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Maternity Care and Liability: Most Promising Policy Strategies for Improvement

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A B S T R A C T

Background: The present liability system is not serving well childbearing women and newborns, maternity care clinicians, or maternity care payers. Examination of evidence about the impact of this system on maternity care led us to identify seven aims for a high-functioning liability system in this clinical context. Herein, we identify policy strategies that are most likely to meet these aims and contribute to needed improvements. A companion paper considers strategies that hold little promise.
Methods: We considered whether 25 strategies that have been used or proposed for improvement have met or could meet the seven aims. We used a best available evidence approach and drew on more recent empirical legal studies and health services research about maternity care and liability when available, and considered other studies when unavailable.
Findings: Ten strategies seem to have potential to improve liability matters in maternity care across multiple aims. The most promising strategy—implementing rigorous maternity care quality improvement (QI) programs—has led to better quality and outcomes of care, and impressive declines in liability claims, payouts, and premium levels.
Conclusions: A number of promising strategies warrant demonstration and evaluation at the level of states, health systems, or other appropriate entities. Rigorous QI programs have a growing track record of contributing to diverse aims of a high-functioning liability system and seem to be a win–win–win prevention strategy for childbearing families, maternity care providers, and payers. Effective strategies are also needed to assist families when women and newborns are injured.

Introduction and Background

A new report, *Maternity Care and Liability: Pressing Problems, Substantive Solutions* (Sakala, Yang, & Corry, 2013b), and an overview of report highlights in this issue clarify that the current liability system does a poor job of meeting needs of childbearing families, maternity care providers, and maternity care payers, who cover liability-related expenses. Policy interventions 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 defensive maternity practice;
- Fosters access to high-value liability insurance policies for all maternity caregivers;
- Responds appropriately when women and newborns sustain injury;
- Assists families with responsibility for costly care of infants and women with long-term disabilities in a timely, efficient manner; and
- Minimizes legal and administrative costs (Sakala, Yang, & Corry, 2013a).

Policy interventions that might address these chronic concerns fall within four broad categories: Tort reform to modify the traditional legal process for handling claims of negligent injury (Mello & Zeiler, 2008; Studdert, Mello, & Brennan, 2004), tort alternative reform to use other mechanisms to help make

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that system more efficient and responsive to injured patients (Studdert et al. 2004), liability insurance reform to improve liability insurance policies and access to them (Baker, 2005; Sage, 2005), and health care reform that impacts liability matters.

Methods

We used a best available evidence approach to help clarify the potential for specific strategies to meet the seven proposed aims of a high-functioning liability system. Finding no systematic reviews or experimental studies, we preferred studies that took into account potential competing predictor variables and confounding factors within empirical legal studies and health services research traditions. We preferred studies specifically about maternity care and liability, and considered more general studies when maternity-specific research was unavailable. We preferred results from the current or previous liability cycle but, when unavailable, consulted earlier studies. We preferred national or multistate studies to state-level studies. We excluded studies from other countries. We searched PubMed and LexisNexis, with widely varying search terms owing to the diverse topics. The search results, health care news sources, journal table of contents notification services, and referees also pointed to relevant studies. In the absence of better quality empirical sources, we consulted theoretical analyses and commentaries and made judgments, indicated as such, about the plausibility of impacting priority aims.

We deemed strategies that have been shown to impact or may plausibly be expected to impact multiple aims of a high-performing liability system to be priorities for implementation, evaluation, refinement, and—as warranted—spread.

Results

We evaluated 25 strategies that might lead to a higher functioning liability system within maternity care. Ten—a mix of tort alternative, liability insurance, and health care reforms—hold promise for substantive, multidimensional improvement and are discussed herein. The first six have potential to prevent harm and ensure that it is rare. The final four show promise for improving response to harm or claims of harm when they occur. Improvement strategies are needed for both prevention and redress.

Table 1 holds these strategies up to the proposed policy aims. Within the prevention and redress sections in the table and discussion below, the strategies are ordered from greatest to least demonstrated or projected impact across the aims. Fifteen strategies did not hold up well against the proposed aims, in many cases with the benefit of multivariable maternity-specific studies. A companion paper in this issue covers those strategies and studies (Sakala, Yang, & Corry, 2013a).

Prevention: Quality Improvement—A Health Care Reform

Patient safety and other quality improvement (QI) efforts are increasingly viewed as essential for achieving liability system aims (Clark, Belfort, Dildy, & Meyers, 2008; Clinton & Obama, 2006; Hickson & Entman, 2010; Joint Commission on the Accreditation of Healthcare Organizations, 2005; Pearlman, 2006; Pearlman & Gluck, 2005; Sage, 2003; Schoenbaum & Bovbjerg, 2004).

Mello and Hemenway (2004) argued that injury reduction has limited potential to reduce malpractice claims and premium levels because very few who sustain injuries file claims. However, hospitals and health systems that are self-insured, pay malpractice premiums for both facilities and clinicians, have transparent performance reporting, and pay for high-cost newborn injuries have incentives to prevent harm. They have begun to report that rigorous QI programs are leading to improved care and health outcomes, and substantial decreases in claims, payouts, and premiums:

- Over the first decade of its system-wide maternity care QI program, the nation's largest hospital system reduced its primary cesarean rate, improved maternity outcomes, reduced its obstetric malpractice claim rate by two thirds, and brought its cost of claims below costs for "accidents on hospital grounds" (Clark, Meyers, Frye, & Perlin, 2011; Clark, 2009b; Clark, Belfort, Byrum, Meyers, & Perlin, 2008).
- In its 16 hospitals with maternity units, a health system evaluated its liability history and implemented patient

Table 1
Evidence Summary: Effects of Most Promising Reforms on Diverse Aims of Liability System

Interventions	Aims						
	↑ 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	↓ Legal and Administrative Costs
Prevention strategies							
Quality improvement	+*	+	+*	(+)	(+)	(−)	+*
Enterprise liability	(+)	(+)	(+)	(+)	(+)	?	(+)
Leverage of health insurance, accrediting, credentialing, etc.	(+)	(+)	(+)	(+)	(+)	(−)	(+)
Shared decision making	(+)	(+)	(+)	(+)	(+)	(−)	(+)
Aligning legal standard with best evidence	(+)	(+)	(+)	(+)	(−)	(−)	(+)
Liability insurance coverage regulation	(+)	?	?	(+)	(−)	(−)	(−)
Redress strategies							
Disclosure, empathy, apology	(+)	?	?	(+)	(+)	(+)	(+)
Health courts	(+)	?	?	?	(+)	(+)	(+)
Administrative compensation systems	(−)	?	?	?	+*	+*	+*
High-low agreements	(−)	(−)	(−)	(−)	(+)	(+)	(+)

Abbreviations: +, 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; ?, It is difficult to anticipate actual impact.

* Support from assessment includes maternity-related data.

safety programs. Over a 5-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, Kortz, & Knox 2009).

- Reviewing liability claims, a health system identified maternity care as having the 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 improved targeted quality measures by 25% and learned from near misses. Within 3 years, the system recouped costs of investing in and operating the system through reduced self-insurance funding. It experienced large declines in actual compared with expected frequency and severity of claims and a claim-free period of 15 months for the 2007 loss year (Smith & Berry, 2007).
- 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 3 years. On average, in the 3 most recent years, the center saved over $25 million annually relative to average payouts in the initial four years. Sentinel events fell to zero in the 2 most recent years, with similarly favorable results for several severe adverse events, and a very favorable outlook for future payouts (Grunebaum, Chervenak, & Skupski, 2011).
- A safety net tertiary care center implemented a multifaceted labor and birth safety program over 5 years. The number of claims that its insurance companies reserved for financing possible legal expenses declined about 20% annually. The center experienced no claims during the four most recent years, with about 2,400 births annually (Iverson & Heffner, 2011).
- 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 both program implementation and health and liability measures, and do not consider competing explanations for results. An analysis that did consider other variables found a relationship between malpractice claims and the Agency for Healthcare Research and Quality's Patient Safety Indicators of in-hospital complications and safety events:

- In a multivariable analysis, investigators found a strong correlation between changes in Patient Safety Indicator event counts and changes in the volume of claims against obstetrician-gynecologists at the county level in California from 2001 to 2005; Patient Safety Indicator event count changes accounted for about 30% of the variance in malpractice claims (Greenberg, Haviland, Ashwood, & Main, 2010).

Given the consistent finding of an inverse relationship between rigorous QI and liability, multifaceted QI with strong leadership seems to be a priority strategy for liability reduction. These results provide health systems with the "business case for quality" (Hyman & Silver, 2005). Obstetrical quality leader Steven Clark encourages colleagues to focus on the 75% of paid claims consistently associated with substandard care, over which they have some control, versus the 25% unassociated with substandard care, over which they have little control (Clark, 2009a). 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 prevents harm and improves care for those who might have submitted claims in the face of injury and for the vast majority who do not submit claims.

A focus on improving intrapartum care has greatest potential to reduce liability because at least 60% of obstetric negligence claims and more than 80% of payments for injury awarded in suits against these specialists involve this period (Cohen & Schifrin, 2007).

Despite the growth of implementation science, numerous strategies and programs for improving maternity care quality and safety, and interest in reducing liability, few studies measure the impact of specific quality and safety initiatives on liability system aims. Data are needed to better understand the impact of the QI strategies and programs identified in Table 2 on liability-related matters.

These innovations involve a sea change in the conventional culture of safety and error, from deflecting to taking responsibility, conflict to cooperation, limiting access to information to transparency, avoidance and delays to timely resolution of adverse events, failure to learn and apply to seizing opportunities for improvement, and focus on individuals to focus on systems.

Prevention: Enterprise Liability—A Tort Alternative Reform

Many respected health law scholars support a model known as "enterprise liability," which concentrates malpractice liability and responsibility for high-quality health care in hospitals, health plans, and other enterprises while reducing or eliminating clinician liability (Bovbjerg & Berenson, 2006). However, enterprise liability is not easily applied if health professionals are not affiliated with one and only one entity, no state currently offers a legal climate suitable for this model, and it has not been piloted. However, self-insured health systems and integrated delivery systems can embrace many of its elements (Mello & Kachalia, 2010). Enterprise liability addresses core aims of the liability system, because it

- Is consistent with the finding that about two-thirds of injuries owing to error involve individual and system factors, whereas about one third can be attributed solely to individuals (Mello & Studdert, 2008);
- Incents self-insured entities with premiums reflecting past claims experience to foster patient safety, versus limited experience rating with individual liability (Abraham & Weiler, 1994; Peters, 2008);
- Gives liability responsibility to entities that have the benefit of system leaders, centralized planning, and resources for QI programs, which are more difficult for solo and group clinicians (Mello & Studdert, 2008; Peters, 2008; Sage, 2004);
- Fosters health system coordination (Sage, 2005);
- Reduces clinician discomfort, defensiveness, pressure to conceal errors, and stigma, fostering greater cooperation and

Table 2
Maternity Care Quality Improvement Strategies With Potential to Reduce Liability

Strategy	Role in Maternity Care
Using national standardized *safety measures*, "Safe Practices" and "Serious Reportable Events," to measure, report, and improve performance	National Quality Forum, 2010a, 2010b
Using national standardized perinatal care *quality measures and adverse event reporting systems* to measure, report, and improve performance	Hibbard, Stockard, & Tusler, 2003; Levinson, 2008; Main, 2009; National Quality Forum, 2012
Implementing payment reform to align incentives with quality	Center for Healthcare Quality & Payment Reform n.d; Hyman & Silver, 2005, 2006; James & Savitz, 2011; Lantos, 2010; Rosenthal, Li, Robertson, & Milstein, 2009
Implementing maternity care *quality improvement collaboratives* or maternity-focused programs within broad-scope collaboratives	Childbirth Connection, 2012c; Main & Bingham, 2008
Implementing focused *toolkits* to improve practice	Childbirth Connection, 2012b
Implementing *medication safety systems*, including focus on common "high-alert" medications (synthetic oxytocin, narcotics/opioids, epidural or intrathecal medications)	Clark, Simpson, Knox, & Garite, 2009; Institute for Safe Medication Practices, 2008; Keohane & Bates, 2008
Reducing unwarranted *overuse* 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, Jacoby, Xing, Danielsen, & Smith, 2010; Kramer, Rouleau, Baskett, & Joseph, 2006; Marshall, Fu, & Guise, 2011; Martinez-Biarge, Madero, González, Quero, & Garcia-Alix, 2011; Mercer et al., 2008; Murray et al., 2009; Silver, 2010; Silver et al., 2006; Vardo, Thornburg, & Glantz, 2011
Implementing *shared decision making* using high-quality, up-to-date decision aids	Dugas et al., 2012; Frosch et al., 2011; Say, Robson, & Thomson, 2011; Stacey et al., 2012
Developing systems for effective patient-centered *informed consent processes*, 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, Corry, & Applebaum, 2006; Matiasek & Wynia, 2008; National Quality Forum, 2005; Studdert, Mello, Levy et al., 2007
Harnessing potential of *electronic health records* to foster access to full and accurate documentation and data collection and to support appropriate care	Bernstein, Farinelli, & Merkatz, 2005; Cusack, 2008; Eden et al., 2008; George & Bernstein, 2009; Haberman et al., 2009; Nielsen, Thomson, Jackson, Kosman, & Kiley, 2000; Quinn, Kats, Kleinman, Bates, & Simon, 2010
Building effective *teams*, improving interpersonal *relationships and communication* and strengthening *collaborative practice*	Hickson & Entman, 2008; Lyndon et al., 2012; Lyndon, Zlatnik, & Wachter, 2011; Mann & Pratt, 2008; Merién et al., 2010; Nielsen & Mann, 2008; Pratt et al., 2007; Williams et al., 2010
Implementing *high-reliability practice* 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, Propst, Van Doren, & Clark, 2011; Grobman et al., 2011; Hasley, 2011; Knox & Simpson, 2011; Pettker, 2011
Implementing *quality of care peer review systems* (e.g., American College of Obstetricians and Gynecologists Voluntary Review of Quality of Care)	Lichtmacher, 2008; Stumpf, 2007
Using *laborists* (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 & Lorch, 2012
In education programs, renewed focus on teaching *fundamentals of intrapartum care* and common standardized terminology	Cohen & Schifrin, 2007; Devoe, 2009
Taking *safety and emergency preparedness courses*, including Advanced Life Support in Obstetrics, Managing Obstetrical Risk Efficiently, Managing Obstetric Emergencies and Trauma, and PRactical Obstetric MultiProfessional Training	Beasley, Desang, & Winslow, 2005; Childbirth Connection, 2012a; Draycott, Winter, Crofts, & Barnfield, 2008; Grady, Howell, & Cox, 2007; Milne & Lalonde, 2007
Using *simulation* to build skills, knowledge, and teamwork and to prepare for emergencies	Fisher et al., 2011; Gardner & Raemer, 2008; Gardner, Walzer, Simon, & Raemer, 2008; Merién et al., 2010
Creating a *plan for respectful management of serious adverse events*, integrating into organization's culture of quality and safety, and implementing it as needed	Conway, Federico, Stewart, & Campbell, 2011
Conducting *analysis of adverse events* and associated circumstances, and incorporating lessons into care systems	Boothman & Blackwell, 2010; Mulligan & Nechodom, 2008; Schifrin & Ater, 2006; Smetzer, Baker, Byrne, & Cohen, 2010
Carrying out *analyses of closed and open claims* and circumstances associated with them, and incorporating lessons into care delivery systems	Angelini & Greenwald, 2005; Clark, Belfort, Dildy et al., 2008; Crawforth, 2002; Hickson, Clayton, Githens, & Sloan, 1992; Jevitt, Schuiling, & Summers, 2005; Kravitz, Rolph, & McGuigan, 1991; Richards & Thomasson, 1992; Ward, 1991; White, Pichert, Bledsoe, Irwin, & Entman, 2005
When patients are harmed during care processes, implementing national *"Care of the Caregiver" standard*, through just treatment, respect, understanding and compassion, supportive care, and transparency	Denham, 2010; National Quality Forum, 2010a
Developing and implementing *standards and measures for clinician behavior*, and carrying out system-level programs to identify problem clinicians and address shortcomings	American College of Obstetricians and Gynecologists, 2007b; Chervenak & McCullough, 2005; Leape & Fromson, 2006; Rosenstein, 2011; Simpson, 2007
Improving the *accuracy, completeness, and timeliness of data* in the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank, and using them to identify unsafe caregivers	Sibelius & Wakefield, 2010; Weber & Ornstein, 2010
Comparing the *effectiveness of change strategies* and implementing the most effective approaches	Clark et al., 2010

potential to support injured parties and learn from errors (Peters, 2008; Sage, Hastings, & Berenson, 1994);
- Reduces health professional discontent by removing penalties such as threat to reputation, embarrassment, and—regardless of merit—reporting settlements to National Practitioner Data Bank and disclosing claims on applications for admitting privileges, board certification, and liability insurance (Peters, 2008);
- Enables more equitable distribution of liability costs across specialties, sparing obstetrician-gynecologists and other high-risk specialists from disproportionate cost (Abraham & Weiler, 1994; Peters, 2008; Sage, 2004);
- Shields health professionals from periodic liability insurance premium spikes (Peters, 2008);
- Provides large risk pools to ensure that resources are available for large judgments (Abraham & Weiler, 1994);
- Has potential to build in other strategies such as arbitration and no-fault payment (Sage, 2004), schedules for fair and predictable non-economic damages compensation (Abraham & Weiler, 1994), and disclosure and offer;
- Reduces multi-defendant litigation costs by consolidating liability in a single corporate defendant (Abraham & Weiler, 1994; Peters, 2008); and
- Has fostered safety in other industries (e.g., aviation and automobile; Peters, 2008) and is used to compensate workplace injury (Mello & Studdert, 2008).

A recent review of likely effects of this model found that a well-designed enterprise liability system could reduce overhead costs of litigation and liability insurance costs, reduce defensive behaviors, and improve health care quality. Investigators were unable to anticipate effects on the frequency and cost of claims and on physician supply (Mello & Kachalia, 2010).

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

Rather than operating independently, health insurance can and should be linked to liability (Sage, 2005), and potential or actual medical errors should be handled within rather than separate from the health care system. Private and public payers enter into agreements on behalf of beneficiaries and indirectly finance malpractice costs through clinician and facility reimbursement; they thus have a justifiable interest in liability matters. Payers could favorably impact liability issues by acting proactively as purchasers. Sage (2005) argued that,

> 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. (483–484)

Similarly, Sage (2004) has identified ways to better integrate liability coverage into the professional, commercial, and regulatory framework of health care financing and delivery. Insurers, credentialing and accrediting bodies, and others with oversight responsibility or other types of leverage have great, unrealized potential to assume responsibility for the delivery of safe, effective care. They can foster use of QI strategies and tort alternative approaches such as disclosure and apology. The Wyoming Healthcare Commission identified a comprehensive package of strategies that the state can pursue to address medical error and medical injury compensation (Roberts, Glode, & Cadez, 2005). Such leverage could effectively address multiple liability system aims and hasten a culture of safety.

Prevention: Shared Decision Making—A Health Care Reform

Shared decision making (SDM) is a process for providing balanced information about care options to a person who has a specific condition, presenting potential benefits and harms of the options, weighing the person's values and preferences, and reaching and implementing a personalized decision. High-quality decision aids are essential tools for SDM (Ottawa Hospital Research Institute, 2011). This approach has an impressive track record in health care generally (Stacey et al., 2011), an evolving track record in maternity care (Dugas et al., 2012; Say, Robson, & Thomson, 2011), and an increasing role in health care policy in the United States (Frosch et al., 2011).

Decision-making processes and standards are crucial for liability involving decisions to undertake certain care pathways and forgo others. Current standards of informed consent and their implementation often do not serve patients well and pose liability hazards to clinicians (King & Moulton, 2006).

Legal scholars and health services researchers argue that SDM is superior to informed consent from quality and liability perspectives, and should be strengthened and widely implemented (King & Moulton, 2006; O'Connor et al., 2007). This approach can reduce the risk of liability by fostering high-quality clinician–patient communication, because poor communication and breakdown of these relationships lead to lawsuits (King & Moulton, 2006), including among childbearing families (Sloan et al., 1993). Monico, Calise, and Calabro (2008) identified benefits of SDM, including improved patient autonomy and understanding, reduced use of unwanted medical procedures, improved communication and trust between patients and clinicians, and clear delineation of mutual responsibilities. They argue that better patient understanding and acceptance of possible outcomes, and more realistic expectations, reduce exposure to liability.

SDM can reduce liability by 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 malpractice system stakeholders that are inclined toward adversarial relationships have retarded this and have shaped clinician approaches to consent form and documentation practices. Consequently, stakeholders are 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 relationships and communication have been hampered. Clinicians can reduce risk of liability by entering into agreements with patients that clarify roles and responsibilities and involve patients in decision making (Green, 1988).

In an instructive study, prospective mock jurors found that a clinician followed the standard of care when care decisions emerged from the use of quality decision aids. The study suggested that a decision aid provides greater protection against a determination of malpractice than the clinician's word or a medical record note about provision of information. Presenting a decision aid to mock jurors educated them about the complexity of the situation, documented content that had been

presented to the "patient," and demonstrated that the "physician" had taken great care to support the patient's knowledge and decision making. Use of the tool seemed to prevent the situation when jurors might feel that a test or procedure should have been undertaken as a precaution, despite evidence or patient preferences to the contrary (Barry, Wescott, Reifler, Chang, & Moulton, 2008). Use of decision aids may thus alleviate pressure for defensive assurance practices that fully informed patients decline (Moulton & King, 2010).

The 9 months of pregnancy provide an opportunity to use SDM for many maternity care decisions. The Informed Medical Decisions Foundation and Childbirth Connection are collaborating to develop, assess, and make available maternity care decision aids for childbearing women (Romano, 2012).

Prevention: Align Legal Standards with Best Evidence—A Tort Alternative Reform

Clinicians are held to a legal standard of care in negligence cases that can deviate from the best current evidence about safe and effective practice. Thus, the current liability system does not reliably hold providers accountable for best practice, despite the system aim of deterring harm. An important improvement strategy is to align legal standards with evidence-based practice (Hines, 2006; Massie, 2004; Peters, 2000; Williams, 2004).

Clinicians in about 21 state court systems are 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, Gohagan, & Merenstein, 2007). The reasonable person standard in other states holds that practice should reflect care that a reasonable clinician would take in a particular situation.

This focus on actual practice has practical limitations (Hines, 2006; Meadow, 2002) and raises serious quality concerns. Unwarranted practice variation is widespread across geographic areas, facilities, and clinicians in maternity care (Baicker, Buckles, & Chandra, 2006; Clark, Belfort, Hankins, Meyers, & Houser, 2007) and in health and medicine generally (King & Moulton, 2006). Pervasive gaps between evidence and practice reflect both overuse of unwarranted practices and underuse of beneficial practices in maternity care (Sakala & Corry, 2008) and across medicine (Institute of Medicine Committee on Quality of Health Care in America, 2001). Behavior-based standards can thus provide perverse incentives to not improve: It is legally safe to use a practice that has been shown to be effective in rigorous research only when use by enough clinicians has rendered it the standard of care (King & Moulton, 2006).

Incentives that are thus misaligned with quality (Hines, 2006; King & Moulton, 2006) are especially alarming within maternity care, which had a head start, beginning in the 1970s, in developing systematic reviews summarizing the weight of the best evidence about effects of specific forms of pregnancy and childbirth care (Chalmers, Enkin, & Keirse, 1989). Consequently, thousands of systematic reviews—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)—are available to help guide maternity care decisions and to point the way for legal standards.

An alternative to realigning the standard of care with best evidence would be to expand 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 (Peters, 2000).

Although some propose using clinical practice guidelines to identify standards of care (e.g., Newman, Chu, & Webel, 2011), the guidelines do not reliably reflect the most valid scientific evidence. Current challenges include persisting moderate to low quality of many clinical practice guidelines (Alonso-Coello et al., 2010), considerable variation in processes used to develop guidelines in the United States (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, 2011), the extent to which national maternity care guideline recommendations reflect expert opinion or weak scientific evidence (Chauhan, Berghella, Sanderson, Magann, & Morrison, 2006; Wright et al., 2011) and are phrased in intentionally ambiguous ways (Clark, Belfort, Byrom et al., 2008), and the challenge of developing and updating guidelines for all relevant clinical topics (Bovbjerg & Berenson, 2012).

Courts in many states are governed by the *Frye* (1923 case) test for related decisions about admission of evidence (e.g., about causation of injury). *Frye*, which governs many of the most populous states (Cheng & Yoon, 2005), adopts existing standards within the field under scrutiny, regardless of the rigor used to establish them. 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 & Faigman, 2005).

The competing *Daubert* standard from the *Daubert* trilogy of cases (1993, 1997, 1999) has replaced *Frye* in over half of states. This requires judges to ensure that testimony and other medical evidence are scientifically trustworthy. The *Daubert* case itself supported admitting a meta-analysis about pregnancy care. The intent of the Supreme Court's *Daubert* "gatekeeping revolution" was to "incorporate scientific sensibilities into the legal culture," regardless of its acceptance in the community of practice (Saks & Faigman, 2005). However, *Daubert* implementation has been problematic owing to limitations in the scientific literacy of judges (Saks & Faigman, 2005), who often feel unprepared to apply scientific standards (Gatowski et al., 2001).

It is a priority to extend *Daubert* to all jurisdictions and to find effective ways to assist judges in carrying out this standard. Judges might benefit from scientific training as a criterion for appointment, access to assistance of scientific experts, pretrial hearings, and access to compendia of systematic reviews. It is important to understand whether judges can reliably have and apply the specialized skills that *Daubert* requires, and whether the health court model (below) would better implement this standard.

It is urgent, as well, to develop a legal standard of care that is parallel to the *Daubert* standard for admission of evidence. This crucial alignment with quality would encourage clinicians to stay abreast of evolving research, help to close evidence–practice gaps, and provide incentives to improve maternity care quality, safety, and outcomes.

Prevention: 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 and imposing a surcharge for a family physician to obtain maternity coverage or for an obstetrician-gynecologist to work in collaborative

practice with midwives (Benedetti et al., 2006). We did not find good data about the extent of insurer-imposed practice restrictions impacting maternity care practice.

These restrictions interfere with professional autonomy (Hale, 2006) and limit practice that is supported by systematic reviews of best evidence (e.g., Guise et al., 2010; Hatem, Sandall, Devane, Soltani, & Gates, 2008; Johantgen et al., 2012). They foster confusion about the safety and efficacy of the practices in question, limit access to valuable care options in communities, and increase expenses.

In exercising their oversight of the insurance industry, states do not seem to have addressed interference with professional practice that is not in the public interest (Sage, 2004). 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 clinicians about high-quality practice. Possible approaches include eliminating such surcharges, making coverage of unwarranted exclusions a condition of doing business in the state, or requiring data to support exclusions or surcharges.

Redress: Disclosure, Empathy, Apology—A Tort Alternative Reform

Many who believe that they or a family member have been injured wish to understand what happened, have their grievance acknowledged, and protect others from a similar experience. Often, an open and honest expression of empathy, an apology when a care provider and/or system was at fault, a pledge that the involved parties will learn from the experience, and timely support for resulting expenses and responsibilities constitute an appreciated and sufficient response from involved clinicians and institutions (Wojcieszak, Saxton, & Finkelstein, 2008). Empathy, apology, and redress are consistent with medicine's focus on caring and healing (Todres, 2006).

Potential defendants using conventional medicolegal risk management strategies avoid communication and refrain from acknowledging responsibility. However, patients and the public strongly desire disclosure of errors (Mazor, Simon, & Gurwitz, 2004), which is supported by many professional groups, including the Joint Commission on the Accreditation of Healthcare Organizations (2006), American Medical Association (1994), American College of Obstetricians and Gynecologists (2007a), and American Academy of Family Physicians (2006). Despite this broad support, a survey of hospital risk managers found great reluctance to disclose error (Lamb, Studdert, Bohmer, Berwick, & Brennan, 2003). Guidelines from the American Health Lawyers Association (Belmont, 2012) and procedures and training for disclosure processes (Conway et al., 2011; Liebman & Hyman, 2004; Weiss & Miranda, 2008) are available to foster needed change.

Most jurisdictions have enacted some form of sympathy/apology immunity laws that may legally protect certain actions, persons, and content. A model law has been developed. Some state laws mandate disclosure (Mastroianni, Mello, Sommer, Hardy, & Gallagher, 2010; Pelt & Faldmo, 2008; Wojcieszak et al., 2008). Most laws have deficiencies that may work at cross-purposes with their aims (Mastroianni et al., 2010). Implications of apology laws for clinician disclosure and the quality of care are unclear (McDonnell & Guenther, 2008). Sorry Works! Coalition leaders argue that the laws can be helpful, are unnecessary for implementing disclosure programs, and should rarely be used in the legal defense of a physician or hospital (Wojcieszak et al., 2008).

The Sorry Works! Coalition encourages rapid root cause analysis of adverse outcomes or events. If negligence is deemed to have been involved, they recommend admission of fault, apology, 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, Banja, & Houk, 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, and avoids appearance of cover-up or deception, which are vulnerabilities if litigation proceeds (Wojcieszak et al., 2008).

Studdert, Mello, Gawande, Brennan, and Wang (2007) suggested that disclosure and apology strategies have limited potential to reduce claims. However, a study of Florida families of infants with birth injuries who made malpractice claims found that anger, communication problems, and perceived deception and lack of honesty were common, and motivation for filing claims included wanting to find out what happened, seeking revenge, wanting to ensure that others avoided similar harm, and needing to air grievances (Hickson et al., 1992; Sloan et al., 1993).

A 15-year disclosure program within a Veterans Affairs Medical Center was associated with substantial improvement in liability payouts, in contrast with trends for other system facilities (Kraman & Hamm, 1999; Kraman, Cranfill, Gamm, & Woodard, 2002). Initial reports of implementation of Sorry Works! principles at a growing number of sites are favorable (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, Blackwell, Campbell, Commiskey, & Anderson, 2009; Quinn & Eichler, 2008).

From 1995 to 2007, after implementation of a disclosure and offer program at the University of Michigan, the average monthly rate of new claims fell from 7.02 to 4.52 per 100,000 patient encounters and monthly rate of lawsuits fell from 2.13 to 0.75 per 100,000 patient encounters. Median time from claim reporting to resolution fell 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 during the study period. The contribution of the program cannot be determined as malpractice claims declined in Michigan near the end of the study period (Kachalia et al., 2010). In surveys, both medical faculty and the plaintiff's bar had favorable views of the program (Boothman et al., 2009). It is credited with accomplishing what 40 years of tort reform had not: Respectful working relationships between the health system and the trial bar (Wojcieszak et al., 2008).

We found no reports of the impact of apology and disclosure principles applied to maternity care, which may face distinctive challenges, including the high premium placed on healthy newborns and parents' use of the tort system to secure costs of caring for injured children. Evaluation of a maternity care disclosure project is under way (Kachalia & Mello, 2011).

These principles involve a notable culture change in health care microsystems, and go far toward addressing several persistent liability concerns without statutory change or major reorganization in the legal or health care systems.

A recent review of the limited record and potential of disclosure and offer programs in medicine generally found that

they have potential to reduce claims frequency, payouts, overhead costs, and liability insurance premiums; and to improve the culture of safety. Investigators could not anticipate the impact on defensive assurance behaviors and physician supply (Mello & Kachalia, 2010).

Redress: Health Courts—A Tort Alternative Reform

Many are concerned that juries lack the specialized knowledge to decide whether medical errors have occurred or what appropriate levels of compensation would be. Similarly, judges who infrequently hear medical liability cases are at a disadvantage. Establishing health courts to handle medical liability disputes might address most aims in our proposed framework. Judges in these courts could have special training and would grow in expertise and have comparative experience across medical liability cases. Neutral independent experts could assist them, with limited scope for trial lawyers (Barringer, Studdert, Kachalia, & Mello, 2008; Common Good, 2006; Mello, Studdert, Kachalia, & Brennan, 2006). Health courts could facilitate legal system use of abundant systematic reviews and foster evidence-based maternity care practice.

Although some express concerns that health courts would violate constitutional civil rights to a jury trial, others argue that a constitutional health court system is possible, noting substitution of administrative for judicial remedies in such contexts as workers' compensation, securities law, and environmental law (Elliott, Narayan, & Nasmith, 2008). An analysis of cases involving constitutional challenges to malpractice reforms concluded that carefully designed health court pilots could withstand such challenges in many states (Mello, Studdert, Moran, & Dauer, 2008).

Health court advantages include the potential to compensate a broader group of patients by shifting from a standard of negligent injury to one of "avoidability" (injury that would not occur with the best practitioners) and to foster equity by using a standardized schedule for non-economic losses. Proponents argue that health courts would involve less uncertainty, apprehension, malaise, and stigma among clinicians and align well with health care QI (Common Good, 2005).

With respect to challenges, this model has not been implemented to date in the United States, although state-level systems are being explored (Common Good, 2006; Roberts et al., 2005). It may have little impact on the large proportion of cases that are not tried in court. It faces the political barrier of opposition by attorney groups and would require creation of a parallel court system.

A recent review of work to pilot and evaluate health courts in the United States found that effects would depend on the specific system put in place. Relative to the tort system, well-designed health courts may reduce legal expenses, reduce provider liability insurance costs, and slightly increase physician supply. This model may not impact claims frequency, the success rate of claims, or the size of awards. Investigators could not predict impact on overhead costs, defensive behavior, and the quality of care (Mello & Kachalia, 2010).

Redress: Administrative Compensation Systems—A Tort Alternative Reform

Administrative compensation systems use administrative bodies rather than the tort system to pay for medical injuries (Studdert & Brennan, 2001a). They conserve or divert resources from legal expenses to injured patients and resolve disputes quicker than the tort system (Studdert & Brennan, 2001a). By removing the stigma and penalty of individual blame, they may increase the likelihood that clinicians learn from errors, improve systems of care, and deter injury. They have the potential to systematically identify cases and resolve claims proficiently (Studdert & Brennan, 2001b).

Within maternity care, administrative systems have the potential to provide efficient and timely assistance overall 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 & Brennan, 1995; Studdert, Fritz, & Brennan, 2000). They were established to foster more affordable medical malpractice insurance; efficiency in claims resolution and victim injury compensation received less adequate attention in their design (Bovbjerg & Sloan, 1998).

The Virginia and Florida programs have intentionally narrow eligibility criteria to keep costs low (Bovbjerg, Sloan, & Rankin, 1997). Participating clinicians continue to pay liability insurance premiums, and most potential claims have remained in the tort system.

Sloan, Whetten-Goldstein, and Hickson (1998) found that obstetricians were far more satisfied with administrative than tort systems, yet most were unhappy with premiums for the former. Evaluation of the first decade of the programs found that they are feasible and efficient, offer important advantages relative to the tort system even when limited in scope, 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). Parents of children with birth-related injuries who filed claims with Florida's program indicated satisfaction with their compensation (Whetten-Goldstein, Kulas, Sloan, Hickson, & Entman, 1999). Some Florida claimants with birth injuries would not have met criteria for compensation in the tort system, whereas many with neurologic birth injuries did not qualify for administrative compensation (Sloan et al. 1998; Stalnaker et al., 1997).

Comparison of administrative and tort claims for newborn injuries and death in the early years of the Florida and Virginia programs found that the administrative systems nearly eliminated legal costs for resolving disputes and were more likely to pay for claims. Those with administrative compensation in Florida received payment for their actual expenses, whereas those with tort payments were overcompensated. Analysis limited to children with cerebral palsy found administrative system undercompensation and even greater tort overcompensation (Sloan, Whetten-Goldstein, Entman, Kulas, & Stout, 1997). Studies of the first decade of the Florida and Virginia programs may not apply to present conditions. Siegal, Mello, and Studdert (2008) provide a detailed overview of the eligibility criteria and claims determination processes of the two programs with the benefit of key informant interviews in 2004 and 2005. They express surprise that this model has not been more widely implemented.

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 (Studdert et al., 1997). 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 & Brennan, 2002).

Legal scholars have studied the Florida and Virginia programs to ascertain lessons for administrative compensation schemes (Siegal et al., 2008), have examined established administrative compensation systems in other countries for lessons for the United States (Mello, Kachalia, & Studdert, 2011; see also Kachalia, Mello, Brennan, & Studdert, 2008), and have designed comprehensive administrative compensation systems for far-reaching impact (Roberts et al., 2005).

A recent review of the potential of administrative systems in medicine found that effects would vary according to program design. Relative to the tort system, administrative systems could greatly reduce the legal expense portion of costs and compensate many more individuals at a given level of expense, reduce provider liability insurance costs, reduce provider defensive behaviors, and improve quality of care. Such a system could generate more claims, process claims with greater ease, expand the standard for compensation to avoidability, and increase the success rate of claims, while the size of awards could fall. Investigators could not predict impact on physician supply (Mello & Kachalia, 2010).

Redress: 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 receive neither less than a lower compensation level nor more than a higher level. Jury awards outside of this range revert to the closer end of the 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 excessively burden insurers and the health system overall. This approach may be well suited to claims for neurologically impaired infants with large future predicted care expenses. It might encourage attorneys to accept cases that they would otherwise forgo (Crane, 2011).

Discussion

This investigation identified numerous promising strategies for improving liability matters across multiple aims within maternity care. These warrant piloting and evaluation at appropriate state, health system, or other levels. Health care systems, liability insurers, and state agencies can lead voluntary experimentation. Some interventions require legislative or regulatory action, continued reorganization of health care, or the development of new infrastructure.

The Agency for Healthcare Research and Quality (2010) is funding several maternity-related pilots under Medical Liability Reform and Patient Safety Demonstration Projects and Planning grants. These include projects to test the relationship between safety and liability, reliably provide evidence-based intrapartum care and improve the handling of adverse events, implement a program of both negotiation and early disclosure and settlement, consider the impact of improved teamwork on liability, and implement a statewide pregnancy-associated mortality review and develop safety recommendations (see also Langel, 2010).

Implementing rigorous QI programs within hospitals and health systems has great potential to improve overall care and lead to plummeting claims, payouts, and liability insurance premiums. This win–win–win preventive approach for patients, providers, and payers should become standard maternity care practice. Leaders can move forward on this leading prevention strategy and on the most promising redress strategy—disclosure, apology, and early offer as appropriate—without the need for new legislation, regulation, or intfrastructure. We have identified five other promising approaches to preventing harm and three other promising approaches to assisting those with injuries. Effective approaches to prevention and redress are both needed. The 10 approaches discussed here offer policy makers a broad range of options for implementation, evaluation, refinement, and—as appropriate—spread.

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