicine generally:

- **Premiums.** An analysis of the association between caps and liability premiums in all fifty states and the District of Columbia from 1999 through 2001 found that premiums of obstetrician-gynecologists were about \$20,000 lower in states with total recovery caps than in states with no caps, but were not different in states with and without non-economic caps. Premiums were about \$15,000 lower in states with “hard” non-economic caps (no exceptions) than in states with “soft” non-economic caps (exceptions), but were not different in states with hard caps and no caps (Guirguis-Blake et al. 2006).
- **Award sizes.** In the National Practitioner Data Bank, non-economic caps were not associated with malpractice payments made on behalf of obstetrician-gynecologists, 1990–2001, in all states and the District of Columbia (Currie and MacLeod 2008). (Self-insured corporations are not required to report to this source.)
- **Physician supply.** An analysis of the county-level impact of non-economic damages caps on obstetrician-gynecologist supply per 100,000 women aged fifteen to forty-four from 1985 to 2000 found that caps above \$250,000 were not associated with an increase in obstetrician-gynecologist supply, overall or in rural counties. Caps at \$250,000 were not associated with increased supply overall, but were associated with a 5% increase in supply in rural areas, where about 20% of the U.S. population resides (Encinosa and Hellinger 2005). →

- **Physician supply.** In an analysis of all 51 jurisdictions from 1991 through 2003, Yang and colleagues found that four different types of caps (caps limiting punitive damage awards and caps on non-economic damages: at \$250,000, between \$250,000 and \$500,000, and greater than \$500,000) were not associated with two measures of obstetrician-gynecologist supply (2008).
- **Physician supply.** Chou and Lo Sasso found that state caps on non-economic damages were not associated with the initial practice settings of obstetrician-gynecologists who completed their training in New York from 1998 to 2003 (2009).
- **Hospital maternity services.** A county-level analysis from 1985 through 2000 found that caps on non-economic damages were associated with a slightly increased likelihood of a hospital maternity service (0.27% in all counties, 0.26% in non-metropolitan counties) (Zhao 2007).
- **Interventions and outcomes.** An analysis of 51 jurisdictions from 1991 through 2003 found that VBAC rates were significantly higher and cesarean section rates were significantly lower in state years when caps on non-economic damages were in force. The effect size increased with the stringency of the cap: caps of \$250,000 or less were associated with a 1.92 percentage point higher VBAC rate, caps between \$250,001 and \$500,000 with a 1.37 percentage point higher rate, and caps above \$500,000 with a 1.25 percentage point higher rate. Higher caps on non-economic damages were associated with lower total and primary cesarean rates (Yang et al. 2009). However, caps were not associated with five measures of adverse outcome (Yang et al., 2012). Yang and colleagues estimated that a non-economic damages cap at the \$250,000 level would have averted 12,800 cesarean sections in the country in 2006 (2009) among the more than 1.3 million such procedures that were performed (Martin et al. 2009).
- **Outcome.** An analysis across all states from 1980 through 2001 found that non-economic damages caps were associated with a 6% decrease in black newborn death in the first six days of life, a significant reduction only in models that did not include state-specific trends. No reduction was found for white infant death in the first six days or with total caps (Klick and Stratmann 2007).
- **Interventions and outcomes.** Using birth certificate data from 1989 through 2001, Currie and MacLeod reported a contrary result, that caps on non-economic damages were associated with a 5% increase in the likelihood of cesarean section, with some variation in size of effect among subgroups. They also reported an association of non-economic caps with a 6% increase in preventable childbirth complications, but did not find an association with labor induction or augmentation or low five-minute Apgar scores, used as a measure of newborn health. They hypothesized that with reduced fear of liability, physicians are less restrained from carrying out profitable, timesaving procedures (Currie and MacLeod 2008).

In addition to the above national studies, an analysis of the impact of California's \$250,000 non-economic damages cap on high-end jury verdicts found a distinctive impact in the maternity context. The caps' fiscal impact differed across different types of injuries. Caps were associated with lowest reductions in total awards — in the range of 2% to 5% — for the largest and most costly class of claims against obstetrician-gynecologists, newborns with severe neurological injuries, versus much greater reductions for other types of injuries across all clinical areas averaging 67%. They conclude that plaintiffs with the most severe injuries were at highest risk for inadequate compensation (Studdert, Yang et al. 2004).

The impact of non-economic damages caps on maternity care premiums, award size, obstetrician-gynecologist supply, and access to maternity services appears to be modest at best. Studies of impact on cesarean rates are contradictory, with the best case avoiding a fairly small portion of cesareans. A national study found no impact on five measures of outcome, another found reduced black newborn death in one model but not another, and a third associated caps with an increase in preventable complications.

Collateral Source Rule

Fairness concerns have arisen over the longstanding practice of letting injured persons collect the full amount of judgments in lawsuits even if insurance or some other “collateral source” pays for part of their losses (Fleming 1966). Collateral source rules recognize that multiple recovery for all or part of a plaintiff’s damages adds to liability expenses. Therefore, some states require that malpractice awards be reduced by amounts received from collateral sources, adjusted by any insurance premiums or other costs that the plaintiff bore. Other states permit defendants to present evidence to the jury about amounts available from collateral sources, so that the jury can consider these amounts when awarding damages (Budetti and Waters 2005).

A recent review of better quality studies found fairly strong evidence that collateral source rule may reduce health insurance premium levels, but is not related to the frequency of claims, payouts for claims, legal expenses, malpractice premium levels, assurance defensive behaviors, physician supply, and outcomes of care (Mello and Kachalia 2010). Four relatively recent national multivariable studies specific to maternity care found modest impact of this reform at best, including one that reported an adverse association:

- A recent analysis from 51 jurisdictions from 1991 through 2003 found no statistically significant relationship between collateral source offset and measures of obstetrician-gynecologist supply (Yang et al. 2008), mode of birth (Yang et al. 2009), or six measures of birth outcome (Yang et al. 2012).
- Currie and MacLeod, investigating national data from 1989 through 2001, found that collateral source offset was not associated with the likelihood of cesarean section, labor induction or augmentation, preventable labor and birth complications, or low five-minute Apgar scores (2008).
- A county-level analysis from 1985 through 2000 found that mandatory offset of collateral source rule was associated with a slightly increased likelihood of having a hospital maternity service in the county: 0.60% for all counties, and 0.76% in non-metropolitan counties (Zhao 2007)
- In two models assessing the association between collateral source rule and death of newborns in the first six days of life across states from 1980 through 2001, collateral source rule was associated with a 5% to 7% increase in mortality of black newborns. The investigators suggest that this rule may weaken the desired pressure to avoid harm by reducing the likelihood that attorneys will accept clients (Klick and Stratmann 2007).

Expert Witness Rule

Many believe that the tort system has led to development of the so-called professional medical witness who travels from courtroom to courtroom to testify in lawsuits. The perception that such itinerant experts will compromise their integrity to provide testimony to support the side of the case that has engaged their services has seriously undermined confidence among obstetricians and other health professionals in the fairness of the negligence system (Fisher et al. 1995).

A recent analysis of expert physician witnesses in cases of neurologic birth injury litigation closed from 1990 to 2005 in 34 states and the District of Columbia corroborated these concerns. Just 71 “frequent witnesses” (testifying in 10 or more cases) participated in 89% of all neurologic birth injury cases. The finding that 79% of the frequent witnesses worked at least three-fourths of the time for either plaintiffs or defendants raised concern about the provision of biased information. Compared with frequent defendant witnesses, frequent plaintiff witnesses were older, were less likely to have subspecialty board certification, and had fewer academic publications (Kesselheim and Studdert 2006).

Although these results have been interpreted as a sign of problems in the expert witness system, it is unreasonable to expect witness equipoise. Due to the deep antipathy in this environment, it is plausible that attorneys would want to avoid working with experts with a history of testifying for the other side, be it plaintiff or defense. It is also plausible that expert witnesses align consistently with one or the other side due to genuine differences in understanding of basic and controversial questions, such as the origins of cerebral palsy. Further, repeat witnesses have a history of previous depositions and trial testimony under oath and are obliged to adhere to past testimony to avoid dismissal of their current testimony. In addition, peer pressure and fear of retribution for testifying on behalf of plaintiffs may limit some witnesses to working on behalf of defendants.

In response to unease that physicians are being judged by laypersons on juries guided only by such experts, some states have specific standards for medical experts, for example, requiring that they be of the same specialty as the physician being sued or that they be practicing physicians (Budetti and Waters 2005). Variation in the approach to expert witness rule across jurisdictions poses challenges for a national analysis. However, the sole recent national multivariable study in the maternity field did not detect an impact of this reform:

- In an analysis of data from 51 jurisdictions from 1991 through 2003, expert witness rule was not associated with two measures of increased obstetrician-gynecologist supply (Yang et al. 2008), decreased total or primary cesarean rates or increased VBAC rates (Yang et al. 2009), or six measures of improved birth outcomes (Yang et al. 2012).

Joint and Several Liability Rule

In the traditional tort system, all defendants being sued for negligence are subjected to “joint and several” liability, which means that any defendant who is found to have been responsible for a negligent injury can be required to pay the full amount of an award, regardless of how many other defendants were also at fault (Levmore 1994). The rationale is that it is fairer to require a negligent party to pay more than his or her share of an injury than to deny compensation to the victim of injury. However, concerns have arisen that this rule has created an incentive to sue as many defendants as possible, particularly large institutions such as hospitals, to ensure that someone has sufficient assets to pay the damages. Conversely, some surgeons favor joint and several liability, as they will likely be named in any case and welcome others to share the responsibility. A recent review of better quality studies across all clinical areas concluded that, on balance, this reform does not reduce claims payouts, legal expenses, and malpractice premiums, and does not improve physician supply and quality of care; with more limited evidence suggesting no effect on claims frequency and defensive assurance behaviors (Mello and Kachalia 2010).

We found three relatively recent studies of the impact of this reform in the maternity field:

- In their analysis of data from 51 jurisdictions from 1991 through 2003, Yang and colleagues found that joint and several liability reform was not associated with two measures of obstetrician-gynecologist supply (Yang et al. 2008), total or primary cesarean rates or VBAC rates (Yang et al. 2009), or six birth outcome measures (Yang et al. 2012).
- Currie and MacLeod (2008), investigating national birth data from 1989 through 2001, found that joint and several liability reform was associated with a 7% decrease in the likelihood of cesarean section and a 13% decrease in preventable complications of labor and birth, but not with labor induction or augmentation or with low five-minute Apgar scores, used as a measure of newborn health. They argue that this reform aligns malpractice risk more closely with the physician's own actions and may help increase accountability of hospitals.
- In two models assessing the association between abolition of joint and several liability and death of newborns in the first six days of life across states from 1980 through 2001, the reform was associated with a small increase in white newborn mortality, which was not robust, however, to inclusion of state-specific trends (Klick and Stratmann 2007).

Periodic Payment of Awards

Traditionally, defendants who are found to have negligently injured a person often must pay all damages that are owed in a lump sum at the end of the legal action. Since awards often include estimated future losses, such as lost income or future medical expenses, some argue that it is unfair to require payment of all damages immediately, including estimated future damages that may never materialize (Budetti and Waters 2005). A medical malpractice insurer can also benefit by spreading the payments over a longer period, with any unused portion potentially being retained by the insurer. Periodic payments also allow insurers to more accurately predict their losses and in turn to set more consistent insurance rates. However, as reported in a study of Florida families of infants with birth injury, a large proportion of families used up-front payments to make major purchases, such as vehicles and homes that are adapted for people with disabilities (Sloan et al. 1993). Nonetheless, these concerns have led to state laws that permit some damage awards to be paid periodically.

A recent review found limited research suggesting that periodic payment reform does not reduce claims payouts or improve physician supply. Conclusions could not be drawn about its relationship with legal expenses, defensive assurance behaviors, and quality of care, and results were mixed regarding claims frequency and liability insurance costs (Mello and Kachalia 2010). Two relatively recent national multi-variable studies found no benefit for this reform in the context of maternity services:

- An analysis of data from 51 jurisdictions, 1991–2003, found no association between periodic payment and two measures of obstetrician-gynecologist supply (Yang et al. 2008); 3 measures of mode of birth (Yang et al. 2009); and six measures of birth outcome (Yang et al. 2012).
- A county-level analysis from 1985 through 2000 found that periodic payment was not associated with increased likelihood of having a hospital maternity service in the county, both nationally and in non-metropolitan counties (Zhao 2007).

Pretrial Screening

Some states require or had required malpractice cases to be screened by a medical review panel before the cases go to court. Pretrial review is intended to identify cases that lack merit and to encourage the parties to settle the case without litigation (Levmore 1994). Some states permit the results of the pretrial review to be admitted as evidence if the case proceeds to court (Budetti and Waters 2005). A recent review of the better quality evidence concluded that results of a few well-designed studies suggest that pretrial screening panels are not effective in claims cost, claims frequency, and liability insurance premiums, and may reduce defensive assurance behavior. The evidence was unclear with respect to the relationship of this reform with legal expenses, physician supply, health insurance premium levels, and quality of care (Mello and Kachalia 2010). Similarly, Struve concluded that there is no good evidence that theoretical advantages of pretrial screening have been realized, and noted that many states that had adopted this reform have repealed or invalidated it (2004).

Two relatively recent national multivariable studies assessed the impact of pretrial screening in maternity care:

- A national analysis of data from 51 jurisdictions, 1991–2003, found that pretrial screening panels were associated with a small (0.07%) but statistically significant positive effect on the vaginal birth after cesarean rate and a statistically significant negative effect on the cesarean rate (0.28%) and primary cesarean rate (0.27%) (Yang et al. 2009). However, pretrial screening was not associated with measures of obstetrician-gynecologist supply (Yang et al. 2008) or with improved birth outcome measures (Yang et al. 2012).
- A multiple regression analysis found no relationship in 2002 between the availability of either mandatory or optional submission panels at the state level and annual malpractice insurance premiums of obstetrician-gynecologists, along with numerous other measures of liability system cost, timeliness, and efficiency across all clinical areas (White et al. 2008).

Statute of Limitations

Another type of access constraint involves shortening the length of time that patients have to file a malpractice suit after the event that gives rise to the claim (Levmore 1994), known as the “statute of limitations.” As some injuries do not manifest themselves immediately, statutes of limitations/repose often have special provisions that extend the time for bringing a lawsuit for some period after the injury should reasonably have been discovered. Statutes of limitations address the issue of “certainty,” which has been an important consideration for states looking at the affordability of malpractice coverage. Malpractice insurance companies need to retain sufficient reserves to cover potential lawsuits, and the longer the period of time for possible cases to arise, the greater the outstanding liability that insurers must be prepared to accommodate. Therefore, prolonged uncertainty about liability affects the premiums that malpractice insurers charge. Most states have shortened the amount of time that parties claiming negligent injury have to bring a lawsuit (Budetti and Waters 2005).

Prolonged uncertainty can also impact care providers’ sense of vulnerability, and this can be especially troubling for maternity care providers. Whereas a statute of limitations for a 25-year-old is on average 2 years, it is 12 years for a newborn (Shea et al. 2008).

A recent review of better quality studies found a fair amount and strength of evidence showing no impact of shortened statute of limitations on claims payments, defensive assurance behavior, and physician

supply, and inadequate evidence to understand impact on legal expenses, and quality of care. Limited evidence suggested some reduction in liability insurance premiums. Results for claims frequency and liability insurance were equivocal (Mello and Kachalia 2010). In many jurisdictions, newborns are entitled to a longer statute of limitations than older people. We found no empirical research on the impact of shortening the statute of limitations within the maternity care field.

Tort Alternative Reform

Arbitration, Mediation

The traditional tort process is harsh for both the aggrieved and defending parties and has been likened to war (Johnson 2000). By contrast, mediation and arbitration offer opportunities to save time and expense associated with protracted legal struggles, soften the experience for the involved parties, and help preserve relationships (Dauer and Marcus 1997; Johnson 2000). Some states have established alternatives to going to court, for example, by permitting physicians to require that disputes with their patients be resolved by a binding decision of a third-party arbitrator, rather than by judicial process. Another approach makes arbitration voluntary, but enforces arbitration agreements when they are made or at least permits the findings to be introduced into court (Budetti and Waters 2005). Some scholars favor a court-ordered arbitration model, which is well established in other litigation contexts and constitutional. Such an approach would rely on skilled decision makers focusing on the merits of the case versus on settlements, and would work toward an earlier resolution than conventional claims (Metzloff 1992).

Arbitration relies on an arbitrator rather than a judge or jury, typically rests on traditional tort theory of liability, and can involve binding decisions. Mediation, a more flexible negotiation facilitated by a neutral third party, emphasizes autonomy, informed decision making, and confidentiality for reaching a mutually acceptable decision. The latter has greater potential for avoiding the harshness of the traditional tort system and for promoting learning and healing (Todres 2006).

Most discussions advocating for these strategies are hypothetical. In an earlier study with state-level data from 1974 to 1986, Zuckerman and colleagues found that allowing arbitration agreements did not have a statistically significant effect on liability premiums and malpractice claim frequency or severity (1990). A pilot project in New York City involved 19 mediated cases and found satisfaction among the parties, irrespective of outcome, settlements in the majority of cases, and attorneys on both sides estimating that they spent about one-tenth the time that would have been required to prepare for a trial (Hyman and Schechter 2006). Interviews with participants in 31 mediated lawsuits across 11 hospitals found satisfaction across many parties (plaintiff and defense lawyers, plaintiffs, hospital representatives, insurers) and identification of ways to improve hospital safety. While mediation has the potential to aid healing, improve patient care, shorten litigation processes, and reduce its costs, the absence of physician participation reduced the potential impact on patient safety (Hyman et al. 2010). New York State is currently piloting a “judge-directed negotiation” model through the Agency for Healthcare Research and Quality Patient Safety and Medical Liability Reform Demonstration Projects program (AHRQ 2010). The effect of arbitration and mediation on the maternity field does not appear to have been studied. Mediation may be an important tool when bundled with other strategies, such as disclosure and apology.

Liability Insurance Reforms

Joint Underwriting Associations

When legislators perceive medical liability coverage to be unavailable or unaffordable, they may consider implementing a risk-sharing mechanism to serve as a market of last resort. A common risk-sharing mechanism is the joint underwriting association (JUA), with a state either authorizing or requiring one or more carriers to issue medical liability insurance policies to health care providers that are unable to obtain insurance from the voluntary market insurers (Danzon, Epstein and Johnson 2004). If the JUA's premium income is insufficient to cover legal expenses and losses, each member insurance company is assessed a pro rata share of the shortfall (Burda 1986).

JUAs add value to a market as a mechanism for providing insurance coverage to anyone who needs it (Sloan et al. 2005). However, JUA establishment by itself does not address the price or affordability of the insurance product. Established liability insurers have usually rejected those who are insured by JUAs. Some may tend toward higher claims costs. Insurance coverage from JUAs is typically more expensive than coverage in the traditional insurance market; hence these entities are used when there are insurance availability concerns. JUAs have limited benefits in markets where affordability of existing coverage is the most pressing problem (Sloan et al. 2005).

Given the relatively small risk pools for midwifery and birth center liability insurance, and the potential for a single large payout to result in unaffordable premium rates, JUAs may be important mechanisms for making coverage reliably available to those groups. In 1993, the Washington State legislature enacted a bill requiring the Office of the Insurance Commissioner to create a Joint Underwriting Association for Midwifery and Birthing Centers (Myers and Myers-Ciecko 2004) (<http://www.washingtonjua.com>). Another JUA model offers liability insurance to diverse entities, inclusive of maternity services. For example, the Pennsylvania Professional Liability Joint Underwriting Association offers coverage to physicians, certified nurse-midwives, and birth centers (<http://www.pajua.com>). Evaluation of JUA contributions to maternity services, including the potential for this model to foster reliable coverage across the full complement of maternity services, is warranted.

Investment Regulation

Regulators have overseen insurers' investments as a protection against avoidable spikes in liability insurance premiums. In 1990, the National Association of Insurance Commissioners (NAIC) adopted a model law restricting an insurer to no more than 20% of its admitted assets in non-investment grade bonds, with additional restrictions on the proportion of assets in the lower-rated categories. Several states adopted the model law or similar restrictions on junk bonds (Nordman et al. 2004). In 1996, the NAIC adopted a comprehensive model law covering all insurer investments. The model law set certain limits on the amounts or relative proportions of different assets that insurers could hold to ensure adequate diversification and limit risk (Nordman et al. 2004). However, it was later changed to the "prudent person" approach, which allows insurers greater discretion in their allocation of investments if they can demonstrate adherence to a sound investment plan (Nordman et al. 2004). Regulators are authorized to intervene if an insurer fails to meet this general requirement. Insurance companies are required to maintain records and file quarterly financial statements with regulators in accordance with statutory accounting principles that seek to determine an insurer's ability to satisfy its obligations (Hoyt and Powell 2006). In the best case, investment regulation addresses a small portion of liability challenges in maternity care.

Rate Regulation

About a third of states use rate regulation. In theory, this has the potential to keep prices high enough to prevent insolvency and low enough to make liability insurance more affordable. However, no comparative studies have assessed this strategy (Mello 2006b). Rate regulation could hasten insolvency if regulators are overly responsive to pressure for low premiums, as has occurred with automobile insurance (Sage 2004a).

Within the scope of rating regulations, Geistfeld proposed that without experience rating practitioners generally cannot limit premium levels by providing high-quality care, making class rating for medical malpractice on the basis of specialty and geographic area unfairly discriminatory. This penalizes, for example, a professional who makes the socially valuable choice of practicing obstetrics in a low-income community. Geistfeld's proposed solution is to set a uniform premium level for all medical professionals in a jurisdiction, regardless of specialty or geographic area (2005). This has special and favorable implications for maternity care providers and others in clinical areas at higher liability risk and for geographic areas and could as well foster access to types of services with small, vulnerable risk pools (e.g., midwives, birth centers). It would directly address the deep sense of liability system injustice that appears to be salient in the obstetrics community.

Geistfeld also observed that setting premium levels on the basis of specialty, geographic location, and claims experiences could create individual incentives to reduce error and protect patient interests. He notes, however, that occurrence of liability does not reliably indicate occurrence of malpractice (Geistfeld 2005). This proposal, moreover, does not account for the great extent to which medical injury is a function of system factors (Mello and Studdert 2008), the tension between liability focus on individuals and patient safety goals (Woods 2005), and the health care system trend of consolidating individuals into large groups and as employees of hospitals and health systems.

More incremental proposals for insurance rate regulation involve oversight and monitoring of the adequacy of insurance rates to assure that they meet rate-filing standards (Nelson 2000) and to ensure that filings are commensurate with market fluctuations (Brierton 2004). In the best case, rate regulation would address a small portion of liability challenges in maternity care.

Premium Subsidy

One approach to concerns about the affordability of liability insurance and the potential for premium levels to be a barrier to access to maternity care is to provide direct subsidies to clinicians for premiums, a strategy that has been considered or implemented in several states (Smits et al. 2009). We found one evaluation of a maternity caregiver premium subsidy program. Due to concern about access to maternity caregivers, especially in rural areas, the state of Oregon instituted a malpractice premium subsidy program for obstetrician-gynecologists, family physicians (FPs), general practitioners (GPs), and certified nurse-midwives in 2004. After implementation of the subsidy program, the number of clinicians providing maternity services in all groups, most prominently among FPs and GPs, continued to decline in the state. A survey found that access to malpractice premium subsidies was not associated with continued provision of maternity services in a multidisciplinary population that had identified liability premium costs as the leading factor in discontinuation of maternity services four years earlier (Smits et al. 2004; Smits et al. 2009).

Patient Compensation Funds

Some states have adopted the insurance reform of creating patient compensation funds (PCFs) (Schrero 1979). States with PCFs limit health care provider claims to a specified monetary level. Redress for

amounts above the monetary limit is available to injured parties through a PCF (Hudson 1990). Thus, regardless of the size of an award against them, providers are responsible for only a certain amount of damages (Budetti and Waters 2005). PCFs offer certainty to health care providers and their insurers by establishing a limit on the magnitude of losses the caregiver's insurer must bear, adding predictability to pricing medical liability insurance coverage. If frequency does not rise, medical liability premiums should remain relatively stable (Sloan et al. 2005).

An investigation in 2004 identified nine states with PCFs and one that had discontinued a PCF (Sloan et al. 2005). Typically, PCFs are funded from liability premiums and investment returns, rather than state subsidies. Health care providers pay premiums to private primary insurers as well as surcharges to the state PCF. As a result, PCFs may improve insurance availability but can be expensive. On the basis of interviews with the PCF representatives and review of literature on this topic, the investigators concluded that PCFs function as passive financial intermediaries with no special contribution to patient safety, loss prevention, and claims management. The report did not specifically reference maternity matters (Sloan et al. 2005).

Patient Compensation Funds create moral hazard for primary insurers (as they have less incentive to defend claims that exceed their policy limits) and adverse selection for providers (as providers who are at low risk for future claims may drop out of the PCF after the PCF becomes expensive, leaving only high-risk providers enrolled).

In 2011, the New York State Legislature established a Medical Indemnity Fund created from 1.6 percent of hospital inpatient maternity care revenues to cover future medical and other necessary expenses of neurologically impaired newborns as they occur. Defendants or their insurers will be responsible for covering all other costs. As plaintiffs will be required to obtain a determination of provider negligence and causation through the court system, the Fund does not free up legal expenses of litigation or hasten resolution and payments to families (Greater New York Hospital Association 2011).

A recent assessment of effects of patient compensation funds affirmed that the limited contribution of current models in shifting liability cost burden away from health professionals and insurers. Investigators note, however, the potential for patient compensation programs to incorporate incentives for quality improvement and to reduce legal and liability insurance costs by incorporating early offer and disclosure programs (Mello and Kachalia 2010).

Summary

The effect of caps on non-economic damages has been well studied within maternity care, with studies finding modest and narrow impact at best. A smaller number of studies have examined effects of several other traditional tort reforms within maternity care, with generally disappointing results. Despite strong interest in limiting payouts as a strategy for keeping malpractice premiums in check, the relationship between the two appears to be weak at best (Baicker and Chandra 2005b). With one exception, the remaining reforms considered above have not been evaluated in the context of maternity care. However, there is little more general support for these strategies. Where data are sparse, even if the reforms proved to be effective at achieving their aims, they would still be of limited value due to their focus on a narrow segment of the liability system concerns that warrant the attention of policy makers.

We found some important discrepancies between results of liability reforms in medicine generally and maternity care in particular. Whereas evaluation of tort reforms collectively and with respect to caps on non-economic damages have shown a desired impact in medicine overall, their impact in maternity care is modest at best. This underscores the importance of conducting liability research in specific clinical areas, as previously shown in a study of newborn and emergency room injuries (Sloan et al. 1993).

Many reforms that health care providers and professional associations have advocated and policy makers have supported focus on clinician and liability insurer interests and do not directly address interests of childbearing women and newborns and those who pay for their care (Hyman and Silver 2005). To meet the needs of all stakeholders, policy makers will need to implement and assess interventions with the potential for multi-faceted impact, which are discussed in the following section.

Substantive Interventions with Potential to Address Multiple Aims

This section begins with six promising strategies for preventing injury, which are followed by four promising strategies for responding to injury or claims of injury. Within each group, specific strategies are ranked according to the range of liability systems aims that they have been shown to impact, or might plausibly impact (Table 4). High-performing legal, liability insurance, and health care systems address both dimensions. Most of the strategies have not been expressly evaluated with respect to maternity care, and some have a very limited track record generally. However, states and other entities can pilot, assess, and refine these more promising strategies for preventing and redressing injury. Maternity-specific demonstrations will be of value in light of the size and significance of the population involved, the prominent role of maternity care and costs of such care within the health care system, the relatively high level of associated liability risk, and the possibility that the effect of an intervention in this context differs from impacts in other clinical areas or overall.

Federal government initiatives to improve the liability system will soon contribute to our understanding of these innovations. The Agency for Healthcare Research and Quality (AHRQ) is funding several maternity-related pilots under Medical Liability Reform and Patient Safety Demonstration Projects (RFA-HS-10-021) and Planning Grants (RFA-HS-10-022). These include projects to test the relationship between safety and liability, to reliably provide evidence-based intrapartum care and improve the handling of adverse events, to implement a program of both negotiation and early disclosure and settlement, to consider the impact of improved teamwork on liability, and to implement a statewide pregnancy-associated mortality review and develop safety recommendations. The demonstration projects will produce results within a tight three-year time frame (2010). Langel provides details of the demonstration projects (2010). AHRQ has solicited proposals for more state and health care system patient safety and medical liability demonstration projects and planning grants, but has not reviewed applications in the absence of Congressional funding (Norman 2011).

The Patient Protection and Affordable Care Act (PPACA) authorized \$50 million for states and health care systems to test Alternatives to Current Medical Tort Litigation, and the administration requested \$250 million for similar but more ambitious purposes. However, Congress did not fund these programs. PPACA directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to review and report on results of federal grants to identify alternatives to tort litigation and their impact on the Medicaid and CHIP programs by the close of 2016.

While some promising interventions require legislative changes and/or the establishment of new legal or health care structures and relationships, others are being or could be tested without such changes.

Health care systems, liability insurers, and state agencies can lead various types of voluntary experimentation. These strategies also present new opportunities for state and federal policy makers to provide leadership on substantive solutions with the potential to favorably impact a range of liability system aims. The strategies discussed in this section have the potential to favorably impact multiple aspects of a high-functioning liability system, including keeping costs in check, promoting patient safety, assisting those with injuries, and calming the concerns of health professionals (Kachalia and Mello 2011).

Prevention

Quality Improvement: A Health Care Reform

Malpractice scholars and health policy and clinical leaders increasingly agree that patient safety and other initiatives to improve health care quality are essential for achieving multiple liability system aims (Clark, Belfort, Dildy et al. 2008; Clinton and Obama 2006; Hickson and Entman 2010; Joint Commission on the Accreditation of Healthcare Organizations 2005; Pearlman 2006; Pearlman and Gluck 2005; Sage 2003; Schoenbaum and Bovbjerg 2004). However, the legal system itself exerts little pressure on providers to improve the quality of care (Hyman and Silver 2006).

A large body of underutilized systematic reviews can be used to address considerable gaps between maternity practice and best current evidence, to greatly improve the quality of maternity care, and to reduce current unwarranted practice variation (Sakala and Corry 2008). Systematic reviews also identify effective strategies for improving maternity care quality (Chaillet and Dumont 2007; Chaillet et al. 2006; Kongnyuy and Uthman 2009; Meri  n et al. 2010), health care quality generally (Wensing et al. 2006), and patient safety (Leape et al. 2002; Shojania et al. 2002). A collaborative multi-stakeholder process involved leaders from across the health care system in creating a “Blueprint for Action: Steps Toward a High-Quality, High-Value Maternity Care System,” identifying priority liability and other recommendations for improving the systems in which maternity care is delivered (Angood et al. 2010). To support implementation of the recommendations, Childbirth Connection provides access to key resources on the *Transforming Maternity Care* website at <http://www.transform.childbirthconnection.org>.

Mello and Hemenway argued that injury reduction has limited potential for reducing malpractice claims and premium levels in light of the low level of filing claims among those who sustain injuries (2004). This may be the case when insurers who pay for losses are not motivated to leverage quality improvement efforts and are independent entities from providers of care (Mello, Studdert, Thomas et al. 2007). However, hospitals and health systems that are self-insured, pay malpractice premiums of both hospitals and clinicians, have transparent performance reporting, and pay for high-cost newborn injuries have increased incentives to reduce injury.

Maternity care quality and safety improvement programs have begun to report that rigorous quality improvement programs are leading to improved care and health outcomes as well as substantial decreases in claims, payouts, and premiums:

- The nation’s largest hospital system, with about 220,000 births annually across 21 states, improved maternity outcomes, reduced its primary cesarean section rate, reduced its obstetric malpractice claim rate by two-thirds, and brought its cost of claims below the level of the category “accidents on hospital grounds” over the first decade of its system-wide quality improvement program (Clark et al. 2011; Clark 2009a; Clark, Belfort, Byrum et al. 2008). →

- In its 16 hospitals with maternity units, a health system conducted on-site risk assessments and gap analysis to align practice with evidence and standards, reviewed claims and near-miss data, implemented patient safety programs, and measured outcomes. Over a five-year period, birth trauma decreased from 5.0 to 0.2 per 1,000 births, birth-related occurrences that could lead to a claim decreased from 7.2 to 2.5 per 1,000 births, the average cost per claim decreased from \$1 million to less than \$500,000, and the number of new claims decreased by 48% (Simpson et al. 2009).
- The first phase of a perinatal safety initiative in 14 hospitals from across the country involved adopting team communication processes, simulation training, and evidence-based care bundles. The sites improved care processes, reduced maternal and newborn complications (averting an estimated 144 adverse maternal or newborn events), and improved liability measures. Relative to baseline, participating hospitals experienced a 39% decrease in claims per 1,000 births (versus 10% for non-participating hospitals) and a growth in the proportion of new claims that were resolved without payment (Premier 2012).
- Reviewing ten years of liability claims, a health system identified maternity care as the clinical area with greatest potential for improving patient safety. After implementing a protocol-driven electronic system that monitors adherence to standards of care and provides real-time alerts, the four participating hospitals achieved a 25% improvement in four targeted quality measures and learned from near misses. Within three years, the system recouped all costs of investing in and operating the system through reduced self-insurance funding. It experienced large declines in actual as compared with expected frequency and severity of claims and a claim-free period of 15 months for the 2007 loss year (Smith and Berry 2008).
- In the seventh year of implementing a comprehensive patient safety program, a tertiary academic referral center achieved a 99.1% decrease in obstetric liability payouts relative to the average of the first three years. On average in the three most recent years, the center saved over \$25 million annually relative to the average payouts in the initial four years. Sentinel events plummeted to zero in the two most recent years, with similarly favorable results for maternal death, permanent Erb's palsy, and hypoxic ischemic encephalopathy, and a very favorable outlook for future payouts (Grunebaum et al. 2011).
- A safety net tertiary care center implemented a multi-faceted labor and birth safety program over five years, and found that the number of claims that its insurance companies reserved for financing possible associated expenses declined about 20% annually. They experienced no actual claims during the four most recent years, with about 2,300 to 2,500 births annually (Iverson and Heffner 2011).
- In 2003, a risk insurance company and risk management foundation affiliated with a major university instituted a premium discount program for maternity providers who complete specific patient safety activities, and found that "early results show a drop in malpractice claims frequency and a downward trend in adverse outcomes" (McCarthy 2007).

The studies generally juxtapose time trends for program implementation with time trends for health and liability measures, and do not analyze competing explanations for the results. A complementary analysis that did consider other variables found a relationship between malpractice claims and the Agency for Healthcare Research and Quality's Patient Safety Indicators (PSIs) of in-hospital complications and safety events:

- In a multi-variable analysis, RAND investigators found a strong correlation between changes in total PSI event counts and changes in the volume of claims against obstetrician-gynecologists at the county level in California from 2001 through 2005; PSI event count changes accounted for about 30% of the variance in malpractice claims. The authors suggested that interventions that improve patient outcomes have the potential to reduce claims submissions (Greenberg et al. 2010).

The hospital and health system reports are remarkably consistent in finding a strong inverse relationship between rigorous quality improvement and liability. This growing body of evidence and similar results obtained in other countries (e.g., Milne and Lalonde 2007) lend strong support for multi-faceted quality and safety programs with strong leadership as a priority strategy for liability reduction. They provide health care organizations with the “business case for quality” (Hyman and Silver 2005). Obstetrical quality leader Steven L. Clark encourages his colleagues to focus on the 75% of paid claims associated with substandard care, over which they have some control, versus the 25% not associated with substandard care, over which they have little control (Clark 2009b). He and his team concluded, “we are absolutely confident that adoption of our approach on a national level could, within 5 years, both dramatically reduce adverse perinatal outcomes and to a large extent eliminate the current obstetric malpractice crisis” (Clark et al. 2011).

Such an approach shifts from the redress focus of the tort system to prevention, and it improves care for both those who might have submitted claims in the face of injury *and* the vast majority who would not have submitted claims.

Consistent implementation of safe, high-quality care might also help dispel the corrosive liability-associated apprehension and malaise that appear to take a heavy toll among obstetrician-gynecologists. Stakeholders would benefit if administrators and maternity caregivers felt justifiably confident and proud of their demonstrated improvement and reliable provision of high-quality maternity care. Improved care could lead to reduced injury, fear, anger and litigiousness, claims and lawsuits, liability payouts, and insurance premiums on the one hand, and to improved relationships, clinician-patient communication, and professional satisfaction on the other. The work of helping families bring babies into the world has great potential to be joyful and positive. Two comprehensive maternity care quality improvement programs have reported positive impact on both care and clinicians’ experiences, but have not reported possible impact on liability measures. A state program involving 15 hospitals found improvement on most structure and all process measures over an 11-month period, as well as improvement in ratings of job satisfaction, working conditions, and hospital management (Simpson et al. 2011). Similarly, an academic medical center achieved significantly improved patient safety and reported concurrent perception of improved job satisfaction, teamwork culture, safety culture, and management (Pettker et al. 2011).

A focus on quality improvement and achieving high-functioning perinatal units during the intrapartum period (Simpson and Knox 2003) has especially great potential for impacting liability experiences because at least 60% of obstetric negligence claims and more than 80% of the payments for injury awarded in suits against these specialists are associated with this period (Cohen and Schiffrin 2007).

The case study of anesthesiology suggests that parallel gains are achievable in maternity care and other fields (Stoelting and Khuri 2006). Anesthesiology leaders prioritized patient safety. The specialty’s comprehensive approach to quality and safety was associated with a decline in mortality from two per 10,000 to one per 200,000 to 300,000 anesthetics administered (Lanier 2006). These efforts led to reduced liability premiums and informed the *To Err Is Human* report (Institute of Medicine 2000).

Despite the growth of implementation science, numerous strategies and programs for improving quality and safety, and a common theme of reducing liability, there is a paucity of data about the impact of these initiatives on liability system aims. Data are needed to better understand the impact of the strategies and programs in Table 5 on liability-related matters.

Table 5. Maternity Care Quality Improvement Strategies with Potential to Reduce Liability

Strategy	Role in Maternity Care
Using national standardized <i>safety measures</i> , “Safe Practices” and “Serious Reportable Events,” to measure, report, and improve performance	National Quality Forum 2010, 2012a
Using national standardized perinatal care <i>quality measures</i> and <i>adverse event reporting systems</i> to measure, report, and improve performance	Hibbard et al. 2003; Levinson 2008; Main 2009; National Quality Forum 2012b
<i>Implementing payment reform</i> to align incentives with quality	Hyman and Silver 2005, 2006; James and Savitz, 2011; Lantos 2010; Rosenthal et al. 2009
Implementing maternity care <i>quality improvement collaboratives</i> or maternity-focused programs within broad-scope collaboratives	Childbirth Connection, 2012b; Main and Bingham 2008
Implementing focused <i>toolkits</i> to improve practice	Childbirth Connection 2012c
Implementing <i>medication safety systems</i> , including focus on common “high-alert” medications (synthetic oxytocin, narcotics/opioids, epidural or intrathecal medications)	Clark, Simpson et al. 2009; Institute for Safe Medication Practices 2008; Keohane and Bates 2008
Reducing unwarranted <i>overuse</i> use of interventions that are associated with sentinel events and serious maternal and newborn morbidity, including cesarean section and labor induction	Elkamil et al. 2011; Gilbert et al. 2010; Kramer et al. 2006; Marshall et al. 2011; Martinez-Biarge et al. 2012; Mercer et al. 2008; Murray et al. 2009; Silver 2010; Silver et al. 2006; Vardo et al. 2011
Implementing <i>shared decision making</i> using high-quality, up-to-date decision aids	Dugas et al. 2012; Frosch et al. 2011; Say et al. 2011; Stacey et al. 2011, Vlemmix et al. 2012
Developing systems for effective patient-centered <i>informed consent processes</i> , consistent with the predominant “patient” standard of informed consent and childbearing women’s desire for information prior to consent	American College of Obstetricians and Gynecologists 2005; Declercq, Sakala et al. 2006; Matiassek and Wynia 2008; National Quality Forum 2005; Studdert, Mello, Levy et al. 2007
Harnessing potential of <i>electronic health records</i> to foster access to full and accurate documentation and data collection and to support appropriate care	Bernstein et al. 2005; Cusack 2008; Eden et al. 2008; George and Bernstein 2009; Haberman et al. 2009; Nielsen et al. 2000; Quinn et al. 2010
Building effective <i>teams</i> , improving interpersonal <i>relationships and communication</i> and strengthening <i>collaborative practice</i>	Hickson and Entman 2008; Lyndon et al. 2012; Lyndon et al. 2011; Mann and Pratt 2008; Meri��n et al. 2010; Nielsen and Mann 2008; Pratt et al. 2007; Williams et al. 2010

Implementing <i>high-reliability practice</i> that aligns care with best evidence and reduces practice variation, including use of clinical decision support, protocols, explicit evidence-based guidelines, checklists, etc.	Clark et al. 2011; Clark, Belfort, Byrom et al. 2008; Clark, Belfort, Saade et al. 2007; Fausett et al. 2011; Grobman et al. 2011; Hasley 2011; Knox and Simpson 2011; Pettker 2011
Implementing <i>quality of care peer review systems</i> (e.g., American College of Obstetricians and Gynecologists Voluntary Review of Quality of Care)	Lichtmacher 2008; Stumpf 2007
Using <i>laborists</i> (maternity care hospitalists) for labor and birth care, which may foster retention of core knowledge and skills, high intrapartum competence, on-site provider presence throughout labor, appropriate use of interventions to control onset of or hasten labor, better maternal experience, better health professional satisfaction	Devoe 2009; Gussman n.d.; Srinivas and Lorch 2012
In education programs, renewed focus on teaching <i>fundamentals of intrapartum care</i> and common standardized terminology	Cohen and Schiffrin 2007; Devoe 2009
Taking <i>safety and emergency preparedness courses</i> , including Advanced Life Support in Obstetrics, Managing Obstetrical Risk Efficiently, Managing Obstetric Emergencies and Trauma, and PRactical Obstetric MultiProfessional Training	Beasley et al. 2005; Childbirth Connection 2012a; Draycott et al. 2008; Grady et al. 2007; Milne and Lalonde 2007
Using <i>simulation</i> to build skills, knowledge, and teamwork and to prepare for emergencies	Fisher et al. 2011; Gardner and Raemer 2008; Gardner et al. 2008; Meriën et al. 2010
Creating a <i>plan for respectful management of serious adverse events</i> , integrating into organization's culture of quality and safety, and implementing it as needed	Conway et al. 2011
Conducting <i>analysis of adverse events</i> and associated circumstances, and incorporating lessons into care systems	Boothman and Blackwell 2010; Clark et al. 2012; Mulligan and Nechodom 2008; Schiffrin and Ater 2006; Smetzer et al. 2010
Carrying out <i>analyses of closed and open claims</i> and circumstances associated with them, and incorporating lessons into care delivery systems	Angelini and Greenwald 2005; Clark, Belfort, Dildy et al. 2008; Crawford 2002; Hickson et al. 1992; Jevitt et al. 2005; Kravitz et al. 1991; Richards and Thomasson 1992; Ward 1991; White et al. 2005
When patients are harmed during care processes, implementing national <i>"Care of the Caregiver" standard</i> , through just treatment, respect, understanding and compassion, supportive care, and transparency	Denham 2010; National Quality Forum 2010
Developing and implementing <i>standards and measures for clinician behavior</i> , and carrying out system-level programs to identify problem clinicians and address shortcomings	American College of Obstetricians and Gynecologists 2007b; Chervenak and McCullough 2005; Leape and Fromson 2006; Rosenstein 2011; Simpson 2007
Improving the <i>accuracy, completeness, and timeliness of data</i> in the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank, and using them to identify unsafe caregivers	Sibeliuss and Wakefield 2010; Weber and Ornstein 2010
Using implementation science to assess the <i>effectiveness of change strategies</i> and implementing effective approaches	Clark et al. 2010; McMaster University 2012

The innovations in Table 5 involve a sea change in the conventional culture of safety and error: from limiting access to information to transparency and disclosure, from avoidance and delays to timely resolution of adverse events, from failure to learn and apply to seizing opportunities for improvement, from focus on individuals to focus on systems, from deflecting to taking responsibility, and from conflict to cooperation. They better align maternity care with the six aims for improvement — care is safe, effective, patient-centered, timely, without waste, and equitable — as originally delineated in the *Crossing the Quality Chasm* report (Institute of Medicine 2001) and as extended to maternity care (Carter et al. 2010).

In addition to maternity care quality improvement, a number of strategies, discussed below, also “seek common ground” and find a “third way” (Bovbjerg et al. 2001; Budetti 2005) to better align and coordinate health care and liability concerns.

Enterprise Liability: A Tort Alternative Reform

Many respected health law scholars have supported shifting malpractice liability to hospitals, health plans, and other enterprises while reducing or eliminating clinician liability, an approach known as “enterprise liability” (Bovbjerg and Berenson 2006). Under the pure form of this model, health professionals are not named as defendants in suits alleging malpractice, but assume the limited role of fact witnesses. Hospitals, health systems, and other enterprises become legally accountable for the actions of their affiliated health professionals and responsible for operating well functioning organizations with high-performing caregivers. Legislative and voluntary approaches have been proposed, as has a joint corporate and individual liability arrangement. The original developers of the model note that the focus on individual clinician liability took shape and was suited to a time when isolated clinicians used hospitals as a workshop and hotel for their patients, in contrast to the present when care is primarily provided under the auspices of hospitals, integrated delivery systems, and health insurers. They argue that the individual focus is obsolete, and the preferred entity delivers rather than merely finances care (Abraham and Weiler 1994). However, enterprise liability is not easily applied to the current health care system since health professionals are not necessarily affiliated with one and only one entity.

The enterprise liability model addresses fundamental aims of the liability system, as it:

- is consistent with the finding that about two of three injuries attributable to error involve both individual and system factors, directly implicating institutions in most harmful medical errors, whereas about one in three can be attributed solely to individuals (Mello and Studdert 2008)
- incents self-insured hospitals and others that are charged premiums reflecting past claims experience to take responsibility for patient safety (especially with exclusive hospital enterprise liability model), versus current focus on individual liability with limited and more actuarially challenging caregiver experience rating (Abraham and Weiler 1994; Peters 2008)
- gives liability responsibility to entities that have the benefit of system leaders, centralized planning, and resources for quality improvement programs, which are more difficult for solo and group clinicians (Mello and Studdert 2008; Peters 2008; Sage 2004a)
- fosters health system coordination (Sage 2005)
- reduces clinician stigma, discomfort, defensiveness, and pressure to conceal errors, fostering greater cooperation and potential to support injured parties and learn from errors (Peters 2008; Sage et al. 1994)
- reduces health professional discontent by removing penalties such as threat to reputation, embarrassment, and — regardless of merit — reporting of settlements to National Practitioner Data Bank and disclosing claims on applications for admitting privileges, board certification, and liability insurance (Peters 2008)

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- enables more equitable distribution of liability costs across specialties and spares obstetrician-gynecologists and other high-risk specialists who may face a catastrophic outcome from a single mistake from paying disproportionately (Abraham and Weiler 1994; Peters 2008; Sage 2004a)
- shields health professionals from liability insurance premium spikes in hard phases of liability cycle (Peters 2008)
- provides large risk pools to ensure that resources are available for large judgments (Abraham and Weiler 1994)
- has potential to build in other strategies such as arbitration and no-fault payment (Sage 2004a), schedules for fair and predictable non-economic damages compensation (Abraham and Weiler 1994), and disclosure and offer
- reduces multi-defendant litigation costs by consolidating liability in the single corporate defendant (Peters 2008; Abraham and Weiler 1994),
- has fostered safety in other industries (e.g., aviation and automobile) (Peters 2008) and is used for worker's compensation of workplace injury (Mello and Studdert 2008).

Enterprise liability is compatible with various health system reform trends. These include the consolidation of clinicians into large practices and the increasing employment of clinicians by often self-insured hospitals and health systems. This model is compatible with the growth of accountable care organizations, bundled payment systems, and other delivery and payment innovations that align quality and value (Commonwealth Fund Commission on a High Performance Health System 2009; Mechanic and Altman 2009; Network for Regional Healthcare Improvement 2008). Episode-of-care payments are especially well suited to maternity care (Miller 2009). Many considerations relevant to enterprise liability in the context of managed care at the end of the last century pertain to present circumstances (Sage 1997).

Despite strong support and a compelling rationale, this model has not been piloted. No state currently offers a legal climate suitable for enterprise liability, but self-insured academic medical centers and integrated delivery systems include many elements and incentives of enterprise liability (Mello and Kachalia 2010).

A recent review of the likely effects of this model concluded that a well-designed enterprise liability system has the potential to reduce overhead costs of litigation and liability insurance costs, to reduce defensive assurance behaviors, and to improve health care quality. The investigators were unable to anticipate effects on the frequency and cost of claims (although the latter would be shifted in whole or in part from health professionals) and on physician supply (Mello and Kachalia 2010).

Leverage of Health Insurance, Accreditation, and Credentialing: A Health Care Reform

Rather than operating as ships passing in the night, health insurance can and should be linked to the liability system (Sage 2005). Potential or actual medical errors should be handled within rather than separate from the health care system. As private and public payers enter into agreements on behalf of beneficiaries and indirectly finance malpractice costs by reimbursing clinicians and facilities, they have a justifiable interest in liability matters. Currently, the primary policy connection between the two is through the liability component of payments in Medicare's fee schedule (see Appendix I). Payers could favorably impact liability issues by operating as proactive purchasers. Sage argued:

Policymakers should link financial relief for the malpractice crisis to selected improvements in safety and accountability within the health care system, such as voluntary error reporting and analysis, better communication with patients and families, and pay-for-performance mechanisms. The most straightforward way to accomplish this is through health insurance, particularly the Medicare and Medicaid programs (2005, 483–84).

Similarly, Sage has identified ways to better integrate liability coverage into the professional, commercial, and regulatory framework of health care financing and delivery (2004a). There is great unrealized potential for insurers, credentialing and accrediting bodies, and others with oversight responsibility or other types of leverage to take greater responsibility for the delivery of safe, effective care. These groups can foster use of the full range of safety and other quality improvement strategies (Table 5), as well as tort alternative approaches such as disclosure and apology. The Wyoming Healthcare Commission has issued a report identifying a comprehensive package of strategies that the state can pursue to address medical error and medical injury compensation (Roberts et al. 2005). The leverage under such circumstances might result in broader adoption of and greater impact on aims of the liability system and might hasten movement toward a culture of safety, in comparison with voluntary improvement initiatives.

Shared Decision Making: A Health Care Reform

Decision-making processes and standards are crucial considerations for liability involving decisions to undertake certain care pathways and forgo others. Current standards of informed consent often involve acquiescing to a clinician's recommendation through a generally brief process, often after a decision is made in an unspecified manner and just before implementing it. There are flaws in both the older informed consent standard that clinicians should disclose what they think a patient should know and the newer standard, now in effect in about half of U.S. jurisdictions, that a clinician should disclose what a reasonable patient would want to know. From a malpractice perspective, the clinician standard insulates physicians who adhere to local standards from infringement on patient autonomy, while leaving those who deviate from local standards to improve care or disclosure vulnerable to liability. Conversely, the patient standard leaves physicians vulnerable to liability in the absence of clear guidance about the "material risks" of interest to a "reasonable patient" (King and Moulton 2006).

Legal scholars and health services researchers increasingly argue that the shared decision-making model is superior to current informed consent standards and should be strengthened and widely implemented (King and Moulton 2006; O'Connor et al. 2007). This approach can help foster evidence-based practice and ensure that clinical decisions reflect patients' values and preferences. Shared decision-making processes provide full information about benefits and harms of various options, which may be clearly defined, standardized, and derived from both comparative effectiveness research and research with suitable patients. These processes also involve sharing of information between clinicians and patients, including consideration of patients' values and preferences, which are crucial with "preference-sensitive" choices when evidence does not clearly suggest a specific path and patient values and preferences should be the primary determinants of choice (King and Moulton 2006).

High-quality decision aids are essential tools for shared decision making (Ottawa Hospital Research Institute 2012). Without such tools, shared decision making would be burdensome and challenging for clinicians, and their own preferences may have undue impact on decision making. The tools help people understand benefits and harms of the various options, consider their own values and preferences, and engage in decision making. The current Cochrane Review evaluating effects of decision aids in people facing screening or treatment decisions includes 86 studies. The review found, among other results, that decision aids perform better than usual care processes in improving knowledge, helping people feel informed, clarifying personal values, helping people become engaged in decision making, helping people feel clear about their decision, reducing the likelihood of choosing major elective invasive surgery, and improving patient-clinician communication. Benefits were found for decision aids that provided greater detail, that described probabilities of outcomes, and that included values clarification relative to alternatives (Stacey et al. 2011).

In addition to the impressive overall track record, this approach has an evolving evidence base in maternity care (Dugas et al. 2012; Say et al. 2011; Vlemmix et al. 2013), is increasingly recognized as a standard of maternity care practice (Gee and Corry 2012), and is becoming well-integrated into health care policy in the United States (Frosch et al. 2011).

The benefits of shared decision making for patients and clinicians extend to liability (King and Moulton 2006). This approach can reduce risk of liability by fostering high-quality communication between clinicians and patients. Many studies have found that a high proportion of lawsuits are initiated due to poor communication and the breakdown of these relationships (King and Moulton 2006), and this has been documented in the context of lawsuits for newborn injury (Sloan et al. 1993). Monico and colleagues identify relevant benefits of shared decision making, including improving patient autonomy and understanding, reducing use of unwanted medical procedures, improving communication and trust between patients and clinicians, and clearly delineating mutual responsibilities. They argue that better patient understanding, acceptance of possible outcomes, and avoidance of unrealistic expectations can reduce clinician exposure to liability (2008).

The potential contribution of shared decision making to liability is in moving the clinician and patient from a hybrid tort to a contractual relationship (Green 1988; Monico et al. 2008). Green argued that courts have encouraged viewing informed consent standards within contractual or consensual relationships, but this transition has been retarded by insurance companies, defense attorneys, and other elements of the malpractice system that are inclined toward adversarial relationships and have advised health care providers about matters such as consent forms and documentation practices. As a result, clinicians, patients, and the legal community have been confused and uncertain about whether informed consent is a protection for clinicians, a right of patients, or a way to facilitate good communication and care; and clinician-patient relationships and communication have been hampered. Green recommended that clinicians reduce risk of liability by entering into agreements with patients that clarify roles and responsibilities and involve patients in decision-making processes (1988).

In an instructive study, prospective jurors indicated that a clinician followed the standard of care when care decisions emerged from the use of quality decision aids. Use of hypothetical scenarios suggested that a decision aid provides greater protection against a determination of malpractice than the clinician's word that the information had been provided or a note in the medical record about the provision of information. The presentation of a decision aid to mock jurors educated them about the complexity of the situation, documented the content that had been presented to the "patient," and demonstrated that the "physician" who provided the decision aid had gone to great lengths to support the patient's knowledge and decision making. Importantly, use of the tool appeared to prevent the situation when jurors might feel that a test or procedure should have been undertaken as a precaution, despite current evidence or the patient's preferences to the contrary (Barry et al. 2008). This suggests that use of decision aids may alleviate pressure for defensive assurance practices that fully informed patients decline (Moulton and King 2010).

Analysts envision a situation in which legal standards foster routine use of shared decision making and protect patients' access to scientific information needed for decision making and their autonomous right to either make decisions or defer to decisions of their clinicians, (King and Moulton 2006; O'Connor et al. 2007). To reach the potential of shared decision making, they argue, patients and clinicians must routinely experience autonomous partnerships, clear standards must be established for disclosing benefits and harms, decision tools will need to be credentialed to ensure their integrity, financial incentives and legal standards will support informed decision making, and the tools will need to include information about current gaps in knowledge (King and Moulton 2006; O'Connor et al. 2007).

Proponents have identified roles for state and federal governments in the transition to clinical and legal shared decision-making standards. Through statutes or case law, states can incorporate shared medical decision making into informed consent requirements and provide related supports such as identifying approved credentialing bodies. Clinicians could meet shared decision-making standards by using a credentialed decision aid or decision coach or by providing detailed information about benefits and harms of alternative care pathways, followed in all cases by discussion with the patient about options and preferences, leading to a decision. Use of a credentialed tool or coach would likely provide firmer evidence of adherence to shared decision-making processes than clinician-led provision of evidence (King and Moulton 2006; Moulton and King 2010). The federal government could incentivize adoption of shared decision-making requirements, designate a credentialing body for decision aids, and promote and fund research about clinical outcomes and patient preferences that can contribute to the creation of decision aids (King and Moulton 2006).

States and the federal government have embarked on this path (Frosch et al. 2011). Use of decision aids may reduce risk of liability in Washington State because legislation passed in 2007 recognizes shared decision making as a high standard of informed consent. Another provision of the law, a demonstration project of the feasibility and financial implications of this model on preference-sensitive decisions in primary care, is under way. This law also established a method of certifying high-quality decision aids. Lawmakers in Maine and Vermont passed similar legislation to promote shared decision making in 2009, with other states exploring related legislation (Kuehn 2009; Moulton and King 2010).

Section 3506 of the federal Patient Protection and Affordable Care Act of 2010 authorizes a federal Program to Facilitate Shared Decisionmaking to foster collaborative patient-clinician processes that engage patients in decision making, provide them with information about trade-offs in treatment options, and include patient preferences in care plans. The law directs the Secretary of Health and Human Services to enter into a contract to establish standards and a decision aid endorsement process, to establish a program to develop and update decision aids, and to make grants to help implement shared decision making. Funds have not been appropriated for these provisions (Frosch et al. 2011).

The nine months of pregnancy provide a special protracted opportunity for shared decision-making processes relating to many pregnancy, intrapartum, and postpartum matters. The intrapartum and early postpartum periods provide opportunities for shared decision making, and also involve decision-making challenges in terms of the fast pace at which circumstances unfold, the physical and mental demands on childbearing women at this time, and many interventions in current use during this relatively brief period. The Ottawa Health Research Institute's inventory of quality-assessed decision aids currently includes 24 decision aids for maternal and newborn topics (Ottawa Hospital Research Institute 2012). Each decision aid in the inventory is rated for a series of content, development, and effectiveness quality criteria that the International Patient Decision Aids Standards (IPDAS) Collaboration developed to assess the quality of decision aids (Elwyn et al. 2006; International Patient Decision Aid Standards Collaboration 2012). There are gaps in maternal and newborn decision aid topics, and the quality ratings of existing decision aids vary. Further development of quality decisions aids for these populations and evaluation of the impact of shared decision making on maternity care liability matters and other areas are priorities. The Foundation for Informed Medical Decision Making and Childbirth Connection have recently begun a collaboration to develop, assess, and make available decision aids to help childbearing women participate in maternity care decisions (Romano 2012).

Align Legal Standards with Best Evidence: A Tort Alternative Reform

Lawyers, judges, legislators, advocates, and others increasingly rely on empirical scholarship (“empirical legal studies” and health services research) to support health-related legal policies, in contrast to legal argumentation or other opinion and guidance (Mello and Zeiler 2008). While there have been calls to better align the legal standards of care with the medical standard of evidence-based practice, and important steps have been taken in this direction, the potential to improve quality by relying on empirical research appears to be largely unrealized in practice in courts relating to standards of care and evidence (Hines 2006; Massie 2004; Peters 2000; Williams 2004; Van Tassel 2012). Of great concern, the legal standard of care to which clinicians are held in negligence cases often deviates from the best current evidence about safe and effective practice, and the current liability system thus fails to reliably hold clinicians accountable for best practice. This conflicts directly with the liability system aim of deterring harm. An important strategy for improving the medical liability system is to align its standards with evidence-based practice.

Clinicians in about 21 state court systems continue to be held to the traditional community or statewide legal standard of care (locality rule): their practice should be in line with the customary practice of other clinicians in the area (Lewis et al. 2007). Other states rely on a reasonable person standard, that practice should reflect care that a reasonable clinician would take in a particular situation. This focus on actual practice has serious limitations. A community may not have a single standard of care. Expert witnesses may not know about clinician behavior beyond their own practice settings. Well-paid witnesses face financial conflicts of interest and often differ in assessments of the standard of care (Hines 2006). Human memory is prone to error, and trials may occur many years after precipitating events (Meadow 2002). These conditions foster a system that is widely understood to be capricious and arbitrary.

Increasing recognition of the extent of unwarranted practice variation in maternity care (Baicker et al. 2006; Clark, Belfort, Hankins et al. 2007) and across health and medicine generally (King and Moulton 2006) and pervasive gaps between evidence and practice (Institute of Medicine 2001) clarify that behavior-based standards can serve as perverse incentives. The practice variation research of John Wennberg and colleagues has found that variations in practice style, health system supply, and other external factors frequently preclude the delivery of optimal care. They have identified the extent to which medical practices are underused, overused, or lack a clear basis for decision making. Supply-sensitive care varies by the availability of services rather than the needs and preferences of patients and is prone to overuse. Many practices that have clearly been shown to be effective are underused and vary greatly across geographic areas, facilities, and clinicians. Decisions relating to preference-sensitive care with trade-offs and no clear single course of action should be guided by values and preferences of patients, but are often sensitive to non-medical and non-patient factors and can vary broadly (King and Moulton 2006; Wennberg and Peters 2002).

Extensive overuse, underuse and uncertainty or trade-offs have been recognized in maternity care since the safety and effectiveness of hundreds of pregnancy and childbirth care practices were assessed through systematic reviews (Chalmers et al. 1989) and summarized in effectiveness tables (Enkin et al. 1989) nearly a quarter of a century ago. Although systematic reviews are the optimal methodology for knowing what works in health care (Institute of Medicine Committee on Standards for Standards for Systematic Reviews of Comparative Effectiveness Research 2011) and thousands of systematic reviews are now available to help guide decision making about maternity care, considerable gaps between evidence and practice persist (Sakala and Corry 2008), and professional guidelines make very limited

use of these exceptional high-quality resources (Chauhan et al. 2006; Wright et al. 2011). Practice variation compromises the integrity of the standard of care that a customary or reasonably prudent clinician would provide whenever that standard and the care provided does not reflect best medical practice or the preferences of well informed patients (King and Moulton 2006). In the worst case, the custom itself is negligent (Hines 2006). However, it is legally safe to use a practice that has been shown to be effective in rigorous research only when its use by enough clinicians has rendered it the standard of care (King and Moulton 2006). These anti-quality incentives are especially alarming in the context of maternity care, which had a head start, beginning in the 1970s, in the organization of rigorous evidence and development of systematic reviews summarizing the weight of the best evidence, and inspired the establishment of the Cochrane Collaboration to extend this work to all areas of health and medicine.

Applying the science-based standard for admission of evidence that now governs many state courts to the standard of care in medical malpractice cases would address many concerns with outdated legal standards of care, and could especially apply in states with a reasonable clinician standard (Hines 2006). Some circuit and state court cases have supported this application, and others have rejected it (Hines 2006; Shuman 2001).

Courts in many states are governed by the *Frye* (1923 case) test for admission of evidence (e.g., about causation of injury), which adopts existing standards within the field under scrutiny, regardless of the rigor used to establish them. *Frye* governs many of the most populous states, including California, Florida, Illinois, Michigan, New York, and Pennsylvania (Cheng and Yoon 2005). The *Frye* test “is vague, is easily manipulated, obscures the relevant inquiry, imposes a protracted waiting period on the use of sound new evidence and techniques, and lacks any definition of when a scientific proposition has become generally accepted” (Saks and Faigman 2005).

Increasingly, the competing *Daubert* standard from the *Daubert* trilogy of cases (1993, 1997, 1999) is replacing *Frye*. The *Daubert* case itself supported admissibility of a meta-analysis about pregnancy care. *Daubert* is codified in the Federal Rules of Evidence, 702, and has radiated into over one-half of state courts, which follow at least a basic *Daubert* approach. In scientific fields, this requires judges to be knowledgeable about research methods, and to assess methods and results that support expert evidence and principles used to apply the evidence to the case in question. Testimony and other evidence must be shown to be scientifically trustworthy. The intent of the Supreme Court’s *Daubert* “gatekeeping revolution” was to “incorporate scientific sensibilities into the legal culture” (Saks and Faigman 2005).

Daubert calls for the admission of scientifically valid evidence, regardless of its acceptance in the community of practice (Saks and Faigman 2005). However, there are concerns that courts in *Daubert* states generally do not adhere to the standards due to limitations in the scientific literacy of judges (Saks and Faigman 2005). For example, a survey of hundreds of state court judges found that nearly all supported the gatekeeper role, and nearly two-thirds felt that they were making the required admissibility decisions, whereas just a fraction exhibited knowledge of the meaning of the error and falsifiability standards and the ability to apply them to examples of expert testimony. They gave more weight to general acceptance as an admissibility criterion than to the scientific standards. Nearly one-half felt that their education had not prepared them to determine the admissibility of evidence (Gatowski et al. 2001). A close reading of cases found that “judicial opinions displaying sophisticated application of *Daubert* or other thoughtful focus on the validity of the proffered expertise” are rare (Saks and Faigman 2005).

It is a priority to extend the *Daubert* standard to all jurisdictions, to find effective ways to assist judges in carrying out this standard, and to extend *Daubert* to determinations of the legal standard of care. Extension to legal standards of practice would align legal incentives with quality and safety, encouraging professionals to stay abreast of evolving research and to embrace lifelong learning, reducing lags in practice change and improving the quality, safety, and outcomes of maternity care. To foster this transition, judges could benefit from assistance of scientific experts, an option that the American Association for the Advancement of Science is investigating. Pretrial conferences to examine evidence and programs to improve judges' scientific literacy could help (Waters 2006). Scientific expertise could be an important criterion for judicial appointments. Ready access to compendia of systematic reviews in the various fields of health and medicine could assist judges, lawyers, and other stakeholders in integrating the scientific standards of evidence into the legal system. Proffered evidence could be assessed using the GRADE system (Grading of Recommendations Assessment, Development and Evaluation) to rate its quality and the strength of recommendations (Guyatt et al. 2008; Jaeschke et al. 2008). Finally, it is important to understand whether it is reasonable to expect judges to have and apply the specialized skills that *Daubert* requires, and whether the health court model (see below) would offer a better structure for appropriate use of best available evidence and implementation of this standard.

A more modest proposal that would address concerns about perverse legal incentives is to allow a “respectable minority” or “two schools of thought” doctrine that provides legal protection to those who wish to deviate appropriately from custom or reasonable person standards. However, the proposal to use care at selected medical centers to identify qualifying practices does not directly tie the standard to rigorous high-quality evidence (Wennberg and Peters 2002).

Some have proposed that practice according to clinical guideline recommendations be considered a legal “safe harbor” (Newman et al. 2011). At present, however, it would be inappropriate to assume that clinical practice guidelines reliably reflect the most valid scientific evidence for various reasons, including the failure of U.S. guidelines to meet standards of the Institute of Medicine’s *Clinical Practice Guidelines We Can Trust* and low likelihood that guidelines in obstetrics and gynecology meet most of the standards (Kung et al. 2012; Shaneyfelt 2012), the persistent finding that many clinical practice guidelines are of moderate to low quality (Alonso-Coello et al. 2010), the considerable variation in processes used to develop national guidelines (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines 2011), the extent to which national maternity care guideline recommendations may reflect expert opinion or weak scientific evidence (Chauhan et al. 2006; Wright et al. 2011) and be phrased in intentionally ambiguous ways (Clark, Belfort, Byrom et al. 2008), and the challenge of developing and updating guidelines in all of the relevant clinical areas (Bovbjerg and Berenson 2012). There are also concerns about fairness of prior statutory reforms that admit guidelines to “shield” defendants but disallow them as a “sword” for plaintiffs (Mello 2001). The science of guideline development is young, developers have various aims and use diverse procedures, and the resulting content and quality vary. Safe harbor proposals could make an important contribution in the future if guidelines consistently adhere to standards in the Institute of Medicine report on trustworthy guidelines (2011).

Liability Insurance Coverage Regulation: A Liability Insurance Reform

Many liability insurance policies offered to maternity professionals constrain practice, for example, by excluding coverage of vaginal birth after cesarean, levying a surcharge for a family physician to obtain maternity coverage, or imposing a surcharge for an obstetrician-gynecologist in collaborative practice with midwives (Benedetti et al. 2006). These restrictions interfere with professional autonomy (Hale 2006) and can limit practice that is supported by systematic reviews of best evidence (e.g., Hatem et

al. 2008) and professional organizations (e.g., the American College of Obstetricians and Gynecologists 2010). They have the effect of creating confusion about the safety and efficacy of the practices in question, limiting access to valuable care options in communities, and/or increasing expenses. As discussed in Appendix I, we did find good data about the extent of insurer-imposed practice restrictions.

In exercising their oversight of the insurance industry, states do not appear to have addressed interference with professional practice that is not in the public interest (Sage 2004a). Greater involvement of states could help to better align the liability system with best scientific evidence, improve the quality of care, and send clear signals to health professionals about high-quality practice. Possible approaches include making coverage of unwarranted exclusions or elimination of surcharges a condition of doing business in the state or requiring actuarial data to support such exclusions or surcharges.

Redress

Disclosure, Empathy, Apology: A Tort Alternative Reform

Many who believe that they have been injured strongly wish to understand what happened, to have their grievance acknowledged, and to protect others from a similar experience. For many, communication of an open and honest expression of empathy, an apology when a caregiver and/or system was at fault, a pledge that the involved parties will learn from the experience, and timely support relating to resulting expenses and responsibilities constitute an appreciated and sufficient response from involved health professionals and institutions (Wojcieszak et al. 2008). This approach is central to the Institute for Healthcare Improvement's plan and tools for respectful management of serious adverse events (Conway et al. 2011). From the health system perspective, empathy, apology, and redress are within the traditional medical focus on caring and healing (Todres 2006). This strategy also falls within the collaborative legal tradition, which has been useful within family law and has been characterized as follows:

Collaborative law focuses more on finding solutions than on finding fault. It recognizes concepts of fairness. This process is controlled by the parties and involves both total transparency and total respect for all involved. Collaborative law is a voluntary, non-adversarial dispute resolution process, involving a series of meetings with parties and attorneys in a structured process individualized to the case. ... all parties ... work collaboratively toward a resolution unique to the facts of the case and not limited by traditional legal remedies (damages) (Clark 2011).

In conventional medico-legal risk management strategies, potential defendants limit communication with patients who might have been harmed and refrain from acknowledging responsibility and apologizing. However, patients and the public strongly support disclosure of errors (Mazor et al. 2004). A Joint Commission standard has required hospitals to disclose unanticipated outcomes to patients since 2001 (2006). The American Medical Association's Code of Medical Ethics calls for full disclosure of health status to patients, including complications resulting from errors (1994). The American College of Obstetricians and Gynecologists supports disclosure and open discussion about adverse events with patients and families (2007a). The American Academy of Family Physicians considers disclosure of errors to be the standard of care and offers resources to members (2006). The American Health Lawyers Association provides guidelines (Belmont 2012). While many institutions now encourage disclosure and apology, a survey of hospital risk managers identified considerable reluctance to implement the policy (Lamb et al. 2003). Procedures and training for disclosure processes (Liebman and Hyman 2004; Weiss and Miranda 2008) may help change behavior.

Most jurisdictions (34 states and the District of Columbia) have enacted some form of sympathy/apology immunity laws that may specify legal protections that apply to certain actions, persons, and content. Most protect communications of sympathy, but not admissions of fault, and a model law has been developed. Nine state laws mandate disclosure. Six states have both types of laws, and 13 have neither (Mastroianni et al. 2010; Pelt and Faldmo 2008; Wojcieszak, Saxton, and Finkelstein 2008). Implications of apology laws on physician disclosure and the quality of care are unclear (McDonnell and Guenther 2008); most laws have deficiencies that may work at cross-purposes with their aims (Mastroianni et al. 2010). Sorry Works! Coalition leaders argue that apology laws can be helpful but are not needed for implementing disclosure programs, and should rarely be used in the legal defense of a physician or hospital (Wojcieszak et al. 2008).

Mastroianni and colleagues analyzed this body of law and concluded that most laws have weaknesses that may discourage the types of disclosure and information that many patients desire by not protecting or clarifying the legal status of such disclosure. Many also limit options for apology and weaken the laws' impact on malpractice lawsuits. They argue that patients view disclosure and apology as being intertwined, and that improved statutory design could address many flaws. They propose best practices in disclosure and apology statutory design. Finally, they caution that laws cannot change culture: institutions must foster needed progress by supporting health care workers in improving communication and related processes (2010).

The Sorry Works! Coalition encourages root cause analysis of all adverse outcomes or events and rapid determination of whether error was involved. If negligence is deemed to have been involved, they recommend apology, admission of fault, and offer of fair compensation. If careful assessment suggests that negligence was not involved, they recommend expression of sympathy without admission of fault or offer of compensation, and vigorous defense in the face of litigation (Wojcieszak et al. 2006; Wojcieszak et al. 2008). Sorry Works! leaders argue that many calls to trial lawyers can be prevented by good customer service that communicates promptly, defuses anger, preserves relationships (staying "on the same side of the table"), and avoids any appearance of cover-up or deception, noting that avoidance and cover-up are vulnerabilities if litigation proceeds (Wojcieszak et al. 2008).

Studdert and colleagues raised concerns about the potential for disclosure and apology strategies to reduce claims: first, because just a small portion of those with medical injury currently sue caregivers and facilities and, second, because many who have been harmed do not recognize the source. Disclosure could thus generate claims that otherwise would not have been made. While the researchers support disclosure and compensation of those with injury, their model of consequences of implementing this strategy suggests it might not achieve the objective of reducing claims (Studdert, Mello, Gawande et al. 2007). Nonetheless, more recent key informant interviews with individuals from diverse stakeholders perspectives found that the disclosure, apology, and offer model is more promising than any other liability reform option, both on its own merits and as it can avoid the political gridlock of other strategies (Bell et al. 2012). This is consistent with our determination that this is highest rated redress strategy (Table 4).

An earlier review found just one published study that directly examined the impact of a disclosure program on liability (Kachalia et al. 2003). That analysis found that a Veterans Affairs Medical Center that had been one of the highest paying facilities among a peer group of 35 facilities dropped to the lowest quartile after implementing a disclosure program. The facility's experience of full disclosure over a 15-year period involved payouts that were considerably lower than those of both the system-wide Veterans health facilities and the private sector (Kraman and Hamm 1999; Kraman et al. 2002). Initial reports of implementation of the Sorry Works! principles at a growing number of sites through event management policies and programs are favorable (Wojcieszak et al. 2008).

Following implementation of a disclosure and offer program at the University of Michigan, from 1995 to 2007 the average monthly rate of new claims declined from 7.02 to 4.52 per 100,000 patient encounters and monthly rate of lawsuits declined from 2.13 to 0.75 per 100,000 patient encounters. Median time from claim reporting to resolution dropped from 1.36 to 0.95 years. Average monthly cost rates significantly decreased for total liability, patient compensation, and non-compensation-related legal costs. Incident reporting rose sharply with the new program. The contribution of the program is difficult to assess as malpractice claims declined overall in Michigan near the end of the study period (Kachalia et al. 2010). Average litigation costs declined sharply, and the university invested insurance savings in patient safety initiatives. Surveys indicated that both university medical faculty and the plaintiff's bar in southeastern Michigan viewed the program favorably, and other hospitals and health systems are implementing similar programs (Boothman et al. 2009). The University of Michigan program is credited with accomplishing what forty years of tort reform have failed to do: establish respectful working relationships between the health system and the trial bar (Wojcieszak et al. 2008). The COPIC Insurance Company has achieved similar results from its 3 Rs Program: recognize (unanticipated events), respond (promptly), and resolve (any related matters), a no-fault variant (Boothman et al. 2009; Quinn and Eichler 2008).

Among filed medical malpractice claims, fuller and earlier access to information has the potential to expedite the process of abandoning lawsuits, which is more common than settling or adjudicating them. A study of nearly 3,700 claims against Massachusetts providers that were closed in the period 2006-2010 found that the most common reason for dropping claims was obtaining information that changed plaintiff lawyers' understanding of the value of the case or claim. This suggests that earlier access to information might prevent the filing of many claims (Golann 2011).

These principles involve notable culture change in health care micro-systems, but go far toward addressing several persistent liability concerns without major reorganization of the legal or health care systems. Organizational champions can lead these programs, and successful programs can be expanded and replicated (Mello and Gallagher 2010).

Empirical evidence is beginning to be available about effects of different approaches to disclosure and offers of compensation (Murtagh et al. 2012). However, we did not find reports of the impact of apology and disclosure principles applied to maternity care, which may have increased challenges with adopting disclosure principles due to the high premium placed on fully healthy newborns and possible views that a newborn death is more tragic than that of an older adult. Further, families sustaining newborn injury may have few other options for help with economic responsibilities than the conventional tort system. Sorry Works! leaders recognize this economic dilemma, but argue that excellent communication and customer service are essential in cases of newborn injury and can strengthen a defense, if necessary (Wojcieszak et al. 2008). A study of Florida families who made claims on behalf infants with birth injuries is consistent with this perspective: anger, communication problems, and perceived deception and dishonesty were common, and expressed motivations for filing claims included wanted to find out what happened, to air grievances, to seek revenge, and to ensure that others avoid similar harm (Hickson et al. 1992, Sloan et al. 1993). A project funded within the Agency for Healthcare Research and Quality's program of Medical Liability Reform and Patient Safety Demonstration Projects is investigating maternity care disclosure (Kachalia and Mello 2011).

A recent review of the limited record and potential of disclosure and offer programs found that they have the potential to reduce claims frequency, payouts, overhead costs, and liability insurance premiums;

and improve the culture of safety. Investigators could not anticipate the impact on defensive assurance behaviors and physician supply. They note that self-insured hospital systems offer optimal conditions for implementing this strategy, which may be less successful in other situations (Mello and Kachalia 2010).

Health Courts: A Tort Alternative Reform

The establishment of health courts dedicated to hearing medical liability disputes offers an opportunity for addressing most of the fundamental problems identified at the beginning of Part II. Many have expressed concern that a jury is not well positioned to make an informed decision about whether a medical error has occurred or to decide on an appropriate level of compensation due to the members' lack of specialized knowledge. Similarly, judges who only occasionally hear a medical liability case are at a disadvantage. As discussed above, judges have had difficulty fulfilling roles that the *Daubert* standard expects of them. A potential remedy for this deficiency is the creation of health courts that are designed to hear medical liability cases exclusively (Barringer et al. 2008; Common Good 2006; Mello et al. 2006). The judges in these courts may have special training, would grow in expertise over time with medical terminology and knowledge, and would have comparative experience across medical liability cases to serve as a basis for evaluating medical liability disputes. Neutral independent experts would assist them, with limited scope for trial lawyers.

Concerns have been expressed that health courts would violate the constitutional civil rights of plaintiffs and defendants to a jury trial. Others argue that it would be possible to design a constitutional health court system, noting that many precedents have substituted administrative for judicial remedies (e.g., workers' compensation, securities law, and environmental law) and that expected benefits (especially with lessons from pilots) to patients, the public, providers, and insurers would provide compelling rationale (Elliott et al. 2008). An analysis of 132 cases involving constitutional challenges to malpractice reforms similarly concluded that carefully designed health court pilots could withstand constitutional challenges in many states (Mello et al. 2008). Health courts may have little impact on the large proportion of cases that are not tried in court. This model has not been implemented to date in the United States, but state-level systems are being established (Common Good 2006; Roberts et al. 2005).

An attractive feature of health courts is moving from a standard of negligent injury to providing compensation under a broader "avoidability" standard (injury that would not occur with the best practitioners), with injuries that could have been avoided eligible for compensation. A much broader group of injured patients would be eligible for compensation for economic losses, with a more standardized schedule for non-economic losses than present variable approaches. Proponents argue that such courts would foster more consistent standards of care with less uncertainty, apprehension, malaise, and defensive behavior among caregivers. The proposal is aligned with efforts to promote patient safety and to improve health care quality, and would reduce the stigma currently associated with claims for malpractice (Common Good 2006).

The American Bar Association argues that health courts would add a level of bureaucracy to the court system and does not support this model. The Association rather favors expanded use of dispute resolution and arbitration methods already used by courts (American Bar Association 2011). Although political barriers, such as the opposition of trial lawyer groups, and the challenge of implementing a new system would need to be overcome, health courts could be designed with features to address many of the fundamental problems with current approaches and are supported by many leading medical liability scholars, clinical leaders, policy makers, and quality and safety experts (Common Good 2006; Mello et al. 2006).

A recent review of work to pilot and evaluate health courts in the United States found that effects would vary based on the policies, structures, and processes put in place. The investigators propose that relative to the current tort system, well-designed health courts have the potential to reduce legal expenses, reduce provider liability insurance costs, and slightly increase physician supply. They speculate that this model would be unlikely to impact claims frequency, the success rate of claims, or the size of awards. They were unable to predict possible impact on overhead costs, defensive assurance behavior, and the quality of care (Mello and Kachalia 2010).

Administrative Compensation Systems: A Tort Alternative Reform

An administrative compensation system would replace the existing tort system with one in which injuries that were caused by medical care are compensated through an administrative body (Studdert and Brennan 2001a). The underlying rationale is to conserve or divert resources for legal expenses to fulfill the liability system's objective of fair and just compensation of those sustaining injury. The chief advantages of this model are in reducing both legal expenses of dispute resolution and the lengthy time for resolving such claims (Studdert and Brennan 2001a). Further, this can prevent use of the tort system for financial assistance by injured persons in the absence of negligence, which providers often experience as capricious and unjust. Removing the stigma and great penalty of blame of individuals has the potential to improve injury deterrence by learning from errors to improve systems and care. Proponents of medical administrative compensation systems in the United States identify the potential for more systematic case identification, more expert resolution of claims, better monitoring and education, and greater incentives to exercise precaution if the system includes some form of experience rating (Studdert and Brennan 2001b).

Within maternity care, administrative systems have the potential to provide efficient and timely assistance more generally and for families of newborns requiring costly ongoing care. Two established administrative birth injury compensation funds operate in the United States, in Virginia and Florida, offering alternatives to the tort system for malpractice cases relating to some classes of newborns (Horwitz and Brennan 1995; Studdert, Fritz et al. 2000). They were implemented within a broader package of tort reform initiatives during the medical malpractice crisis of the 1980s aimed at ensuring availability of affordable medical malpractice insurance. Efficiency in claims resolution and improved compensation of injury victims did not receive adequate attention in the design of these programs (Bovbjerg and Sloan 1998).

The Virginia and Florida programs are very limited by legislative design (Bovbjerg et al. 1997). Eligibility criteria for program benefits were narrowly defined to keep costs low. As a result, participating physicians continue to pay medical malpractice insurance premiums, and most potential claims have remained in the tort system. Limited funding has constrained the ability of the existing programs to compensate less severe injuries that seldom give rise to tort claims. Expanded eligibility standards would likely require a much broader financing base, such as through general revenues or a dedicated tax funded from a group larger than health professionals. An investigation found that in Virginia and Florida, neither participating hospitals nor physicians notified prenatal patients about the programs (Bovbjerg and Sloan 1998). Given their limited funding, the programs themselves may be averse to publicizing availability of benefits. A referee of this report who has participated in the Florida program since its inception clarified that the program requires participating physicians and nurse-midwives to give signed informed consent about it at the first prenatal visit and requires hospitals to repeat this at admission.

Sloan and colleagues found that obstetricians were far more satisfied with administration than tort systems, yet most were unhappy with the premiums for the administrative programs. The programs were

not associated with obstetrician reports of increased maternity caseloads or of increased proportions of high-risk patients (Sloan, Whetten-Goldstein, and Hickson 1998). An evaluation of the first decade of the programs found that the administrative programs are feasible and efficient, offer important advantages relative to the tort system even when limited in scope, require an administrative structure to be effective, can be adversely impacted by concurrent filing of tort claims, could be further refined for greater impact, and might attract political opposition if expanded (Bovbjerg et al. 1997). A study found that parents of children with birth-related injuries who filed claims with Florida's program were satisfied with their compensation (Whetten-Goldstein et al. 1999). Some Florida claimants with birth injuries would not have met criteria for compensation in the tort system, while many with neurologic birth injuries did not qualify for compensation (Sloan, Whetten-Goldstein, Stout et al. 1998; Stalnaker et al. 1997).

A comparison of administrative and tort claims for newborn injuries and death in the early years of the Florida and Virginia programs found that high rates of parents in both groups blamed someone for the harm. While the administrative system did not eliminate use of lawyers, it nearly eliminated legal costs for resolving disputes. Those who pursued administrative compensation appeared to be more satisfied with their lawyers. Satisfaction with the administrative system was largely a function of receiving compensation. Multi-variable analysis found that families seeking retribution and families that had experienced poorer quality care were more likely to use the tort system than the administrative system. Such analysis also found that payment for claims was more likely in the administrative system, in the case of high economic loss, and with lower family income. Multivariable analysis also found that those with administrative compensation in Florida received payment for their actual expenses, while those with tort payments were overcompensated. Analysis limited to children with cerebral palsy found even greater tort overcompensation and administrative system undercompensation (Sloan, Whetten-Goldstein et al. 1997).

A more comprehensive administrative program could attract political and judicial scrutiny as a threat to interests of lawyers and through concerns about the right to sue. Efficiency and affordability are key issues. It remains to be answered whether data collection, prevention efforts, and quality improvement can be enhanced after removal of traditional fault-based tort approaches (Studdert et al. 1997). Estimates suggest shifting to no-fault and channeling money that currently covers legal expenses to injured persons could compensate a much larger proportion of injured patients (Mello and Brennan 2002). Two recent major laws — the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 and the Patient Protection and Affordable Care Act of 2010 — will undoubtedly reduce the demands on continuing and any new administrative programs through provisions that will benefit many children and women with disabilities such as the elimination of preexisting condition barriers, elimination of caps on benefits, coverage of behavioral care, and extension of dependent coverage to age 26.

Legal scholars have studied the Florida and Virginia programs to ascertain lessons for broad-scope administrative compensation schemes (Siegal et al. 2008). They have also designed comprehensive administrative compensation systems for far-reaching impact, with the following core features: trained adjudicators outside tort system to make compensation decisions, compensation decisions are based on a standard of care that is broader than the negligence standard — avoidable classes of events or medical injuries that normally would not occur, compensation criteria are evidence-based, and consistent standardized guidelines are followed for economic and non-economic losses (Roberts et al. 2005). An earlier analysis of 280 obstetrical claims found that treating avoidable classes of events through an administrative compensation system would be feasible, could cover two-thirds of paid claims and three-quarters of indemnity payments, would likely save much expense and time per case, and would be unlikely to generate an unmanageable number of new cases (Bovbjerg et al. 1991).

Investigators have also examined established administrative compensation systems in other countries for lessons that might apply to the United States. Systems in New Zealand, Sweden, and Denmark have successfully limited costs of liability while improving access to compensation, hastening decisions, preserving relationships, standardizing compensation, and addressing physician discipline and health care quality improvement. Successful elements of those programs could be adapted and tested through demonstration projects (Mello et al. 2011; see also Kachalia et al. 2008).

A recent review of the potential of new administrative compensation systems in the United States found that effects would vary based on the policies, structures, and processes put in place. The investigators propose that relative to the current tort system, well-designed administrative systems have the potential to greatly reduce the legal expense portion of costs and compensate many more individuals at a similar level of expense, to reduce provider liability insurance costs, to reduce provider defensive assurance behaviors, and to improve quality of care. They argue that an administrative system would generate more claims due to the lack of need for an attorney, greater ease in claims processing, and possible expansion of the standard for compensation from negligence to, e.g., no-fault or avoidability, while the size of awards could fall. A broadened standard would increase the success rate of claims. They were unable to predict impact on physician supply (Mello and Kachalia 2010).

High-Low Agreements: A Tort Alternative Reform

In a high-low agreement, attorneys agree at some point before a jury award and without disclosing to the jury that the plaintiff will neither receive less than a lower compensation level nor more than a higher level. A lower or higher jury award reverts to the closer end of the agreed-upon range. Such agreements address multiple aims of the liability system by simultaneously providing reassurance that a patient will receive some level of compensation and that a payout will not be excessively burdensome to insurers and the health system overall. This type of agreement may be well suited to claims regarding neurologically impaired infants with large future predicted care expenses. It also might encourage attorneys to accept cases that they would otherwise forgo (Crane 2011).

Summary

The current liability system poorly addresses needs of childbearing families, maternity care providers, payers and purchasers of maternity care and others. Interventions are needed to address diverse liability system aims and both prevent harm and respond appropriately when it occurs. A series of interventions has the potential to address diverse aims and better meet the needs of key stakeholders — childbearing women, newborns, and families, as well as those who provide and pay for their care. Some require regulatory or statutory changes and new infrastructure. Others can be implemented without such measures, through strong leadership and evolving health care culture.

Conclusion

Our investigation found that more reliable empirical studies do not corroborate many widely held beliefs about maternity care and liability:

- We did not find evidence of the severe adverse impact that this system is believed to have on premium affordability.
- We did not find evidence of extensive avoidance defensive practice or, with respect to mode of birth, extensive assurance defensive practice.
- Despite widespread concern about the vulnerability of maternity professionals to legal action and frivolous suits, in the practice of an average obstetrician-gynecologist, negligent injury of mothers and newborns appears to occur more frequently than any claim (warranted or not, obstetric or gynecologic), and far more frequently than any payout or trial.
- Although liability attention is particularly focused on newborn harm, mothers may be several times more likely than newborns to experience negligent injury.
- While maternity-specific data are not available, a tiny fraction — about 2% — of those who experience negligent injury appear to make a claim, about half of those receive any compensation for damages, and most of the payouts appear to go to legal expenses rather than plaintiffs.
- Despite widespread belief in the value of caps on non-economic damages, better empirical studies find that they have at best minimal impact of limited scope in the context of maternity care. A smaller evidence base provides no strong support for the effectiveness of a series of other tort reforms in the context of maternity care.

Other notable maternity-specific concerns include the following:

- Some liability insurance policies restrict access to essential maternity services through exclusions (e.g., vaginal birth after cesarean) or surcharges (e.g., for physician collaborative practice with midwives or family physician maternity care), but the extent and implications have not been measured at the national level.
- An abundance of systematic reviews are available to guide maternity practice, but legal standards for clinical care and for admission of evidence frequently provide incentives *not* to provide and uphold care consistent with best evidence.
- Ambiguity about the legal roles and responsibilities of clinicians and childbearing women impedes optimal decision making.
- The legal system compensates some seriously injured newborns facing long-term, high-cost care when the negligence standard is not met.
- Liability matters are distressing to many caregivers who experience the fluctuation of liability insurance premiums, liability claims, and other liability matters as capricious; who may be singled out for responsibility when systems have failed; and who are poorly supported in the face of adverse events.
- Studies do not support the effectiveness of reforms that maternity care providers have most strongly advocated and policy makers have frequently implemented. →

- Maternity care payers, purchasers, credentialers, and other stakeholders with an interest in a high-functioning liability system have often failed to leverage opportunities to improve liability matters.
- Relatively few studies characterize the impact of the liability system on maternal-fetal medicine subspecialists, family physicians, midwives, and birth centers. These provider groups appear to experience less liability-related discontent and greater professional satisfaction than general obstetrician-gynecologists. There are concerns but no strong data about access to affordable insurance products for groups with small risk pools that may be greatly impacted by one or a few claims.

This report contributes to understanding and addressing the widespread liability-related distress and unhappiness of maternity care providers. It identifies many liability-related aspects of professional practice that may be confusing, uncertain, ambiguous, misunderstood, and/or anxiety arousing to health professionals and may disproportionately impact maternity care clinicians. In Part I, these include confusion about the safety and efficacy of practices that are both supported by best evidence and discouraged by terms of liability insurance policies; whether the cost of liability insurance premiums is onerous for maternity care providers; the likelihood of experiencing a claim, payout, or trial; and the likelihood of being responsible for injuring a woman or newborn. In Part II, these include uncertainty about whether a claim might be filed on behalf of a baby years after providing care to the child, ambiguity about the respective responsibilities of clinicians and childbearing women in clinical decision making, discrepancies between behavior-oriented legal clinician standards and evidence-based practice, tension between traditional denial of injury and evolving standards of disclosure, uncertainty about the integrity of expert witnesses and whether juries and judges are qualified to make determinations about clinical questions, and the tort system as a potential source of assistance to parents facing long-term expenses of caring for injured newborns even when care did not meet the legal standard of negligent injury.

Part II presents a framework of seven aims of a high-performing liability system in maternity care. It clarifies that many strategies that clinicians have most strongly advocated and that policy makers have implemented in numerous jurisdictions are unlikely to resolve these chronic sources of tension and address the interests of clinicians, childbearing women and families, and those who pay for maternity care. However, a series of reforms that hold promise for better serving all of these stakeholders, both in preventing harm and in responding appropriately when it occurs, warrant piloting and evaluation.

There is reason to be hopeful about achieving a high-functioning liability system if stakeholders pursue strategies that hold promise and abandon those that have shown disappointing results and/or fail to address essential aims of a high-functioning liability system. While some promising strategies require statutory or regulatory changes and new infrastructure, others — and most notably, rigorous clinical quality improvement programs and disclosure and offer programs — can move ahead with dedicated, visionary leadership.

With respect to strategies for preventing adverse events, initial reports of the impact of maternity care quality improvement programs on a range of liability indicators suggest that such programs have great potential for multi-faceted improvement. Enterprise liability is also a promising preventive strategy that is harmonious with trends for patient safety and broader accountability through payment reform, care coordination, and the formation of Accountable Care Organizations, and consolidation of providers and health care organizations. Those who pay for care, credential caregivers, and accredit facilities and programs could use their leverage to accelerate maternity care quality improvement. Implementation of shared decision making with high-quality decision aids might relieve providers of liability for chosen care

pathways. Better alignment of liability system standards of care and standards for admitting evidence with evidence-based practice would address current perverse incentives counter to quality improvement and widespread practice variation. State insurance regulators could foster high-quality care through measures to align liability insurance policies written in their jurisdictions with best evidence.

With respect to reparative strategies to address injury, health care organizations can implement programs that disclose and respond to adverse events without major system reorganization. Early reports on positive multi-faceted effects of such programs are impressive, but maternity-specific analyses are lacking. Health courts would require new structures, but might address several widely recognized shortcomings of current medical malpractice litigation and might also foster alignment of legal with epidemiologic standards of evidence. Administrative compensation systems hold promise for efficiently and rapidly paying for damages of women and newborns. Finally, high-low agreements are a simple strategy for limiting losses of providers and insurers and ensuring some level of compensation for those with injuries.

Appendix I.

Research Priorities for Understanding Impact of the Liability Environment on Maternity Care

This appendix identifies important topics for further research within the scope of Part I of this report, and summarizes the limited material that we found on these topics.

Liability Insurance Policies Available to Maternity Care Providers

Important questions relating to underwriting for maternity caregivers include:

- Do claims-made policies impact caregivers' autonomy, behavior, and satisfaction (as reported in a state-level study, Benedetti et al. 2006)?
- To what extent do liability insurance policies impact the quality of maternity care and women's autonomy by restricting access to care that is supported by best current research (e.g., vaginal birth after cesarean (VBAC), collaborative physician practice with midwives); or by imposing surcharges for collaborative practice or family physician maternity care? Notable proportions of four different groups of maternity providers identified in a recent state-level study identified such concerns (Benedetti et al. 2006), and 13% of participants in the 2009 American College of Nurse-Midwives liability survey reported that the affordability or availability of liability insurance had caused them to stop offering or attending vaginal birth after cesarean (Guidera et al. 2012).
- Does the liability insurance system have a role in defining appropriate professional practice, or should that be left entirely to the health care system through, e.g., scope of practice statements, collaborative agreements, clinical guidelines, and institutional protocols guided by best current evidence? →

- How has the growth of physician- and hospital-directed insurance companies impacted midwifery and birth center liability coverage and practice, and access to this care?
- To what extent are liability insurance products available to midwives with national credentials (certified nurse-midwives, certified midwives and certified professional midwives) and freestanding birth centers, which have an established record of safe practice, but relatively modest revenue and small risk pools?

Maternity Care Provider Experience of Liability Insurance

Compensation for Liability Expenses in Professional Fees

The national standard physician payment system, Medicare's Resource-Based Relative Value Scale (RBRVS), has since its introduction in 1992 included compensation for liability premium expenses (Grimaldi 1991). Each service code in the fee schedule includes components for the physician's work, practice expenses, and liability insurance costs. The professional reimbursement formula adjusts each component by a geographic practice cost index. On average, work payments account for 52% of total payments, practice expenses account for 44%, and liability insurance for 4% (Maxwell et al. 2007). This fee schedule is adjusted annually and periodically to keep relative values current. Many physicians do not feel that Medicare reimbursement is adequate. However, it is widely acknowledged to favor specialty care.

Medicare pays for a tiny fraction of maternity care, but its fee schedule has maternity codes and greatly influences fee schedules of other payers. Thus, in theory, payment for professional services covers liability premium costs, with consideration given to liability cost variation across specialties and geographic areas, and professionals do not need to change their style of practice or experience an income loss to cover premium expenses. This raises the following questions:

- Do components for liability premium expenses within professional fees in Medicare's RBRVS provide adequate compensation for actual maternity care liability premium expenses?
- If yes, do private insurer and Medicaid program maternity professional fee schedules carry over this included compensation for liability expenses by reimbursing at similar or more generous levels? (A recent simulation of what obstetrician-gynecologists would have earned in 2007 if all of their services were paid under the Medicare fee schedule found that their mean hourly simulated rate of \$146 was 18% below their actual hourly rate of \$178, and their mean annual simulated compensation of \$258,000 was 16% lower than their actual compensation of \$308,000 [Berenson et al. 2010].)
- If professional services fee schedules adequately compensate maternity care professionals for liability premium costs, could better understanding of these matters reduce maternity professionals' concerns about liability premium levels?

Impact of the Corporatization of Medicine on Liability Insurance Coverage

There has been a sharp increase in physician consolidation into larger groups and in hospital and health plan acquisition of physician practices since the mid-2000s (Kocher and Sahni 2011, O'Malley et al. 2011). The 2008 Socioeconomic Survey of ACOG Fellows, compromised by a response rate of 26%, suggests that in 2007 at least 45% of obstetrician-gynecologists may have been free of direct responsibility for

purchasing liability insurance: 36% of respondents were in salaried positions, and 9% worked in multi-specialty groups with an average of 129 physicians. Liability insurance arrangements for those who identified single-specialty group practice (27% of respondents with an average of 6 clinicians in the group) and military (2%) settings may have been mixed (American College of Obstetricians and Gynecologists 2008). In a multivariable analysis, a recent Michigan study found that, among obstetrician-gynecologists, paying over \$50,000 for liability insurance was associated with decreased career satisfaction, in comparison with having premiums covered by employers (Xu, Siefert et al. 2008b). The broader implications of this trend for maternity issues are unclear, raising the questions:

- To what extent are maternity services being provided by clinicians who are employed by large group practices, hospitals and health plans that provide liability insurance? How does such a shift impact liability experiences and behavior of clinicians and the cost and structure of the coverage? When liability insurance is provided by corporate entities, what is the mix among occurrence, claims-made, and claims-made with tail policies; and what are implications of these patterns?
- What proportion of maternity care providers currently experiences payment of liability premiums as a challenge, in light of shifting clinician employment trends?

Impact of Liability Premiums on Economic Viability of Specific Types of Maternity Caregivers and of Birth Centers

We found no meaningful information about the impact of liability premiums on the economic viability of maternal-fetal medicine subspecialists. Regarding the important question of whether combined gynecologic and obstetric practice involve higher premiums than similar coverage for a practice of gynecology alone, we found one excellent older national study that may not apply to current conditions. In 1992, the national average premium for a \$1 million/\$3 million mature claims-made policy for combined practice was \$43,853, 57% higher than a comparable policy for gynecology practice alone. The differential ranged from \$862 to \$35,532, and the increased cost over gynecology alone ranged from 4% to 146% (Norton 1997).

With respect to family physicians, Table 1 suggests that those who do and do not offer maternity care had virtually identical premiums and premiums as a share of receipts overall nationally in 2003 (Pennachio 2005). Two earlier studies that may no longer be applicable reported higher family physician premium charges with provision of maternity care. Nationally, Norton found an increase of about 70% for similar coverage, to \$16,000, for premiums of those providing maternity services versus gynecology care alone in 1992. Across jurisdictions, the maternity increment ranged from no difference to an additional \$44,822, and from 0% to 565% of the non-maternity premium. Norton reported that in 1992 most liability insurers structured premiums to distinguish among family physicians who provided no maternity care, prenatal and intrapartum care, and cesarean section (1997). Larimore and Sapolsky found an average increase of 50% for coverage of maternity services, to \$22,000, in a Florida survey in 1991. Both groups in the Florida study worked similar hours and saw a similar number of patients per week, but family physicians providing maternity care had much higher net incomes (\$164,000 versus \$104,000) and were more likely to rate their psychological and financial compensation as adequate and to say they would again choose medicine as a career. They reported 30% fewer non-maternity claims than those not providing maternity care and few maternity claims, and served an overall younger clientele (1995). Just a small proportion (5%) of family physicians who do not provide maternity services and responded to their professional society's practice survey identified the cost of liability premiums as a barrier to provision of maternity services (there was a 13% survey response rate, and data were weighted to reflect the organization's membership profile) (American Academy of Family Physicians 2011).

American College of Nurse-Midwives leaders reported that average malpractice insurance premiums for nurse-midwives increased greatly during the most recent hard phase of the insurance cycle. Insurers who write policies for physicians may cost-shift some of the charges for covering larger and more frequent maternity-related payouts to non-maternity physicians, whereas such cost shifting is not an option when writing policies for nurse-midwives. Escalating payouts may thus threaten the ability of midwives to remain in the market (Silverman 2004). The average premium of nurse-midwives may represent a greater proportion of their gross income than physicians, and malpractice pressure may have a greater economic impact on them. Because midwifery and birth center insurance risk pools are much smaller than physician and hospital pools, premium increases can be formidable if insurers continue to provide coverage after one or more large payouts. There is likely to be less competition for their business and fewer choices among insurance products due to their lower pools, volumes, and revenues.

Further, providing discretionary procedures to compensate for financial pressure is not compatible with the traditional conservative practice values of many midwives, birth centers, and family physicians (Reime et al. 2004). Some more lucrative forms of care, such as cesarean section, are beyond the scope of practice of midwives, birth centers, and many family physicians. Groups that may be more likely and better positioned to avoid overtreatment, and can thus make important health system contributions, may be more vulnerable in the maternity market.

We also did not find data to clarify the degree to which malpractice insurance levels are a burden for safety net maternity care providers and organizations, given the generally lower levels of reimbursement through Medicaid programs.

Important questions related to impact of liability premiums on the various maternity caregivers include the following:

- What are the financial implications of including maternity care in obstetrician-gynecologists' scope of practice, versus an exclusive gynecology practice, including liability premiums, practice expenses, revenue, and net compensation?
- What are the liability premiums, overall practice expenses, revenue and net compensation of maternal-fetal medicine subspecialists, and the proportion of their premiums within total expenses, revenue, and net compensation?
- To what extent and at what level do family physicians pay a liability insurance premium surcharge for coverage of maternity care? Is levying such a surcharge an appropriate industry practice if it is not levied for other types of care provided? Is there actuarial support for this practice? To what extent do policy surcharges for maternity care practice impact access to family physician maternity care in rural areas and overall?
- What are the financial implications of including maternity care in family practice, including liability premiums, practice expenses, revenue, and net compensation?
- What are the financial implications of liability premiums for the economic viability of midwives and freestanding birth centers?
- What are the financial implications of liability premiums for safety net maternity care providers and organizations?

Maternity-Related Claims and Payouts

Obstetrician-Gynecologist and Maternal-Fetal Medicine Subspecialist Experience with Maternity-Related Litigation

It is a priority to inform the relevant stakeholders with accurate, trustworthy information about the frequency of obstetrical caregivers' experience with claims and suits and their resolution, including associated expenses. Currently available data provide a limited and rough understanding of these matters. Better studies are needed to clarify:

- What are the likelihood, disposition, and costs of maternity-related claims brought against obstetrician-gynecologists and maternal-fetal medicine physicians?

Family Physician Experience with Maternity and Non-maternity Litigation

While a 1991 survey of family physicians in Florida found that the absence of maternity-related claims in those who did not provide maternity care was offset by a 30% increase in non-maternity claims (Larimore and Sapolsky 1995), we were unable to identify any nationwide or more current data about the frequency and severity of malpractice claims against family physicians who provide maternity care.

It is a priority to inform the relevant stakeholders with accurate, trustworthy information about the frequency of family physicians' experience with maternity-related claims and suits and their resolution, including associated expenses. Currently available data provide a limited and rough understanding of these matters. Better studies are needed to clarify:

- Do the frequency and disposition of claims and the severity of settlements and verdicts differ between family physicians who do and do not provide prenatal care or full-scope maternity care?
- How do the frequency and disposition of family physicians' maternity and non-maternity claims and the severity of their respective settlements and verdicts compare?

Midwifery Experience with Litigation

The National Practitioner Data Bank, one of the only systematic national sources of nurse-midwifery liability data, received 484 reports about nurse-midwives from September 1999 through March 2005. Of the 484 reports, 375 have a maternity-related liability code. The median claim payment made on behalf of nurse-midwives during this period was \$225,000. Self-insured corporations are not required to report to the Data Bank (Jevitt et al. 2005).

It is a priority to inform the relevant stakeholders with accurate, trustworthy information about the frequency of midwives' experience with claims and suits and their resolution, including associated expenses. Currently available data provide a limited and rough understanding of these matters. Better studies are needed to clarify:

- What are the likelihood, disposition, and costs of maternity-related claims brought against midwives with national credentials, i.e., certified nurse-midwives and certified midwives, as well as certified professional midwives?

Meritorious Versus Non-Meritorious Claims, Including Those with Serious Injury

Studies have found that from 26% to 40% of medical liability claims lack merit, and 16% to 47% of non-meritorious claims receive payment (Studdert and Mello 2007). An analysis of 1,452 claims that closed or resolved from 1984 to 2004 from five malpractice insurance companies in four regions included obstetric and three other clinical areas. Investigators found that 13% to 16% of total costs involved claims without error (Studdert et al. 2006). In that study, injury to an infant was a predictor of payment for non-meritorious claims and was highly correlated with obstetric claims and greater severity of injury. Non-meritorious payments for newborn injury appear to be driven by both sympathy of jurors and decisions to settle to avoid the possibility of a higher level of jury-awarded payment. With injured infants, it appears that the “sympathy factor pervades the entire process” (Studdert and Mello 2007). Similarly, when Harvard Medical Practice Study investigators analyzed all claims associated with a large random sample of hospital cases, neither negligent adverse events nor adverse events without negligence were associated with payment to the plaintiff; permanent disability was the only significant predictor of payment (Brennan et al. 1996). Others have reported that the presence of major newborn injury predicts payment (Bors-Koefoed et al. 1998).

Based on a study of Florida families of newborns with birth injuries, Sloan and colleagues commented that the common complaint that families do not tolerate a “less than perfect baby” is misleading: the vast majority of families faced tragic consequences (1993).

Priority research questions about lawsuits without injury and/or negligence are:

- What portion of lawsuits brought against maternity care providers does not involve negligent injury, and what portion of administrative and indemnity costs are associated with these cases?
- What is the frequency of lawsuits brought against maternity care providers on behalf of children with serious long-term disability that is and is not attributable to negligence? How does the legal system resolve these cases? What are the legal expenses and payments to parents? Are payments adequate for the families’ expenses?

Accuracy of Maternity Care Providers’ Understanding of Their Risk of Liability

Liability pressure is frequently cast as a cloud that overhangs maternity care practice. For example, an article about professional liability in *Obstetrics & Gynecology* states, “although health care has never been safer for the woman and her fetus, it has never been more dangerous to the physician” (Hankins et al. 2006, p. 1382). Risk of liability is frequently presented as a rationale for the current technology-intensive style of maternity care, including record-level cesarean rates. It is thus important to understand whether maternity professionals have an accurate understanding of their vulnerability to claims, settlements, lawsuits, and judgments against them.

Older studies comparing perception and experience found that physicians believe their vulnerability to be considerably worse than it actually is. A Harvard Medical Practice Study survey of New York physicians reported combined results for three specialties at high liability risk: obstetrics, neurosurgery, and orthopedics. While fewer than 2% of patients who were injured due to negligence in the state filed claims, the physicians estimated that 69% sustaining negligent injury did so. Moreover, whereas the annual rate of suits per 100 New York high-risk physicians was 21%, respondents estimated it to be 34% (Lawthers et al. 1992). Similarly, a study of third-year family practice residents in Florida identified fear

of being sued and the high cost of liability premiums as the most common reasons for deciding not to attend births; however, the residents erroneously believed that family physicians were more likely to be sued for maternity than non-maternity components of their practice, and also overestimated the average cost of premiums quoted by state carriers for family medicine physicians in the first year of practice by 350% (Larimore 1993). More recently, and with reference to obstetrician-gynecologists, Chauhan and colleagues noted that the claims experience reported by members of the Central Association of Obstetricians and Gynecologists was less frequent than the physicians believe, but did not describe actual beliefs. Actual experience, which the authors felt could be generalized to obstetrician-gynecologists nationally, was to experience on average a claim every 11 practice years, a settlement every 39 practice years, and a trial every 70 practice years (Chauhan et al. 2005).

Carrier and colleagues have recently reported that obstetrician-gynecologists were far more likely than adult primary care physicians to agree or strongly agree with all items on the Malpractice Concerns Scale and with the Malpractice Concerns Subscale, when controlling for potential confounding factors. While not reporting separately by specialty, their study also found that “the level of liability concern reported by physicians is arguably out of step with the actual risk of experiencing a malpractice claim” (page 1591). Despite more than three-fold differences in objective measures of liability risk across states, physicians’ malpractice concern was weakly associated with risk, and also appeared insensitive to tort reforms, including caps on non-economic and punitive damages. Their proposed explanations for this discordance included lack of access to accurate risk information, desire to justify behavior motivated by other factors, and human tendency to overestimate risk of unfamiliar possibly catastrophic rare events that are difficult to control (2010).

Explanations offered for this presumed overestimation of liability include liability as a “dread risk” (Carrier et al. 2010), “anchoring” and “priming” cognitive biases that intensify the perception of vulnerability (Minkoff 2012), and liability claims as an assault on the high degree of autonomy, dignity, and prestige that physicians otherwise experience (Sage 2004b). Current, well-conducted studies are needed to understand:

- How do professionals who provide maternity care understand their liability risk, and how does this understanding compare to actual risk?

Claims and Lawsuits Among Safety Net Providers and Disparity Populations

We carried out focused searches to understand liability issues relevant to the provision of maternity care in safety net settings and to disparity populations, and found no sources relating to maternity care claims and lawsuits. It is important to understand the liability experience of safety net providers of maternity services, including liability insurance coverage of community health centers under the Federal Tort Claims Act (FTCA) and “gap” policies for FTCA omissions, as well as coverage of public health providers working under state sovereign immunity statutes. Research is needed to understand:

- How do the issues discussed in the report chapter on Claims and Lawsuits Relating to Maternity Care play out among safety net providers and for disparity populations?

Impact of Patient Protection and Affordable Care Act on Claims Brought on Behalf of Women and Babies

Numerous provisions in the landmark 2010 Affordable Care Act reduce the vulnerability of individuals who sustain injury and require ongoing medical care, and the far-reaching legislation may reduce incentives to file and pursue claims (Hyman and Sage 2011). Research is needed to understand:

- What impact, if any, do the following Affordable Care Act provisions have on the likelihood of experiencing harm and filing and advancing suits on behalf of women and newborns: greatly expanded increase in access to care, elimination of lifetime caps on benefits, elimination of insurance denials due to preexisting conditions, and quality improvement strategies (e.g., performance measurement and reporting, innovative delivery and payment systems)?
-

Incidence of Negligent Injury and Compensation for Claims

Proportion of Maternity Cases Involving Negligent Injury, Proportion of Those Cases That Are Litigated, and Compensation for Litigated Cases

The Harvard Medical Practice Study further explored the extent to which negligent harm led to legal claims, and the outcome of claims for the entire sample. Claims were filed for just 1.5% of all cases of negligent injury (nine total claims). While not reported separately, there must have been few if any maternity claims for negligent injury with just nine claims across all clinical areas (Localio et al. 1991). Over the next ten years, five of the nine negligent injury claims settled with payments to the plaintiff (56%), three settled in favor of the defense, and one jury trial ruled for the defense, resulting in compensation for fewer than 1% of negligent injuries. In an analysis of all claims associated with the original population, neither negligent adverse event nor adverse event without negligence was associated with payment to plaintiffs, and permanent disability was the only significant predictor of payment (Brennan et al. 1996).

A recent closed claims analysis of data from five insurance companies in four regions of the country included maternity-related (23%) and other claims and found that 73% of all claims involving injury due to error received compensation (Studdert, Thomas et al. 2006). In a review of the evidence, Hyman and Silver concluded that the merits of the case were the best predictor of payment and payment levels, and they include a critique of the conclusion of Brennan and colleagues (2006).

In the combined Utah and Colorado samples replicating the Harvard Medical Practice Study, claims were filed for just 2.5% of negligent injury cases and just 3.8% of cases with significant or major disability (Studdert et al. 2000). We did not find follow-up analysis of patterns of settlement or judgment and their associated costs.

Large population-based studies of childbearing women and newborns have not been carried out to update the Harvard Medical Practice Study and the Colorado and Utah studies described in Part I. A well-conducted update is needed with reference to this large population, which constitutes about 21% of hospital discharges and involves considerable liability concern. Given inevitable delays in filing and resolving claims and lawsuits, there is a considerable gap between provision of care and knowledge of any claims and their

resolution. However, to continue to inform maternity professionals, policy makers, and other stakeholders about the degree to which the liability system achieves the aim of compensating individuals for negligent injury, it would be optimal to update the path-breaking studies for this high-liability risk area and ask:

- In the hospital and outpatient care of childbearing women and newborns, respectively, what is the rate and profile of adverse events and adverse events attributable to negligence?
- What proportion of negligent injury leads to claims, and what is the disposition of the claims?
- What proportion of childbearing women and babies experiencing negligent injury do not attempt to bring claims against maternity care providers, attempt to do so but cannot find an attorney willing to take the case, and find an attorney willing to take the case? Why and how many women and newborns fall off the pathway from negligent injury to compensation at key junctures?
- How do women and newborns compare in their likelihood of experiencing adverse events attributable to negligence, in the severity of those events, and in the pathway from negligent injury to compensation?

Deterrence of Negligent Injury in Maternity Care: Traditional Individual Model

Deterrence is a primary justification for the current negligence-based medical malpractice system (Danzon 2000a; Danzon 2000b; Schwartz 1994; Studdert, Mello et al. 2004). Conventional tort theory suggests that by seeking to penalize health care providers whose negligence causes injury to patients, the system gives providers economic and non-economic incentives to take optimal levels of precaution in health care practice, thus improving the quality of care and health outcomes. The economic incentives include, in principle, payments to injured parties and costs of defense, both of which influence the level of malpractice premiums. Non-economic incentives include personal and professional consequences of malpractice suits, such as stress and loss of professional prestige. In theory, high costs of negligence pose substantial penalties that send a clear message to medical providers.

High rates of problems attributable to preventable errors in the path-breaking studies (Leape et al. 1991) raised questions about whether the liability system is effective in deterring avoidable or negligent harm. However, regardless of whether an individual practitioner provides higher or lower quality care, most individual clinicians are not experience-rated; their premiums are based on community rating of practitioner groups, and the premiums rise and fall in insurance cycles (Baker 2005). Those who experience claims and trials lead disrupted lives under a cloud of accusation, but in the Harvard Medical Practice Study, neither negligent adverse event nor adverse event without negligence was associated with payment to the plaintiff (Brennan et al. 1996). Many clinicians experience the workings of the liability system as arbitrary and unfair (Lockwood et al. 2004, 2005). The deterrent signal appears to be weak. While methodologic problems make it difficult to draw firm conclusions, there is little evidence that tort law overall creates incentives for increased safety in and outside of medicine (Mello and Brennan 2002). A comprehensive investigation of this question found that liability has a modest favorable impact on safety and quality and does not cause quality to decline, with defection health care incentives and norms fostering quality and safety problems (Hyman and Silver 2005).

The present system relies extensively on voluntary discipline by professional organizations. However, Public Citizen found that 55% of physicians in the National Practitioner Data Bank with one or more

clinical privilege actions had not experienced state licensing actions. These included many with the most serious types of violations, many with temporary or permanent withdrawal of privileges, and many with a history of malpractice payments (Levine et al. 2011). The organization also reported that a relatively small proportion of individuals with repeated liability insurance payouts appear to be disciplined by state boards (Public Citizen 2005b) and recently determined that the National Practitioner Data Bank fails to identify a large proportion of physicians who provide substandard care due to both lax hospital peer review and loopholes in reporting (Levine and Wolfe 2009). Others have encouraged better practices to improve the comprehensiveness of national liability databases (Weber and Ornstein 2010). At the microsystem level, studies have documented reluctance among many maternity caregivers to speak up about safety concerns (Lyndon et al. 2012) and report medical errors (Anderson et al. 2009).

Individual professionals are in a weak position to avert the large proportion of system-related medical errors (Mello and Studdert 2008). Increasing recognition of the apparent link between systemic quality improvement and reduced liability, as discussed in Part II of this report, is providing health care organizations with incentives to deter harm.

Limited maternity-specific studies confirm the general conclusion that the liability system has not had a deterrent effect or has had a weak effect at best. We found just one early study of the relationship between malpractice pressure and technical quality of maternity care. The technical quality of care by obstetricians in Florida was not associated with their prior malpractice claims experience (Entman et al. 1994). A recent Massachusetts study similarly found no relationship between Massachusetts obstetrician-gynecologists' quality scores (reflecting their performance on quality measures) and their number of either malpractice claims or disciplinary actions (Reid et al. 2010). These findings support neither the idea that the liability system identifies less competent or careful professionals, nor the idea that experience with a claim leads to improved professional practice. An earlier national study of the association between malpractice pressure, indicated by premium levels, and use of prenatal care found that from 1990 through 1992 the likelihood of initiating prenatal care after the first trimester was associated with higher premiums. The authors viewed the impact as small, with a premium decrease of \$10,000 associated with decreases in late initiation of prenatal care of 3% to 6% for black women and of 2% to 5% for white women (Dubay et al. 2001). Thus, a key question for future research is:

- In the traditional individual liability model, what if any deterrent effect does malpractice pressure on the professionals and facilities that provide maternity care have on the occurrence of negligent injury and other types of harm?

Deterrence of Negligent Injury in Maternity Care: Evolving Corporate Model

With the transition of the U.S. health care system to increasing use of innovative models of payment and delivery, and the consolidation of care providers into large groups and/or as employees of often self-insured hospitals and health systems, incentives and resources for quality improvement grow. This poses new opportunities to improve care and potentially reduce liability, which these entities are beginning to seize (see Part II). This raises the following question:

- What favorable impact, if any, does effective implementation of current quality improvement strategies (see Table 5) have on maternal and newborn health outcomes and on various measures of liability?

Proportion of Maternity Care Claims That Meet the Legal Standard of Malpractice and Proportion Involving Avoidable Injury

Health professions often express concern about the burden of non-meritorious claims that do not meet the legal standard of malpractice. Looking at evidence for this question, Hyman and Silver concluded that the problem of patients who deserve damages but do not submit claims dwarfs the problem of patients who sue and do not deserve damages in the United States. They note that plaintiff and malpractice attorneys reject 70% to 80% of requests for representation, often due to weak evidence of liability or small damages (2006). An analysis of 189 perinatal claims across 21 states from a large professional liability insurer that were closed between 2000 and 2005 found that 70% involved substandard care that was causally related to injury, accounting for 79% of all costs associated with the analyzed claims. These conclusions reflect assessments of treating providers and defense consultants. A further analysis of the closed claims found that many adverse outcomes, including many cases within current standards of care, could have been prevented by adherence to relatively stringent protocols (Clark, Belfort, Dildy et al. 2008). Further investigation of these questions is a priority:

- Among claims on behalf of childbearing women and newborns, respectively, what proportion meets the legal standard of negligence and what proportion of occurrences could have been prevented?

Payments to Plaintiffs; Proportion and Amount for Legal Expenses versus Injury Compensation; Verdict versus Payout Levels

Hyman and Silver review the evidence to answer: do injured patients get what they deserve? They conclude that payment and injury are related but patients often do not get what they deserve because “the malpractice system is stingy”; further, the system forces patients to wait for a long time for this under-compensation (2006). They identify studies reporting that defendants win medical malpractice trials from 73% to 81% of the time (2006).

Current evidence suggests that most money awarded to plaintiffs actually goes to others for legal expenses. A recent assessment of legal expenses of maternity care (23% of the claims analyzed) and other types of closed claims found that 54% of all compensation costs went to lawyers, experts, and courts. This legal expense figure rose to 78% for claims involving harmful errors, suggesting that efforts to curb non-meritorious litigation would have a relatively small impact on costs. Claims that did not involve errors accounted for 13% to 16% of the total monetary costs of the liability system (Studdert et al. 2006). The level of medical liability administrative cost exceeds those of other compensation schemes, such as workers’ compensation, by a wide margin. There are concerns that the primary recourse for those who face long-term, high-cost care for children or women with disabilities is through costly litigation that siphons resources from families.

Plaintiffs’ compensation is also affected by reductions in payouts that often follow jury verdicts due, e.g., to insurance policy limits and caps on damages. For example, in Texas from 1988 to 2003, three-quarters of verdicts were reduced, and the average reduction was 29%. Defendants rarely paid what juries awarded. The performance of the tort system should consider these post-verdict “haircuts” (Hyman et al. 2007).

It would be helpful to have trustworthy analyses of compensation for administrative and legal expenses versus plaintiff losses in maternity-related litigation. Sound data are needed to answer the following:

- Among costs of litigation for claims involving childbearing women and newborns, what proportion covers administrative and legal expenses versus damages?
- How do jury awards for maternal and newborn damages compare with the final payments that these plaintiffs receive?

Negligent Injury, Claims, and Damages Recovery in Disparity Populations

We carried out focused searches to understand liability issues relevant to the provision of maternity care in safety net settings and to disparity populations, and found no sources relating to incidence of negligent injury and compensation for claims. Research is needed to understand:

- Are there disparities in women's and newborns' experience of adverse events attributable to negligence, compensation and other issues discussed in the report chapter on Incidence of Negligent Injury and Subsequent Compensation relating to gender, race, ethnicity, language, and culture, as are characteristic of tort law generally (Chamallas and Wriggins 2010)?
- How do safety net care providers and facilities perform in comparison with other maternity care providers and facilities with respect to avoidable harm and negligent injury of childbearing women and newborns?

Defensive Maternity Care Practice

Extent of Liability-Induced Defensive Behavior in Practice of Maternal-Fetal Medicine Subspecialists, Family Physicians, Midwives, and Birth Centers

Virtually all of the studies that have attempted to gauge the extent of liability-induced defensive behavior have focused on obstetrician-gynecologists. It is also important to understand whether there are quality concerns due to defensive assurance or avoidance practices of maternal-fetal medicine subspecialists, family physicians, midwives, and birth centers. With respect to assurance behaviors, tests and procedures are typical in care for the high-risk clientele of maternal-fetal medicine subspecialists, and excess testing is inconsistent with the practice style of many midwives and birth centers and a fair proportion of family physicians (Kennedy and Shannon 2004; Reime et al. 2004). Nonetheless, empirical investigations of these groups are warranted. With respect to avoidance behavior, maternal-fetal medicine subspecialists and birth centers have limited options for clinical care apart from maternity services, whereas nurse-midwives might provide well-woman or reproductive health care if such jobs are available, and family physicians have excellent non-maternity options due to their broad scope of practice. Family physicians and midwives have established traditions of providing care in rural and underserved areas and to underserved populations. Given continuing liability concerns and the importance of access, including appropriate geographical distribution of services, studies of avoidance behaviors in these groups are also warranted:

- Is liability pressure associated with defensive assurance or avoidance behaviors of maternal-fetal medicine subspecialists, family physicians, midwives, and birth centers?

Cesarean Section Decision Making

While cesarean sections are generally quicker, more convenient, and more lucrative to perform (Truven Health Analytics 2013), they pose many risks to maternal and newborn health (Gregory et al 2012). Leading economists conclude that a common response of health professionals to tightening of reimbursements in recent years has been to increase revenue by providing more intervention-intensive care (Ginsburg and Grossman 2005). This is consistent with recent increases in labor induction, cesarean section, ultrasound scans and other imaging and testing, and the increasingly intervention-intensive approach to maternity care. Thus, modest associations of cesarean section and higher liability premiums described in Part I may reflect response to perceived economic pressure of higher premiums. Available studies do not clarify underlying factors, raising the questions:

- Do associations between liability pressure and use of cesarean section and related mode of birth practices reflect response to fear of claims and suits, perceived economic pressure of high premium levels, both, or some other factor?
- Do maternity care providers who pay their own premiums exhibit more mode-of-birth-related defensive behavior than those whose employers provide liability insurance?

Other Maternity Care Decision Making

We found just two national and two state-level studies measuring the relationship between liability pressure and other types of maternity care conventionally believed to be associated with such pressure, such as other procedures, tests, imaging, and referrals. As with cesarean section, in the case of positive associations, it would be optimal to discriminate between actual fear of liability and concern about generating revenue due to perceived economic impact of premiums. We did not find any studies measuring the relationship between liability pressure and avoidance care practices, such as prohibitions against eating and drinking, ambulation, and videotaping during labor, raising the following questions:

- In maternity care practice, is liability pressure associated with assurance practices other than mode of birth, such as excess testing and referrals?
- In maternity care practice, is liability pressure associated with avoidance practices such as restrictions during labor?
- Do maternity care providers who pay their own premiums exhibit more defensive behavior across the spectrum of maternity care practices than those whose employers provide liability insurance?

Liability Pressure, Disparity Populations, and the Safety Net

Despite focused professional searches, we found just one study that examined how any aspect of the liability system functions with respect to disparity populations and safety net providers. That national study of changes in site of prenatal care from 1997-98 to 2002-04 has both worrisome results and concerning methodology. Due to the significance of this topic, we provide details here, and encourage research to fill gaps. Data about source of prenatal care were reported for four national regions. Investigators considered the combined South and Northeast regions to comprise a high-liability zone and combined Midwest and West regions to comprise a low-liability zone, according to the distribution of states with an American Medical Association liability “crisis” designation and/or American College of Obstetricians and Gynecologists “red alert” designation. Eighty-two percent of live births in the resulting high-liability zone were

in states with designations of elevated concern, versus 33% of live births in the low-liability zone. The investigators then compared changes in source of prenatal care in the two zones over time, but did not adjust results for factors associated with source of prenatal care. In the period of interest, the proportion of prenatal visits in hospital outpatient departments grew from 12% to 19% in the high-liability zone and fell from 13% to 9% in the low-liability zone. These trends were more pronounced among prenatal visits involving complications. This indirect evidence raises concern that liability pressure adversely impacts access to care and places exceptional pressure on safety net providers (Coco et al. 2009). A priority research question is:

- What if any impact does liability pressure have on disparity populations and safety net providers?

Liability, Career Satisfaction of Maternity Caregivers, and Maternity Care Quality

Role of Liability Issues in the Relatively Low Career Satisfaction of Obstetrician-Gynecologists

A number of studies identify relatively low obstetrician-gynecologist professional satisfaction and suggest an association with liability issues:

- Recurrent research from the Community Tracking Study (CTS) of the Center for Studying Health System Change clarified that obstetrician-gynecologists have low professional satisfaction in comparison with physicians in other clinical areas. Leigh and colleagues ranked physician career satisfaction across 42 specialties using data from the 2004-05 CTS survey of 6,590 physicians. In adjusted results, obstetrician-gynecologists ranked 39th. Obstetrician-gynecologists were the sole specialty group that was significantly more dissatisfied than the family practice reference group on both the 2004-05 and 1996–97 CTS surveys. By contrast, neonatologists (combined with perinatologists in 2004-05) were significantly more satisfied in both surveys (Leigh et al. 2009). Investigators proposed “rising expectations for perfect birth outcomes and high medicolegal risks” as a possible explanation (Leigh et al. 2002), but did not explore this factor in the survey.
- In further regression analysis of combined results from 1996–1997 and 1998–1999 CTS surveys among obstetrician-gynecologists, a powerful predictor of satisfaction was feeling able to provide quality care. However, the survey did not directly consider liability issues. The authors argue that the low level of career satisfaction within this specialty is a warning sign about structural problems in the maternity care delivery system (Kravitz et al. 2003).
- A nationwide survey of fellows of the American College of Obstetricians and Gynecologists was conducted in 2001 to examine the effect of career pressures on job satisfaction. The study used physician self-rated impact of malpractice insurance concern to measure malpractice pressure (low-, moderate-, or high-impact). Decreased pressure was associated with increased career satisfaction (Bettes et al. 2004).
- In a national 2006 survey of obstetrician-gynecologists, career satisfaction was negatively associated with measures of liability concern (Anderson et al. 2008). →

- Becker and colleagues conducted a survey of obstetrics and gynecology residents at 23 randomly selected residency programs and examined the relationship between job satisfaction and malpractice concerns. The study found an inverse relationship between overall career satisfaction and concerns about malpractice. After controlling for other factors, Investigators found that undertaking the fellowship due to malpractice concerns strongly predicted diminishing career satisfaction (Becker et al. 2006).
- In a large national sample of 24 specialties or specialty groupings, obstetrician-gynecologists, along with general surgeons and those in general surgery subspecialties, had the lowest rated satisfaction with work-life balance (Shanafelt et al. 2013).
- In 2002–2003, Mello and colleagues collected data from obstetrician-gynecologists and five other medical specialty groups at higher risk of liability practicing in Pennsylvania, one of the states hit hardest by rising malpractice costs in the hard phase of the most recent liability cycle. Among the six specialties, obstetrician-gynecologists were most likely to report dissatisfaction, which included the following domains: income, autonomy, relationships (with patients and professionals), practice environment, and broader market environment. Obstetrician-gynecologists in Pennsylvania were significantly less satisfied than their counterparts in the 1999 national Community Tracking Study, and the pooled specialists in Pennsylvania similarly had rates of dissatisfaction that were about twice as great as those in the national 1999 and 2001 samples. Pooled six-specialty survey results and key informant interviews found that liability pressure was associated with both career dissatisfaction and poorer quality of care (Mello et al. 2004).
- A recent Michigan study used multivariate analysis to examine the association of liability issues with career satisfaction of obstetrician-gynecologists. Paying over \$50,000 for liability insurance was associated with decreased career satisfaction, in comparison with obstetrician-gynecologists whose premiums were covered by employers. Personal recent or more distant malpractice claims experience was not associated with career satisfaction. The authors call for research on the impact of the current liability climate on the quality of maternity care (Xu, Siefert et al. 2008b).

It is important to better understand whether the current liability system adversely impacts the well-being of maternity professionals and in turn the provision of care of childbearing women and families, and to disentangle liability-related disaffection from other possible sources of dissatisfaction such as that obstetrician-gynecologists were in the highest quartile for average work hours in the 2004-05 Community Tracking Study (Leigh et al. 2011). The negative effect that malpractice liability burden could exert through physician dissatisfaction has implications beyond defensive assurance and avoidance behavior (Zuger 2004), the main focus of previous research. Health care providers' job satisfaction has been associated with better quality of care (Grol et al. 1985) and with increased patient satisfaction (Haas et al. 2000, Linn et al. 1985), and providers' dissatisfaction has been associated with poor job performance (Kahn and Byosiére 1992), accidents, and errors (Kahn and Byosiére 1992), and greater likelihood of leaving the medical profession, decreasing work hours or changing fields (Buchbinder et al. 2001; Landon et al. 2006; Pathman et al. 2002; Williams et al. 2001). Further research is needed to better understand the following:

- What is the relationship among liability pressure and the well-being and career satisfaction of obstetrician-gynecologists? Does liability pressure adversely impact the quality of the maternity care they provide due to diminished professional well-being and satisfaction?

Role of Liability Issues in the Career Satisfaction of Maternal-Fetal Medicine Subspecialists, Family Physicians, and Midwives

Research is needed to clarify the possible impact of liability pressure on poor career satisfaction of other maternity care professionals. The very limited data that are currently available suggest that this concern is greatest for general obstetrician-gynecologists:

- In the 2004-05 Community Tracking Study, family medicine was the reference group in the adjusted specialty ranking of career satisfaction (without examining subgroups that did or did not provide maternity services). Eight specialties, including neonatologists and maternal-fetal medicine specialists, were significantly more satisfied, and four, including obstetrician-gynecologists, were less satisfied (Leigh et al. 2009).
- Surveys of Florida family physicians providing maternity care found that medico-legal issues were cited as a major contributor to dissatisfaction with their practice. However, relative to family physicians who did not provide maternity services, those who did reported greater financial and psychological satisfaction, were more satisfied with medicine and with family practice, and experienced 30% fewer non-obstetrical claims, while working a similar number of hours (Larimore and Sapolsky 1995).
- We found just one study about the career satisfaction of midwives in comparison with other maternity providers (Xu, Lori et al. 2008). A 2006 Michigan study found nurse-midwives to be overwhelmingly very satisfied (42%) or somewhat satisfied (49%). The contrast with dissatisfaction of obstetrical counterparts in Michigan and in the 2004–2005 national Community Tracking Study is striking. The investigators adapted CTS satisfaction questions to facilitate comparison with national populations. One percent of the Michigan midwives versus 9% of the national obstetrician-gynecologists were very dissatisfied, and 8% of the Michigan midwives versus 12% of the Michigan and 17% of the national obstetrician-gynecologists were somewhat dissatisfied. In Michigan, both groups were asked about current career satisfaction in comparison with satisfaction five years earlier, and the trajectories of the two groups were somewhat different, with 20% of midwives but only 9% of obstetrician-gynecologists saying they were now a lot more satisfied and 33% of midwives versus 16% of the specialists saying that they were somewhat more satisfied. The report did not discuss the relationship between midwives' satisfaction and liability pressure (Xu, Lori et al. 2008; Xu, Siefert et al. 2008b).

There is a need to answer the following question:

- What is the relationship among liability pressure and the well-being and career satisfaction of maternal-fetal medicine subspecialists, family physicians, and midwives? Does liability pressure adversely impact the quality of the maternity care they provide due to diminished professional well-being and satisfaction?

Relationship between Liability Pressure and Disruptive Professional Behavior

In addition to high levels of dissatisfaction in national surveys of obstetrician-gynecologists, disruptive maternity care provider behavior also signals structural problems. Disruptive behavior in maternity care (e.g., insults, outbursts, and eye-rolling) has been reported through a survey of labor and delivery unit nurse managers (Veltman 2007), a commentary on disruptive clinician behavior (Simpson 2007), and a framework for understanding and addressing dysfunctional delivery systems with a case study of obstetric liability pressure (Chervenak and McCullough 2005). A data-based estimate by safety leaders suggests that these matters must be addressed: one-third or more of physicians have a condition that impairs their ability to practice safely for some period during their career. This estimate considers mental

illness, substance abuse, disruptive behavior, physical illness, and knowledge and skill dyscompetencies (Leape and Fromson 2006). Thus, it is important to ask:

- What is the contribution, if any, of liability pressure to disruptive behaviors of maternity care professionals? What is the contribution of such behaviors to adverse events, outcomes of women and newborns, and professional liability?

Liability, Career Satisfaction, and Quality of Care in Safety Net Settings

We carried out focused searches to understand liability issues relevant to the provision of maternity care in safety net settings and to disparity populations and found no sources relating to possible relationships among liability, career satisfaction, and the quality of care in these settings. Research is needed to understand:

- How do the issues discussed in the report chapter on Liability, Career Satisfaction, and Maternity Care Quality play out for safety net providers and in safety net settings?

Liability and Maternal and Newborn Health Outcomes

Related to earlier questions in this appendix about whether the liability system deters maternal and newborn harm or is associated with improved maternity care quality is the question of its impact on health outcomes of maternity care. Available studies of care provided in the last two decades have not found an association between liability pressure and health outcomes:

- Yang and colleagues used a longitudinal design to examine data across fifty-one jurisdictions from 1991 through 2002. They investigated the impact of malpractice risk, defined as premium level, on six adverse birth outcomes: birth injury, low five-minute Apgar score, low birthweight, preterm birth, infant mortality, and maternal mortality. Results suggest that the frequency of adverse birth outcomes is not associated with malpractice premium levels (Yang et al., 2012).
- In a national study of births from 1990 through 1992, Dubay and colleagues examined the effects of malpractice pressure, as indicated by premium levels, on newborn outcome. Premium levels were associated with neither low birthweight nor low Apgar scores (Dubay et al. 2001).

Analyses of 1987 and 1992 Florida data sets were consistent with the more recent national studies (Sloan et al. 1995).

A clearer understanding will require further research to answer:

- What is the relationship between liability pressure and maternal and newborn health? Further, what is the impact on disparity populations?

With respect to the liability system aim of appropriate response when injury occurs:

- How does the liability system impact maternal and newborn health outcomes after injury has occurred, for example, in the degree to which timely and ongoing care are provided and the impact of such care?

Appendix II.

Fact Sheets: Report Findings on Topics of Interest to Policy Makers and Others

To foster broad access to key report findings, this Appendix presents summary fact sheets on topics of interest to maternity care stakeholders. The authors encourage readers to reproduce the fact sheets and widely share them with policy makers, maternity care clinicians, employers, hospitals and health plan administrators, liability insurers, childbearing women and families, and other stakeholders.

Fact Sheet topics are as follows:

- 1. Policy Framework for Improving the Liability Environment for Women and Newborns, Maternity Care Providers, and Payers**
- 2. Affordability of Liability Insurance Premiums to Maternity Care Providers**
- 3. Occurrence of Negligent Injury and of Claims and Payouts in Maternity Care**
- 4. Defensive Practice in Maternity Care**
- 5. Liability-Associated Distress Among Maternity Care Providers: Sources and Solutions**
- 6. Impact of Caps on Non-Economic Damages and other Tort Reforms in Maternity Care**
- 7. Interventions that are Unlikely to Foster Substantive Liability Solutions in Maternity Care**
- 8. Substantive Solutions for Preventing and Responding to Injury in Maternity Care**
- 9. Impact of Maternity Care Quality Improvement Programs on Liability**
- 10. Maternity Care and Liability: Gaps in Knowledge**



1. Policy Framework for Improving the Liability Environment for Women and Newborns, Maternity Care Providers, and Payers

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: The liability system poorly serves maternity care providers, childbearing women and families, and those who pay for maternity care. Traditional liability reforms have prioritized interests of maternity care providers and insurers (e.g., trying to reduce liability insurance premium levels by limiting access to courts and the size of payouts), but not those of women and newborns and maternity care payers. Even with respect to the narrow aims, compelling evidence about the effectiveness of traditional reforms in maternity care is lacking.

Report findings: To meet the needs of all key stakeholder groups, it is important to go beyond the narrow aims of traditional liability reforms. Our review of the impact of the liability environment in maternity care led us to develop a multi-stakeholder framework with seven criteria for a high-functioning liability system in maternity care. Effective policy interventions should:

- Promote safe, high-quality maternity care that is consistent with best evidence and minimizes avoidable harm
- Minimize maternity professionals' liability-associated fear and unhappiness
- Avoid incentives for assurance and avoidance defensive maternity practice
- Foster access to high-value liability insurance policies for all maternity caregivers without restriction or surcharge for care supported by best evidence
- Implement effective measures to address immediate concerns when women and newborns sustain injury, and provide rapid, fair, efficient compensation
- Assist families with responsibility for costly care of infants or women with long-term disabilities in a timely manner and with minimal legal expense
- Minimize the costs associated with the liability system.

Takeaways: The *Maternity Care and Liability* report identifies many ways that the current liability system is failing to protect interests of key stakeholder groups. Despite widespread implementation of reforms over many decades, troubling problems persist. Narrow aims, such as reduction of liability insurance premiums, cannot be expected to address the breadth of problems. Needed progress requires a broader vision.

The proposed framework has the potential to move discourse and policy forward. When options for reform are held up to criteria in the proposed framework, many that have been widely implemented do not appear to meet any of the criteria. By contrast, other reforms have the potential to be win-win-win solutions for maternity care providers, childbearing women and families, and those who pay for their care. Promising reforms warrant piloting and evaluation by states, health systems, or other appropriate entities.

The report found that the effectiveness of reforms in maternity care may differ from their impact in medicine overall or in other clinical areas. For example, combined tort reforms or caps on non-economic damages appear to be marginally effective at best in maternity care but more effective in medicine overall and in other clinical areas. To help maternity care stakeholders, the proposed framework should be applied within this clinical area.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access "Maternity Care and Liability" articles in *Women's Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



2. Affordability of Liability Insurance Premiums to Maternity Care Providers

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: The cost of obstetrician-gynecologists' liability insurance premiums tends to be higher than premiums for most other specialties. High premium levels and the potential for steep increases trouble many obstetrician-gynecologists. As a result, many have strongly advocated for tort reforms with the hope of reducing premium levels.

Report findings: The report examines the cost of liability insurance premiums in the context of typical obstetrician-gynecologist payments and expenses. While liability premiums are an especially salient practice expense, studies have found that premium costs amount to a relatively small and declining portion of total obstetrician-gynecologist practice expenses. In addition to premium increases, premium costs are also impacted by less salient premium declines or stability in soft phases of liability cycles, premium discounts, and inflation. Further, large group practices, hospitals, and health systems generally provide liability insurance for the clinicians they employ. The increasing proportion of clinicians working within these models likely does not pay for liability insurance premiums.

Moreover, obstetrician-gynecologists have above-average incomes among medical specialties. The incorporation of liability premium costs into physician payments may be a factor. The Resource-Based Relative Value Scale, which sets a national standard for physician payment through its fee schedule, includes for each service code components for liability premiums and for other practice expenses, which are calibrated by specialty and geographic area and are periodically adjusted.

Despite strong interest in limiting payouts to plaintiffs as a way to keep malpractice premiums in check, the relationship between the two is weak at best. Tort reforms that aim to limit payouts, including much-advocated caps on non-economic damages, have not been found to be an effective strategy for keeping maternity care provider premium levels in check. They also raise concerns about unfairness to those who are injured, supported by about one-fifth of states that have struck down caps on non-economic damages as unconstitutional (see fact sheet 6).

Takeaways: Liability insurance is generally affordable and available to obstetrician-gynecologists. Tort reforms have limited potential to reduce premium costs and have not been shown to benefit childbearing women and newborns and those who pay for their care. By contrast, a series of recent reports clarify that rigorous quality improvement programs are effective in bringing liability premium levels down. This win-win-win strategy reduces liability for maternity care professionals, improves care and outcomes in childbearing women and newborns, and increases value for those who pay for this care (see fact sheet 9).

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access "Maternity Care and Liability" articles in *Women's Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



3. Occurrence of Negligent Injury and of Claims and Payouts in Maternity Care

Fact Sheet for Stakeholders from *Maternity Care and Liability Report* *

Problem: In comparison with most other clinical areas, maternity care providers are at elevated risk for liability claims and legal proceedings, and many believe that non-meritorious claims are widespread. These are sources of deep discontent.

Report findings: A large carefully conducted state-level study with random samples found that about 0.6% of childbearing women and about 0.2% of newborns sustained negligent injury while receiving care in U.S. hospitals. That and a replication study in two additional states found that the negligent injury rate in hospital labor and delivery units ranged from 0.8% to 1.8%. While childbearing women may be several times as likely as newborns to sustain negligent injury, newborn injuries overall are more severe. Across ten clinical areas in the initial study, childbearing women had the highest rate of negligence among adverse events, at 38.3%. Subsequent research clarified that these landmark studies greatly underestimated rates of harm, but replications in maternity care have not taken place. The patient safety movement has identified extensive opportunity to improve safety, especially in hospitals.

Tracking the initial cases that experts identified as meeting the legal standard of malpractice and not separately reporting maternity-specific data, investigators found that from 1.5% to 2.5% of patients who sustained negligent injury filed a claim. Tracking claims from the initial study to closure, investigators found that less than 1% of those with negligent injury received compensation. A recent closed claims analysis from five insurance companies in four regions of the country, including 23% with maternity-related claims, found that 54% of all compensation payments (and 78% when claims involved harmful errors) went to lawyers, experts, and courts, with a minority going to plaintiffs.

The closed claim analysis found that about 13% to 16% of dollars expended were associated with non-meritorious claims. The legal system does a fairly good job of sorting these out. Dr. Steven Clark, Medical Director for Women's and Children's Clinical Services within the nation's largest hospital system, reports that defense teams have repeatedly found that about 75% of paid claims in maternity care involved substandard care.

Takeaways: One of the two widely accepted objectives of the liability system is to attend to the needs of those who are injured as a result of negligence. Available evidence, not separately available for maternity care, suggests that the present liability system fails in about 99% of cases to compensate people who are injured as a result of medical error. Those who are compensated following injuries due to error may retain for their own needs about one-quarter of the money awarded.

The estimated 25% of paid claims in maternity care that are non-meritorious is substantial but is dwarfed by the roughly three-quarters associated with substandard care. Claims involving negligent injury appear to involve disproportionately greater legal costs.

The report found that in the practice of an average obstetrician-gynecologist, negligent injury of mothers and newborns appears to occur more frequently than any claim (warranted or not, obstetric or gynecologic), and far more frequently than any payout or trial.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access "Maternity Care and Liability" articles in *Women's Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



4. Defensive Practice in Maternity Care

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: Defensive clinical practice — deviating from sound practice primarily to reduce one’s risk of liability rather than to benefit the patient — is believed to be widespread in maternity care. Defensive practice encompasses two types of clinical behavior with different implications for those who receive and pay for care. “Avoidance” behaviors include curtailing high-risk care and dropping maternity care altogether, which may reduce access to care. “Assurance” behaviors include providing unnecessary tests, procedures, and referrals, which increases the cost of care, reduces efficiency, and may expose women and babies to unnecessary harm.

Report findings: Surveys and commentaries of maternity professionals raise troubling concerns about extensive avoidance and assurance defensive behavior in maternity care. However, many do not consider diverse drivers of practice decisions and have very low response rates, limiting the value of these studies. Studies that examine diverse drivers of decisions such as to carry out a cesarean section or to cease maternity care practice found that they are multifactorial.

Three investigations to corroborate reports of extensive *avoidance* behavior in maternity care found sporadic concerns in selected settings; did not substantiate reported levels of relocation, discontinuation of maternity services, or retirement; and/or identified liability as one factor among many others in practice changes. Six formal national studies and six state-level studies were consistent with these: various measures of liability pressure (e.g., premium levels, professional designation as “crisis” or “red alert” states, hard versus soft phases of liability cycles) were not associated with avoidance behavior or had an association under limited circumstances (e.g., older physicians in rural areas).

Six formal national studies and seven state-level studies investigated whether some portion of cesarean sections can be attributed to *assurance* behaviors during the present or previous liability cycle. Most used premium or claim levels as a measure of liability pressure. Results ranged from no relationship to a small positive one, with most studies finding a small positive relationship. At most, the association accounts for a small portion of the substantial increase in the cesarean section rate since the mid-1990s. The few studies of use of other maternity practices found similar results.

Takeaways: Decisions about limiting maternity care practice are multi-factorial. Liability pressure appears to have a modest role at best. Other considerations that have been identified include: having a more balanced lifestyle, fulfilling family duties, needing access to backup, getting adequate reimbursement, being available for ambulatory patients, and carrying out retirement plans. Other factors that have been cited in decisions to close maternity practices or birth centers include: fewer childbearing women in the area, inadequate reimbursement, restrictions on scope of practice, inability to compete with higher salaries offered by other employers, and difficulty securing collaborative practice relationships.

Decisions about whether to perform cesareans are also multi-factorial. A major factor in the recent steep increase appears to be a lowering of the bar for carrying out this procedure, with increased rates for all demographic groups regardless of risk level, along with some growth in the number of higher-risk groups such as older women and women with twins and triplets. Total payments for maternity care with cesareans are about 50% higher than total payments with vaginal births, providing incentives for the surgical pathway, which, especially when scheduled, is beneficial to physicians and hospitals.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access “Maternity Care and Liability” articles in *Women’s Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



5. Liability-Associated Distress Among Maternity Care Providers: Sources and Solutions

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: The vulnerability to legal claims and the cost and volatility of liability premiums are troubling for many obstetrician-gynecologists. Among dozens of medical specialties, obstetrician-gynecologists rank near the bottom in recent studies of professional satisfaction; preliminary investigations suggest that liability-related discontent may play a role.

Report findings: The professional discourse about maternity care and liability of some outspoken leaders suggests great distress, e.g.: “condition critical” and “obstetric litigation is asphyxiating our maternity services” and “although health care has never been safer for the woman and her fetus, it has never been more dangerous to the physician.” Available research suggests that general obstetrician-gynecologists are more dissatisfied, overall and with respect to liability concerns, than perinatologists/neonatologists, family practice physicians, midwives, and physicians in gynecology-only practices.

The *Maternity Care and Liability* report identifies many liability-related aspects of professional practice that may be confusing, uncertain, ambiguous, misunderstood, and/or anxiety arousing to health professionals. These stressors, which may disproportionately impact maternity care clinicians, include:

- discrepancies between legal clinician standards and practice consistent with best evidence
- ambiguity about the respective responsibilities of clinicians and childbearing women in clinical decision making
- confusion about the safety of practices that are supported by best evidence but discouraged by terms of liability insurance policies
- perception that the cost of liability insurance premiums is onerous for maternity care providers
- beliefs about the likelihood of experiencing a claim, payout, or trial
- beliefs about the likelihood of being responsible for injuring a woman or newborn
- beliefs about the frequency of non-meritorious claims and payouts for them
- uncertainty about whether a claim will be filed on behalf of a child years after providing maternal-newborn care
- tension between traditional denial of harm and evolving standards of disclosure
- uncertainty about the integrity of expert witnesses and whether juries and judges are qualified to make determinations about clinical questions
- concern about the tort system as a source of assistance to parents facing long-term expenses of caring for injured newborns when injuries were not due to medical error.

Takeaways: A clear understanding of current evidence about these matters is a starting point for easing professional distress and addressing conditions that give rise to these stressful situations. The considerable evidence about effects of caps on non-economic damages in maternity care (see fact sheet 6) and rational thinking suggest that this most-advocated reform is unlikely to be effective in addressing any of the above-named stressors. However, the report identifies numerous interventions that do show potential for alleviating many of these common stressors, with potential as well for improving care for women and newborns and value for payers. Interventions to alleviate the underlying sources of professional distress warrant the attention of health professionals and policy makers.

Research is needed to understand whether liability-related distress adversely impacts professional satisfaction, professional behavior, and maternity care quality.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access “Maternity Care and Liability” articles in *Women’s Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



6. Impact of Caps on Non-Economic Damages and Other Tort Reforms in Maternity Care

Fact Sheet for Stakeholders from *Maternity Care and Liability Report* *

Problem: To modify the way state court systems function when handling claims of medical malpractice, tort reforms have generally aimed to limit access of potential plaintiffs to courts, reduce the size of awards to plaintiffs, or otherwise alter liability rules. Caps on non-economic damages — i.e., a fixed ceiling on awards for “pain and suffering” and other injuries that are difficult to monetize — have raised concerns about fairness to women and newborns; about one state in five has found them to be unconstitutional. As this and other tort reforms have been the most advocated and widely implemented of liability reforms, it is important to understand their empirical record and plausible effects in achieving liability system aims.

Report findings: The report considered eight tort reforms and the collective impact of combined tort reforms in maternity care, and held these up to a framework (see fact sheet 1) of seven broad aims of a high-functioning liability system for maternity care. Tort reforms prioritize clinician interests relative to the multi-stakeholder framework that includes interests of women and newborns and of those who pay for their care. In nearly all cases, well conducted national studies have evaluated the impact of these reforms in the context of maternity care. Nine national maternity-specific studies have evaluated the impact of the most-advocated tort reform, caps on non-economic damages. In contrast to evidence in health care generally and in some other clinical areas, the effect in maternity care of both collective tort reforms and of caps on non-economic damages is modest at best for physician supply (combined and caps) and for premium levels, award levels, availability of hospital maternity services, use of interventions, and health outcomes (non-economic caps). Similar to evidence in health care generally, the maternity-specific studies of other tort reforms (attorney fee limits, collateral source rule, expert witness rule, joint and several liability rule, periodic payment of awards, and pretrial screening) provided no compelling support for their use. Despite strong interest in limiting payouts as a strategy for keeping malpractice premiums in check, the relationship between the two appears to be weak at best.

Takeaways: The effect of caps on non-economic damages has been well studied within maternity care, with studies finding modest and narrow impact at best. A smaller number of studies have examined effects of several other traditional tort reforms within maternity care, with generally disappointing results.

It is important to consider other strategies that might be more effective in improving the functioning of the liability system for all of the key stakeholder groups. Fortunately, several possible approaches appear to offer win-win-win opportunities for clinicians, women and newborns, and purchasers (see fact sheet 8). The strategy of implementing rigorous quality improvement programs has an impressive maternity care track record in this regard (see fact sheet 9).

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access “Maternity Care and Liability” articles in *Women’s Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



7. Interventions that are Unlikely to Foster Substantive Liability Solutions in Maternity Care

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: A high-functioning liability system in maternity care would meet the needs of clinicians, women and newborns, and payers. It is important to understand which strategies for improvement have been shown, or are likely, to do this, and which are not.

Report findings: The *Maternity Care and Liability* report held 25 strategies that have been proposed and, in many cases, implemented to address persistent liability problems up to a multi-stakeholder framework (see fact sheet 1) for a high-functioning liability system. Fifteen strategies were found to have overly narrow aims and lacked evidence of meaningful effectiveness in maternity care. These included tort reforms collectively and eight specific tort reforms, which, with one exception, have been evaluated in the context of maternity services:

- attorney fee limits restricting the portion of awards that compensate lawyers
- caps on non-economic damages, providing a compensation ceiling for harms that cannot be monetized
- collateral source rule, to prevent a plaintiff from “double-dipping” from multiple sources of compensation
- expert witness rule, to impose standards for expert witnesses
- joint and several liability rule, to limit the defendants who can be named as having had responsibility for harm
- periodic payment of awards, spreading out over time payments to plaintiffs for damages
- pretrial screening, to judge whether claims of plaintiffs are meritorious
- statute of limitations, to limit the time after possible injury when a claim can be filed.

Five liability insurance reforms have limited evidence and limited plausible impact across the seven aims. They are:

- joint underwriting associations, to increase access to liability insurance
- liability insurance investment *and* rate regulation, to keep insurance companies solvent and stabilize rates
- liability insurance premium subsidy, to encourage continued provision of maternity care
- patient compensation funds, to limit the liability levels of traditional policies.

Joint underwriting associations may, if evaluated, be shown to play an important role in access to liability insurance for midwives and birth centers. The single premium subsidy program reported for maternity care was ineffective in retaining maternity care providers. In addition, there is as yet little support for the “tort alternative” strategies of arbitration and mediation in medical liability generally and none in maternity care, though mediation may have a role in combination with some promising strategies (see fact sheet 8).

Takeaways: The reform strategies described above have limited aims. When evaluated in maternity care, impact has been modest at best. Strategies that have been shown to meet or would likely meet the needs of multiple stakeholders are good candidates for implementation and evaluation in states, health plans, or other appropriate entities (see fact sheet 8).

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access “Maternity Care and Liability” articles in *Women’s Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



8. Substantive Solutions for Preventing and Responding to Injury in Maternity Care

Fact Sheet for Stakeholders from *Maternity Care and Liability Report* *

Problem: Tort reforms, the traditional strategies for improving the medical liability system, have narrow aims (e.g., limiting access of plaintiffs to courts and reducing payouts for injury), and do not prioritize needs and interests of childbearing women and newborns and maternity care payers and purchasers. Empirical studies have consistently found that they do not alleviate liability stressors of maternity care providers or offer other potential benefits in maternity care (see fact sheet 6). Strategies that address the needs and interests of all core stakeholder groups are required.

Report findings: The report held 25 improvement strategies up to a multi-stakeholder framework (see fact sheet 1) of seven aims for a high-functioning liability system in maternity care. Six strategies to prevent injury and four strategies to respond to injury or claims of injury have demonstrated or plausible effectiveness across multiple aims.

Promising strategies for preventing injury, in order of ratings across the seven aims, are:

- rigorous clinical quality improvement programs
- enterprise liability — liability located exclusively or partially in organizations that provide care
- leveraging improvement through health care, accreditation, credentialing, and other processes
- shared decision making between women and maternity care providers
- aligning legal standards for care and for admission of evidence with best evidence
- regulating the coverage of liability insurance policies.

Promising strategies for addressing injury, in order of ratings across the seven aims, are:

- programs of disclosure, empathy, apology, and offer of compensation as warranted
- specialized health courts for handling medical malpractice claims
- administrative compensation systems as a replacement for the tort system
- high-low award limit agreements between plaintiffs and defendants.

These strategies have potential to offer benefits to clinicians, women and newborns, and payers. The highest-rated prevention and redress strategies do not require statutory or regulatory action or new major infrastructure and can proceed with strong leadership. Rigorous quality improvement programs have a growing, impressive body of evidence in maternity care, with benefits for all major stakeholder groups (see fact sheet 9). Evaluations of disclosure and apology programs in maternity care are not yet available, but this strategy has shown significant promise in health care overall.

Takeaways: Tort reforms, which have traditionally enjoyed strong clinician and policy maker support, have narrow aims and lack compelling support in maternity care. However, numerous strategies do offer potential for multi-stakeholder improvement. These warrant piloting, evaluation, refinement, and spread as appropriate.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access “Maternity Care and Liability” articles in *Women’s Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



9. Impact of Maternity Care Quality Improvement Programs on Liability

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: The cost and volatility of liability premiums and vulnerability to legal claims are troubling for many obstetrician-gynecologists. There are also concerns about the priority of improving the quality and safety of maternity care and reducing associated costs. Competing views about these matters and about best solutions have impeded progress.

Report findings: The report reviewed 25 strategies that have been proposed and, in many cases, piloted to address persistent liability problems. The most promising strategy overall for preventing harm and reducing liability, with a growing impressive track record in maternity care, is implementation of rigorous multi-faceted quality improvement (QI) programs with strong leadership within hospitals, health systems, and other entities.

The report summarizes results of seven maternity care QI programs that have recently achieved major gains in the quality and outcomes of care and plummeting measures of liability, including claims, payouts, premiums, and payment reserves.

For example, a rigorous QI program implemented in maternity units across 21 states in the nation's largest hospital system with about 220,000 births annually improved maternity outcomes, reduced the primary cesarean section rate, reduced the obstetric malpractice claim rate by two-thirds, and brought its cost of claims below the level of the category "accidents on hospital grounds" over the first decade of this system-wide QI program.

The report identifies and provides references for a broad range of strategies that are currently being used or explored to improve maternity care safety and quality, including quality collaboratives, performance measurement, payment reform, programs for high-reliability practice, programs for team-building and –training, safety and emergency preparedness courses, and opportunities that harness health information technology. It is a priority to understand whether implementation of these strategies can reduce measures of liability.

Takeaways: Dr. Steven Clark, the leader of the most extensive maternity care QI program to date, encourages maternity care providers to focus especially on the roughly 75% of paid claims that defense teams consistently associate with substandard care, over which maternity care providers have control, versus the 25% not associated with malpractice. He and his team concluded, "we are absolutely confident that adoption of our approach on a national level could, within 5 years, both dramatically reduce adverse perinatal outcomes and to a large extent eliminate the current obstetric malpractice crisis."

Implementing rigorous QI programs is a health care system strategy rather than a legal or liability insurance system strategy for addressing liability concerns. It had been shown to have a favorable impact on multiple aims of a high-functioning liability system, including: improved care quality, reduced liability costs, reduced unwarranted practice variation, and reduced clinician distress. It has the potential to favorably impact two other aims: appropriate response to injury and liability insurance coverage that is consistent with high-quality evidence about best practice.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access "Maternity Care and Liability" articles in *Women's Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



10. Maternity Care and Liability: Gaps in Knowledge

Fact Sheet for Stakeholders from *Maternity Care and Liability* Report *

Problem: Despite a growing body of empirical legal studies and health services research illuminating the impact of the liability environment in maternity care, many key liability-related questions have not been studied adequately or at all in this clinical context.

Report findings: A lengthy appendix in the *Maternity Care and Liability* report identifies key knowledge gaps and describes any preliminary evidence in the context of the current or previous liability cycle. Major gaps in knowledge about the impact of liability issues within maternity care include the following:

- Many basic questions are poorly understood with respect to maternal-fetal medicine specialists, family physicians, midwives, and birth centers, relative to general obstetrician-gynecologists and hospitals.
- There is virtually no research to characterize the functioning of the liability system in disparity populations and among safety net providers and settings.
- There is no research to clarify the extent to which corporate entities are responsible for paying for liability insurance of maternity care providers, and implications of this individual-to-corporate transition for all stakeholders.
- There is no national research to clarify the extent to which liability insurance policies interfere with clinical decision making, and implications of those strictures.
- Updates are needed to clarify the extent to which childbearing women and newborns experience negligent injury, and initial research is needed to understand the experience of that group with respect to subsequent care and compensation.
- Research is needed to understand the distribution of damages payments among maternal or newborn plaintiffs, attorneys, legal experts, and other administrative costs, and to understand whether plaintiffs receive adequate compensation.
- Research is needed to compare maternity care professionals' understanding of their likelihood of causing injury due to error and of experiencing various types of legal action relative to the actual likelihood of these occurrences.
- Apart from the well-studied matter of mode of birth, research is needed to understand the extent to which maternity tests, treatments, and referrals involve defensive "assurance" behavior and may be used primarily to demonstrate caution.
- Research is needed to clarify relationships, if any, among liability-associated stress of maternity care providers and their professional satisfaction, behavior, and care quality.
- Research is needed to understand the relationship between the liability system and health outcomes of childbearing women and newborns.

Takeaways: Despite a growing body of informative research about the impact of the liability system within maternity care, many gaps in knowledge remain. Policy makers and other stakeholders would benefit from clearer answers to many basic questions. Promising interventions for improvement should include evaluation components.

* **Learn more:** Sakala C, Yang YT, Corry MP. *Maternity Care and Liability: Pressing Problems, Substantive Solutions*. New York: Childbirth Connection, January 2013. Available at <http://transform.childbirthconnection.org/reports/liability/>. See also open access "Maternity Care and Liability" articles in *Women's Health Issues* 2013;23(1) at <http://www.whijournal.com/issues>.



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Corry and Sakala conceived, planned, and lead Childbirth Connection's long-term national program to promote evidence-based maternity care, which was established in 1999. The program focuses on closing gaps between current practice and practice supported by best evidence. It conducts and commissions systematic reviews and other research to fill evidence gaps and helps stakeholders understand and apply best evidence that is ready for implementation. Childbirth Connection's website (www.childbirthconnection.org) is a vehicle for this work. Sakala and Corry are co-investigators of periodic national *Listening to Mothers* surveys of women's childbearing experiences. They are co-authors of a Milbank Report, *Evidence-Based Maternity Care: What It Is and What It Can Achieve* (2008).

Corry and Sakala work with numerous organizations, agencies, and federal and state policy makers on health care quality improvement efforts. Childbirth Connection's *Transforming Maternity Care* Partnership brings together stakeholders from across the health care system to collaborate to improve the system in which maternity care is delivered. Corry and Sakala led multi-stakeholder teams that developed and issued two direction setting reports: "2020 Vision for a High-Quality, High-Value Maternity Care System" and "Blueprint for Action: Steps Toward a High-Quality, High-Value Maternity Care System." The reports were published in a special issue of *Women's Health Issues* in January 2010. They are working with stakeholders to implement the blueprint's recommendations relating to performance measurement, payment reform, shared decision making, a high-functioning liability system, and other priority improvement strategies. Childbirth Connection maintains a website to foster maternity care quality improvement (transform.childbirthconnection.org).

Carol Sakala has worked for three decades as a researcher, educator, advocate, and policy analyst, with a continuous focus on maternity care quality improvement. She is founding author of "Current Resources for Evidence-Based Practice," a column that is published simultaneously in leading maternity nursing and midwifery journals, and contributed columns from 2003 through 2007. She helped establish and continues to support the Cochrane Pregnancy and Childbirth Group's

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Maureen Corry has over thirty years of executive experience in maternal and infant health promotion and policy. As executive director of Childbirth Connection, she has positioned the organization as a powerful and effective advocate for evidence-based maternity care and maternity care quality improvement. She is a member of the board of directors of the National Quality Forum (NQF) and served as vice chair of NQF’s Consumer Council. She co-chaired NQF’s National Voluntary Consensus Standards for Perinatal Care Steering Committee (2007-08), which recommended a national set of standardized performance measures for prenatal and intrapartum care. She was a member of the American Medical Association-convened Physician Consortium for Performance Improvement Maternity Care Work Group, which developed clinician-level performance measures. She is co-chair of the Maternity Action Team, a national body convened by the National Priorities Partnership and Partnership for Patients to improve the quality and safety of maternity care. She is a member of the Centers for Medicare and Medicaid Services (CMS) Expert Panel to Improve Maternal and Infant Health Outcomes and serves on leadership bodies of Consumers United for Evidence-based Healthcare and the National Committee for Quality Assurance. She received her MPH in 1991 from Yale School of Public Health in health services administration.

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