

A. Specific Aims

The New York State Unified Court System's Office of Court Administration, New York State Department of Health, and five academic medical centers, Beth Israel Medical Center, Maimonides Medical Center, Montefiore Medical Center, Mount Sinai Medical Center, and New York Presbyterian Hospital - Columbia Presbyterian Center, have developed the following goals and objectives for the proposed *New York State Medical Liability Reform and Patient Safety Model* ("the NYS Model"). The NYS Model puts safety first and strives to reduce preventable injuries, improve doctor/patient communication, and ensure that patients receive fair and quick compensation for medical injuries, while also reducing the incidence of frivolous lawsuits and cost of insurance premiums. It is a comprehensive pilot that reforms the medical liability system. It builds on a recent New York court innovation - judge-directed negotiation - and incorporates evidence-based interventions, including a culture of safety and a Disclosure and Early Settlement program.

Goal 1: Develop a culture of patient safety

Obj. 1a: Establish/enhance a proactive approach to patient safety; Obj. 1b: Establish/enhance a process for creating patient safety initiatives when risks are identified through an adverse event; Obj. 1c: Obtain staff buy-in for culture of safety; Obj. 1d: Implement measures to promote culture of safety

Goal 2: Develop a hospital-wide environment that enables and promotes complete adverse events reporting

Obj. 2a: Establish/enhance an environment that promotes comprehensive reporting;

Obj. 2b: Obtain staff buy-in in complete adverse event reporting;

Obj. 2c: Implement an environment conducive to uncensored adverse event reporting

Goal 3: Create a Disclosure and Early Settlement Program for the OB and/or Surgery Departments

Obj. 3a: Establish/enhance a system to identify and report adverse events; Obj. 3b: Establish/enhance a Disclosure and Early Settlement process; Obj. 3c: Obtain staff buy-in and provide training for a Disclosure and Early Settlement Program; Obj. 3d: Implement Early Disclose and Settlement Program

Goal 4: Expand and enhance a Judge-Directed Negotiation Program

Obj. 4a: Select and train judges to participate in Program;

Obj. 4b: Establish process to direct claims to Program;

Obj. 4c: Implement Judge-Directed Negotiation Program

Goal 5: Demonstrate the effectiveness of the NYS Medical Liability Reform and Patient Safety Model

Obj. 5a: Evaluate program outcomes stemming from adverse events; Obj. 5b: Evaluate the Judge-Directed Negotiation Program process; Obj. 5c: Evaluate Disclosure and Early Settlement program; Obj. 5d: Evaluate effectiveness of proactive and responsive patient safety initiatives; Obj. 5e: Analyze Medical Malpractice Data Collection System (MMDCS), NYPORTS, and information from Judge-Directed Negotiation Program

Goal 6: Disseminate reports and lessons learned

Obj. 6a: Disseminate model reform reports statewide and nationally; Obj. 6b: Disseminate reports based on analyses of NYPORTS, MMDCS, and Judge-Directed Negotiation Program data statewide; Obj. 6c: Convene a one-day state-wide conference to report project progress and promote NYS Medical Liability Reform

Goal 7: Expand the NYS Medical Liability Reform and Patient Safety Model

Obj. 7a: Examine the potential for including additional hospital departments and additional hospitals in the NYS Model and begin expansion.

B. Background and Significance

B.1. Review of Literature

The 1999 release of the Institute of Medicine publication, "To Err is Human" brought heightened awareness of the high rate of medical errors and increased attention to ensuring patient safety. Since the publication of this landmark report, health care providers, government institutions, insurance companies, accrediting bodies, public advocacy groups, and other groups focused on health care quality have begun to collect and distribute patient safety data and develop and test various strategies for improvement. In addition to the impact on patients themselves, medical errors impose a substantial burden on other stakeholders, including governments, health insurers, hospitals, liability insurers, and the judicial system.

In the last decade, the number of medical malpractice claims (frequency) has remained fairly stable nationwide, while the size of payouts (severity) has continued to rise.^{1,2} Between 1992 and 2001, median trial awards in the nation's 75 most populous counties increased by 70.4%, from \$253,000 to \$431,000.³ The growth in severity is frequently cited as a leading contributor to rising health care costs.⁴ The State of New York leads the nation in the number of claims filed with the National Practitioner Data Bank⁵ and for the period September 1, 1990 through November 29, 2009, represented 13.6% of reports from all 50 states.

In 2006, Harvard researchers conducted a national study of 1,452 closed malpractice claims to determine the prevalence of frivolous claims - those not involving an injury due to medical error.⁶ Study results showed that in 37% of the closed malpractice cases there was no evidence of error; in 3% there were no verifiable medical injuries. Most of these claims went unpaid, although the administrative costs for defending these unsupported claims amounted to 13%-16% of the total monetary costs of the medical malpractice litigation system. Administrative costs associated with defending claims averaged \$52,521 per claim, with higher average costs for claims that went on to trial (\$112,968). Of the remaining 63%, those claims determined to be the result of medical errors, almost three-fourths received compensation, an average \$485,348. Thus, one in four claims associated with medical error was not awarded payment. Moreover, the time to resolve a claim from the time of injury to disposition averaged five years. Patient plaintiffs must wait years to achieve finality, and with no assurance of compensation, even if warranted.

Nationwide, reforms have focused on capping awards of non-economic damages, as caps offer a fairly direct and simple structural response to cost containment. In 2006, twenty-six states had caps limiting damages in some form⁷. New York State has not enacted caps. In 2009, 46 of 50 states proposed some form of medical liability legislation, including caps, establishment of patient compensation funds, establishment of medical review panels, or tax credits for medical practice premiums. Few were enacted into law.⁸

New York's medical malpractice system is widely considered to be broken. Medical malpractice rates in the state have risen steadily over much of the last decade. The Superintendent of Insurance approved a 14% increase in premiums in 2007 and subsequent rate freezes in 2008 and 2009. Without the freezes, malpractice rates had been projected to increase dramatically. Medical malpractice imposes burdens on the health care as well as the justice system. New York's hospitals have among the lowest operating margins in the country; every dollar that is spent on medical malpractice is taken away from patient care and directly impacts the hospitals' bottom line. Some hospitals in New York have been forced to consider drastic action. For example, in 2008, a Brooklyn hospital, citing high medical malpractice insurance rates, sought to shut down its Obstetrics unit.⁹ A number of state task forces in New York have struggled to

address the medical malpractice issue. Although they have not made significant progress in changing either the tort or insurance systems, they have helped to move the focus to patient safety. The most recent task force was convened by the governor in August 2007. Based on its work, legislation containing tort reform and patient safety initiatives was proposed in 2008 and 2009, but was not adopted. One positive consequence was the expansion to New York County of the judge-directed negotiation program for city hospitals, described below, which has been the foundation of this proposal.

Mello and Brennan identify three alternative medical liability reforms that may hold promise: 1) disclosure-and-offer programs; 2) administrative or specialized tribunals (“health courts”); and 3) creating a legal safe harbor to insulate physicians from liability if they adhere to evidence-based medical safety practices.¹⁰ Although several hospitals are pursuing early settlement approaches, none has been formally evaluated. Health courts are favored by the provider community and insurers, but are generally opposed by plaintiffs’ lawyers. Like safe harbor provisions, they cannot be instituted without legislation. The NYS Model offers the hope of dramatic change, but requires no legislation.

B.2. Significance

The proposed NYS Model takes two medical liability initiatives, a Disclosure and Early Settlement Program and a promising local project, judge-directed negotiations, and combines them into one comprehensive approach that addresses the related problems of high malpractice overhead and lengthy delays in adjudicating claims. At the same time, an evidence-based patient safety intervention will be implemented to create and maintain a culture of patient safety at five large academic medical centers in New York City and a customized process for identifying and implementing patient safety initiatives will be established in each hospital. Implementation of the NYS Model will be facilitated by the creation of two hospital-specific teams, a Patient Safety Team and a Disclosure and Early Settlement Team, that will enable collaboration among medical and risk management personnel.

The five hospital participants in the demonstration project, Beth Israel Medical Center, Maimonides Medical Center, Montefiore Medical Center, Mount Sinai Medical Center, and New York Presbyterian Hospital - Columbia Presbyterian Center, provide services to some of the most economically disadvantaged and medically underserved populations in the nation. Each has a well-established patient safety infrastructure and, most importantly, the engaged and motivated leadership needed to successfully implement the NYS Model and to influence other hospitals in the state to follow suit. New York serves as an excellent proving ground for significant liability reform given the high medical malpractice costs and the absence of tort reform. In light of the high patient volume, the depth of the challenge, and the state’s high visibility, the potential impact is enormous.

C. Preliminary Studies

C.1. Court Innovation

New York State's Office of Court Administration ("OCA") has attacked problem areas through unique and innovative approaches. Specialized courts for major business disputes were established in New York City and in Rochester with the support of the business community, and have been commended for encouraging settlements and more timely resolutions. The OCA's Office of Alternative Dispute Resolution and Court Improvement Programs has developed alternative court models that address the particular needs of the system's most vulnerable litigants. Initiatives include:

- Court-Connected Alternative Dispute Resolution Programs, offering training in mediation skills;
- Community Dispute Resolution Centers Program, partnering with local non-profit organizations that provide mediation, arbitration, group facilitation, and other dispute resolution options as an alternative to court;
- Child Welfare Court Improvement Project, supporting implementation of reforms in child welfare court practices. Begun in 1994 with federal grant funding, the program is now a standard component of OCA.
- Court Appointed Special Advocates Assistance Program, using trained community volunteers to provide Family Courts with independent child advocacy in abuse and neglect cases;
- Children's Centers Program – the nation's first, it provides a safe, supportive and cheerful haven for vulnerable children inside the courthouse and connects families to needed services; and
- Collaborative Family Law Center –opened in September 2009 as part of a larger initiative to reduce the pain and expense of divorce; also a national first.

C.2. Patient Safety

The primary mission of the NYS Department of Health (DOH) is to ensure the safety of patients who receive medical treatment in New York State. It has worked to establish collaborative relationships among all stakeholders, including the New York State legislature, local health care agencies, employee unions, hospital, patient and practitioner associations. Steady progress has been made in developing patient safety solutions that rely on collection and analysis of patient outcome data, dissemination and adoption of evidence-based clinical practices, and use of regulations, as warranted. DOH's accomplishments in the patient safety arena are highlighted below.

- In 1985, New York became the first state to institute a **mandatory** reporting system for hospital adverse events, the New York Patient Occurrence and Tracking System (NYPORTS).
- In 1989, New York became the first state to collect data, analyze, and report publicly on risk-adjusted mortality rates for coronary artery bypass surgery (CABG).
- In October 2000, the Governor signed the Patient Health Information and Quality Improvement Act, which called for the creation of a statewide health information system to collect data on providers and health plans and the establishment of the Patient Safety Center within DOH.
- The NYS DOH conducted biannual Patient Safety Conferences, beginning in 2005, in association with AHRQ and state and regional hospital associations. The first conference, *Working Together-Partnering for Patient Safety*, presented the results of the Department's AHRQ-funded demonstration projects.

- In February 2006, DOH convened a multidisciplinary committee to analyze cases of “wrong side” surgery reported to NYPORTS. The New York State Surgical and Invasive Procedure Protocol was established to prevent future occurrences. A DOH article was published on the AHRQ web site to disseminate the protocol.¹¹
- DOH convened a Medication Error Committee to analyze three years of medication error data (2003-2005) in the NYPORTS system and conduct root cause analysis. Case studies and findings were disseminated through statewide hospital training conducted in 2006 and 2007.
- New York State’s Governor signed landmark legislation in August 2008 to improve patient safety by: 1) improving the process for physician discipline for professional misconduct; 2) providing consumers with information about physician professional misconduct; and 3) improving infection control education and practices.
- DOH sought proposals in February 2009 to advance best practices in pharmaceutical safety; funds of \$4.5 million were awarded to 19 providers.

C.3. Medical Liability Reform

New York State has not enacted recent comprehensive reform. Despite this, there have been individual efforts to improve process and contain costs.

- In 1975, New York enacted a two and one half year statute of limitations on medical malpractice claims.
- Pursuant to New York Insurance Law §315, New York has mandated insurers to report all medical malpractice claims and dispositions, leading to the creation of one of the richest databases of its kind in the nation.
- In 1984, the New York State Department of Health funded the landmark “Harvard Study,” an interdisciplinary study of medical injury and malpractice litigation. Researchers were given access to the MMDCS and the Statewide Planning and Research Cooperative System (SPARCS) database of inpatient discharges and ambulatory surgical procedures, and to 30,000 patient charts. Researchers determined that adverse events occurred in 3.7% of hospitalizations and that 27.6% of adverse events were due to medical negligence.
- Beginning in the Bronx in approximately 2004, the Honorable Douglas McKeon pioneered a new approach for malpractice cases brought against New York City’s eleven public hospitals. The goal was to reduce the high transaction costs and the duration of these cases. The idea behind the approach was that a knowledgeable, specialized judge, working intensively with the parties from the beginning of the suit, can achieve settlements earlier, more effectively and more equitably. The approach has worked. The New York City Health and Hospitals Corporation (HHC) estimates that its annual medical malpractice costs have gone down by as much as \$50 million a year – from a high of almost \$200 million in 2003 - since the project’s inception. Its portfolio of pending lawsuits has declined from 1,400 in 2000 to just over 1,000 in 2009.

C.4. Team Qualifications

The project partners are: the applicant, the New York State Office of Court Administration; the New York State Department of Health; and five hospital demonstration sites in New York City – Beth Israel Medical Center, Maimonides Medical Center, Montefiore Medical Center, Mount Sinai Medical Center, and New York Presbyterian Hospital - Columbia Presbyterian Center.

The lead agency, the **NYS Office of Court Administration (OCA)**, is the administrative arm of the New York State Unified Court System, and is responsible for supervising the administration and operation of the state’s trial courts, which are divided into 13 Judicial Districts and four

Judicial Departments. OCA's Office of Alternative Dispute Resolution and Court Improvement Programs has provided vulnerable participants in the legal system with alternatives to traditional dispute resolution. It has been aided in these efforts by the Center for Court Innovation, a public-private partnership between the New York State Unified Court System and the Fund for the City of New York, which will be a sub-contractor on this project as well. OCA will provide the services of its Division of Grants & Program Development, which administers grant programs in which the court system participates.

The **New York State Department of Health (DOH)** is the state's regulatory governmental body with overall responsibility for protecting the public health of over 19.5 million New Yorkers. Two offices within the Department of Health are collaborating on this demonstration project – the Office of Health Systems Management (OHSM) and the Office of General Counsel (see attached organizational chart). OHSM is responsible for the regulation and oversight of all licensed health care facilities in New York State, the certificate of need process for these entities, and physician misconduct. New York State's \$47.3 billion Medicaid budget is the most expensive in the country. It enrolls over 4 million residents, and covers 50% of all state births and a higher percentage in New York City. The Office of General Counsel, in the Division of Legal Affairs, oversees all the Department's legal activities.

Key members of the Project Management Team for the demonstration project are the Principal Investigator, **Judge Judy Harris Kluger, JD**, Chief of Policy and Planning for New York State Courts; **Judge Ann Pfau**, Chief Administrative Judge of the State of New York, OCA; **Michael Rempel**, Director of Research, Center of Court Innovation; **Janet Cohn, JD**, Deputy General Counsel, DOH; **John Morley, MD**, Medical Director, OHSM, DOH; **Lora Lefebvre, MPA**, Assistant Director, OHSM, DOH; and **Michelle Mello, JD, Ph.D.**, Professor of Law and Public Health, Harvard School of Public Health. Dr. Mello will also oversee and conduct the Evaluation component.

The **Honorable Judy Harris Kluger**, who will serve as the project's Principal Investigator, has over 30 years of legal experience, including 20 years as a judge in the New York State Unified Court System. For the majority of her career as a judge, Judge Kluger presided over the Criminal Court of the City of New York. Since 2003, she has focused on the court operations and planning. In the role of Deputy Chief Administrative Judge for Court Operations and Planning, Judge Kluger initially oversaw the statewide implementation of Integrated Domestic Violence Courts based on a one-family, one-judge model. In 2004, she took over administration of New York State's Drug Treatment Courts, which present an alternative to incarceration of non-violent, drug-addicted defendants. In 2009, Chief Judge Jonathan Lippman appointed Judge Kluger Chief of Policy and Planning. Judge Kluger works with judges statewide to study and develop new strategies to improve the delivery of justice in New York State. Under her leadership, problem-solving courts have proliferated in the state, with nearly 300 operational and more in the planning stages. Problem-solving courts have been established to improve outcomes for specialized cases and include drug and mental health courts; youth courts; community courts; and courts that address sex offenses and domestic violence. Other key participants from OCA include **Judge Ann Pfau, JD**, and **Michael Rempel** of the Center for Court Innovation. The Honorable Ann Pfau was appointed as a judge to the New York City Civil Court in 1997; she was elevated to her current position as Chief Administrative Judge for New York in 2007. Michael Rempel is currently Principal Investigator of a statewide evaluation including more than 80 adult drug courts in New York funded by the Bureau of Justice Assistance.

Representing the New York State Department of Health in the development and implementation of the NYS Model are **Janet Cohn, JD**, Deputy General Counsel; **John Morley, MD**, Medical Director, OHSM; and **Lora Lefebvre, MPA**, Assistant Director, OHSM. Ms. Cohn co-directs the activities of five bureaus within the Division of Legal Affairs, including the Bureau of Professional Medical Conduct, and shares responsibility with Ms. Lefebvre for the Department's efforts to address medical malpractice. She led the Department's participation in the Governor's 2007 Task Force on Medical Professional Liability. Dr. Morley chairs the Office-Based Surgery Implementation Committee and serves as an advisor to the following initiatives: Stoke Center designation, web-based profiles, hospital profiles, and the Cardiac Advisory Committee. Dr. Morley leads the Department's patient safety effort. Ms. Lefebvre assists in the direction of the Department's fiscal, legislative and policy efforts for the Medicaid program, capital initiatives, and medical malpractice.

Michelle M. Mello, JD, PhD, MPhil, Professor of Law and Public Health at the Harvard School of Public Health, is one of the nation's leading academic researchers in the fields of medical malpractice and patient safety. Dr. Mello is dually trained in law and health policy and specializes in empirical investigations of the performance of the medical liability system. Among her current projects is a study of six leading institutional programs to promote disclosure and early compensation of medical injuries, funded by a Health Policy Investigator Award from the Robert Wood Johnson Foundation. She has previously served as a consultant to the New York State Task Force on Medical Liability Reform and is familiar with the State's closed claims database. She has conducted evaluations of a range of medical injury compensation systems in the U.S. and foreign countries, and her previous work also includes case-level analyses of closed malpractice claims for purposes of studying medical injury causation and prevention.

The Project Management Team consists of a diverse group of professionals with expertise in all project components: patient safety, medical malpractice law, court improvement programs, legal training, and medical malpractice insurance. All team members have participated in planning the proposed patient safety or medical malpractice interventions, are eager to participate on the Project Management Team, and have received support from their respective organizations to dedicate the necessary time and resources to accomplish the project goals. Attached are letters of commitment and support from the participating organizations.

D. Research Design and Methods

D.1. Summary of Approach

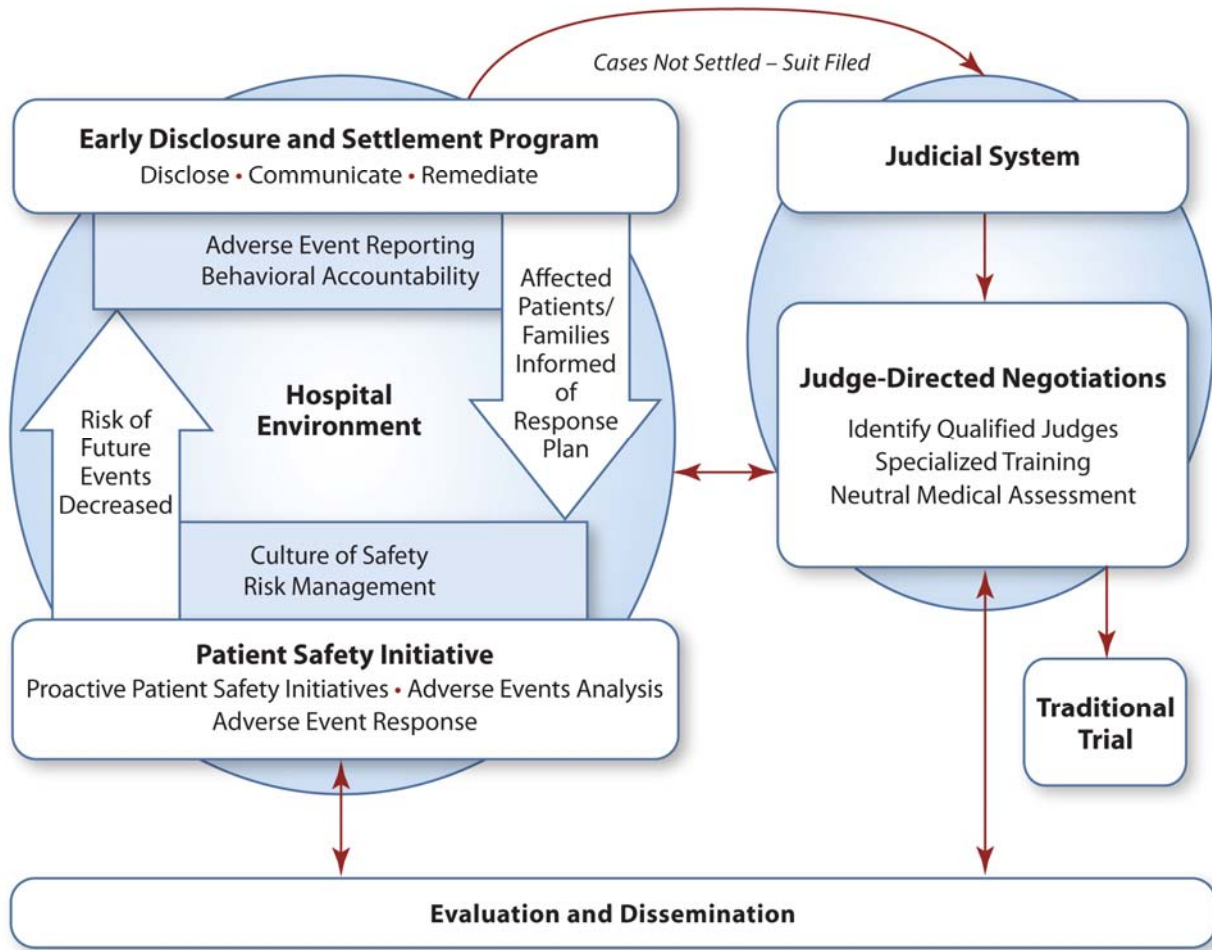
The New York State Unified Court System's Office of Court Administration (OCA), the New York State Department of Health (DOH), and five academic medical centers in New York City (Beth Israel Medical Center, Mount Sinai Medical Center, Maimonides Medical Center, Montefiore Medical Center ("the FOJP hospitals"), and New York Presbyterian Hospital - Columbia Presbyterian Center) will collaborate to implement the New York State Medical Liability Reform and Patient Safety Model ("the NYS Model"). Other stakeholders will participate in the dissemination of the project results and consideration of opportunities for model replication, including the Center for Court Innovation, the New York State Insurance Department, the Greater New York Hospital Association (GNYHA), the Healthcare Association of New York State (HANYS), the Medical Society of the State of New York (MSSNY), and the New York branch of the American College of Obstetricians and Gynecologists (ACOG).

As shown in the graphic below, the NYS Model is comprised of three main components: (1) initiatives to promote a culture of patient safety, (2) an Early Disclosure and Settlement program, and (3) a judge-directed settlement negotiation process for malpractice claims not resolved through early settlement. Each of these three components will be analyzed to identify patient safety initiatives. These three components will interact to inform each other as patient safety initiatives are identified in response to adverse events and closed claims, while prioritizing patient safety and responsible clinical behavior by altering the hospital culture and creating proactive patient safety initiatives. A Project Management Team, consisting of representatives from each of the project participants, will function to connect the three project components and provide a platform for distributing data and assessing work plan performance.

The complete NYS Model will be implemented hospital-wide at each hospital, except for the Disclosure and Early Settlement program, which will begin in at least one department at each facility. Specific clinical interventions will be implemented in the same department(s). To enhance generalizability, Beth Israel and Mount Sinai Medical Centers (Manhattan), Maimonides Medical Center (Brooklyn), and Montefiore Medical Center (Bronx) will implement these components in their Surgery and/or in their Obstetrics and Gynecology ("OB") departments, while New York Presbyterian Hospital - Columbia Presbyterian Center in Manhattan will implement them in its Surgery department alone. The hospitals chose to focus on the OB and Surgery departments after internal review of liability claims and payouts. The clinical events that triggered the largest payouts were related to obstetrical services, mirroring the national experience, followed by General Surgery. General Surgery had greater frequency of claims.

Implementation of the NYS Model will be led by two sets of hospital-specific teams. Each hospital will assemble a Patient Safety Team and a Disclosure and Early Settlement Team. The Patient Safety Team will build on the existing patient safety infrastructure established at each of the participating hospitals and include clinicians, administrators, risk management staff, and one partially grant-funded patient safety resource. The Disclosure and Early Settlement Team will include the hospital's counsel, risk management, and representatives from nursing and the medical staff. Team members will serve as a resource to health providers and to patients and their families following an adverse event.

Medical Liability Reform and Patient Safety – NYS Office of Court Administration



OCA will implement the Judge-Directed Negotiation Program in three administratively distinct counties, Bronx, New York (Manhattan), and Kings (Brooklyn), to handle all medical malpractice claims filed against the participant hospitals that do not settle before filing. The program was modeled after an existing program developed by the Honorable Douglas McKeon, Supreme Court Justice in Bronx County and Presiding Justice of the Appellate Term, First Department, in conjunction with the New York City Health and Hospital Corporation (HHC), which oversees New York City’s 11 public hospitals. McKeon’s aggressive settlement approach has yielded speedier dispositions and lower transaction costs, while assuring fair compensation for injured patients and their families. HHC reports that it has reduced its number of open claims from 1,400 to just over 1,000 and has achieved savings in medical malpractice expense of up to \$50 million annually since the inception of its work with Judge McKeon.¹² In the demonstration project, participating judges will receive formal training following a curriculum developed as part of this project, and all lawsuits against one of the five participating hospitals will be directed to a participating judge immediately upon filing.

The NYS Model is a comprehensive program, incorporating New York’s unique approach to medical malpractice litigation reform while prioritizing patient safety and patient-provider communication. Importantly, it requires no legislative action to proceed. Components of the

NYS Model, such as culture of safety and robust event reporting, have been undertaken within New York State hospitals, and other components have been implemented in other states (e.g., University of Michigan Health System's early settlement model¹³). New York has not yet made significant headway reforming the medical liability system. The NYS Model, if successful, will demonstrate that hospitals, with support from the state, the legal community and the judiciary, can advance medical liability reform without legislation while remaining true to their mission to serve their patients and do no harm.

D.2. Promoting a Culture of Patient Safety

The Hospital Patient Safety Team will promote a culture of safety within the hospital where systems, rather than individuals, are the primary focus of process improvements. The culture of safety is intended to support and enable the identification of processes that contribute to errors and near misses through analyses such as root cause analysis, process mapping, failure mode and effects analysis, probabilistic risk assessment, and sociotechnical probabilistic risk assessment; make changes to improve the processes; and prevent identified errors from repeating. Following this, patient safety initiatives will be developed and implemented. DOH, in collaboration with hospital and physician associations, will assist in identifying emerging best practices by reviewing recently published literature and other sources. DOH will also analyze medical malpractice data collected in the department's Medical Malpractice Data Collection System (MMDCS), cross-reference with other reporting databases, and recommend new, proactive patient safety measures to the hospitals. Each hospital has identified an initial proactive patient safety initiative to implement as part of the NYS Model.

Adverse Event Reporting

Each participating hospital has a robust safety program and performance improvement team already in place that reviews adverse events identified through data software filters or event reporting. To promote comprehensive adverse event reporting and bring performance improvement activities to the next level, each hospital will undertake a review of its current level of reporting across clinical departments and take steps to enhance reporting. Training curricula will be developed and disseminated. A campaign to constantly reinforce the duty to report will be undertaken and systems put in place to make reporting easier and less threatening to the reporter. The hospitals will establish a program to communicate to its staff that the outcomes themselves will not be addressed punitively, but will be analyzed for the reasonableness of the care provided under all the circumstances. Behaviors, not outcomes, will be the target of any corrective actions.

Proactive Patient Safety Initiatives

Using hospital-specific adverse outcomes indices, liability claims, and national trends in medical malpractice suits, the Patient Safety Teams will undertake specific clinical interventions. For example, FOJP member hospitals have jointly identified adverse events in their Obstetrics departments as their greatest risk and will implement two evidence-based, team-oriented interventions: clinical team training to foster better communication. (TeamSTEPPS™)¹⁴ and simulation-based obstetrical training to reduce the risk of preventable injuries. The FOJP institutions have already embarked on team training, bringing in Dr. Michael Leonard, a physician leader in patient safety, for on-site consultations. Through the demonstration project, they will adopt the more rigorous approach utilized in TeamSTEPPS™. TeamSTEPPS™ (Team Strategies and Tools to Enhance Performance and Patient Safety) has been endorsed as the national model for team training in health care by AHRQ and the Department of Defense.¹⁵ The use of simulation training to improve physician performance for such unanticipated events as shoulder dystocia hemorrhage has been shown to be effective. The hospitals will also employ simulation training to target maternal hemorrhage, as well as other poor outcomes.^{16,17}

D.3. Disclosure and Early Settlement Program

The Disclosure and Early Settlement program will build on the successful program developed by the University of Michigan Health System,¹⁸ and Michigan's Chief Risk Officer, Rick Boothman, JD, will serve as a project consultant to guide the model design and advise the participating hospitals on implementation strategies. The Disclosure and Early Settlement Team, comprised of hospital risk managers, clinicians, and administrators, will implement the following process for responding to reports of adverse events: (1) support clinicians and/or risk management staff in making prompt disclosures of injuries to patients and families; (2) provide immediate assistance to families (such as lodging and other services for family members) in the aftermath of the event; (3) conduct a rapid investigation into whether the standard of care was met during the patient's care; (4) when the standard of care was not met, explain the results of the investigation and offer fair compensation, when indicated to settle the incident; (5) when the standard of care was met, explain this to families and indicate that the institution will vigorously defend the involved clinicians; and (6) extract patient safety lessons from incidents investigated. The aims of this approach are to practice transparency, alter the adversarial dynamic between providers and patients at a time that cooperation is critical, achieve quicker dispute resolution, reduce the number of lawsuits filed, and allow providers to review adverse events with an open mind so they can learn from experience and prevent recurrences.

The Disclosure and Early Settlement team will be assembled by each hospital administrator based on recommendations of the Project Management Team. Specific duties of the Team will include the following:

- Convening key decision makers and stakeholders within each institution to consider how to incorporate the "lessons learned" from the Michigan model at their institution and what, if any, adaptations should be made to maximize impact in the local environment. Key questions to be addressed include, for example: Should the institutions develop lists of adverse events that will presumptively be considered compensable, such as the National Quality Forum's "Never Events" list? How will internal and external medical experts be used in the event investigation process? Should compensation offers be made in cases in which the standard of care was met, but the investigation team concludes that some aspect of the care was less than optimal? Should representatives of the hospital's insurer be present during disclosure conversations? Will payments made under this program necessitate reports to the National Practitioner Data Bank, state closed claims database, or regulatory bodies?
- Developing a set of policies and procedures describing the final model and implementation plan. These will be set forth in a Program Manual for use by the Disclosure and Early Settlement Team and hospital- and insurer- based risk managers.
- Designing and implementing a training curriculum for clinical staff, risk managers, and others at the institution. The main thrust of the curriculum will be disclosure and communication training. However, presentations and written informational materials will also be developed to educate clinical staff about the new early settlement model to be used by the institution's insurer and encourage prompt reporting of adverse events to the Disclosure and Early Settlement team.
- Serving as the investigative body that responds to each reported adverse event. The team will be responsible for ensuring seamless response to each event on a designated timeline, from the initial report, to the assignment of cases to lead investigators, to the preparation of investigation findings.
- Coordinating the body that determines whether the standard of care has been met in a case and what compensation, if any, should be offered. The composition of this body will vary from institution to institution depending on factors such as the relationship between the

hospital and the insurer and who has authority to settle claims of various amounts. However, in all institutions, it will include experienced risk managers and physicians in the relevant clinical specialties. It may be structured as a standing committee that meets regularly or as an ad hoc response team that is assembled (in varying configurations) and convened following each adverse event.

- Analyzing the institution's closed claims to identify potential areas for patient safety improvement. This will include both a case-level analysis of each closed incident and macro-level analysis to be conducted periodically of all new, open, and closed claims. Reports will be compiled concerning (1) clear areas for clinical process improvement; and (2) high-loss clinical areas and high-severity injuries, even where no process improvements are obvious to the Disclosure and Early Settlement team.
- Providing regular reports to the Patient Safety Team concerning priority areas for patient safety interventions. The particular content and format of reports will be determined by each institution, but will include periodic joint, in-person meetings during which data from the Disclosure and Early Settlement process are shared and action plans and next steps for patient safety improvement are identified.
- Collecting and recording the necessary data for the evaluation of the Disclosure and Early Settlement program. The evaluation plan is described below.

Based on existing patient volume and the number of adverse events in the participating hospital departments, the number of patient cases that will be handled by the Disclosure and Early Settlement Team(s) is estimated to be about 100 per year.

D.4. Judge-Directed Negotiation Program

It is anticipated that the Disclosure and Early Settlement program will reduce the number of malpractice claims filed by offering a fair settlement before the patient presents a demand for payment. However, some incidents can be expected to proceed to litigation—for example, because the institution and the patient/family disagree about whether the standard of care was met or about the appropriate amount of compensation. The Judge-Directed Negotiation program will be triggered by the filing of a malpractice suit against one of the participating hospitals.

All medical malpractice suits filed against participating hospitals will be assigned to one of judges in the Judge-Directed Negotiation program, who will be assisted by a dedicated Medical Advisor/Program Coordinator funded by the demonstration project, ideally a registered nurse with a law degree. Cases will remain under the supervision of the assigned judge from the first time the parties appear before the court. Judges will follow a case management protocol that calls for them to convene regular meetings with representatives of the litigants for purposes of considering and encouraging settlement. The meetings will begin very early in the litigation, before attorneys develop a strong sense of personal investment in the case. Lawyers and other party representatives must appear at the meetings with full knowledge of the case and the authority to settle. In contrast, in the current system representatives frequently do not have authority to settle, meaning that they must always go back and consult the litigants before agreeing to a proposed settlement. Momentum for settlement is often lost in this process, particularly since the litigants themselves do not attend the settlement conferences and hear the judge's views on the case.

Participating judges will be trained in negotiation and mediation skills. The curriculum for judges will be developed by OCA staff with input from Judge McKeon, the Medical Society of the State of New York and other physician associations, and specialists in mediation and negotiation.¹⁹ It

will include both initial training and continuing education. Participating judges will receive training in: (1) fundamental principles of patient safety, such as the concepts of human factors (e.g., systems failures, individual lapses), and key findings of research about patients' needs following adverse events; (2) "medicine for judges," including medical terminology and concepts, with specific emphasis on common malpractice fact patterns; (3) mediation and negotiation techniques; and 4) fashioning case-specific alternative remedies. Components (3) and (4) will be based in part on Judge McKeon's successful techniques. Examples of these techniques include the following:

- Based on the case filings and initial conversations with the parties, classify cases into those that are particularly ripe for early settlement and those where substantial barriers to settlement exist; adjust the approach to settlement negotiations accordingly. Cases in which there is no dispute that there has been a departure from the standard of care, only about the appropriate amount of damages, warrant aggressive, judge-led settlement negotiations early on, before the laborious and expensive discovery process even takes place.
- Based on the progress of early settlement meetings and knowledge of the involved parties and their attitudes toward settlement, consider whether joint settlement conferences or private meetings with each side would best facilitate resolution of the case. An advantage of routing all malpractice claims involving the participating hospitals to a small number of judges is that judges, defense attorneys, and plaintiff attorneys become "repeat players" who are well known to one another. Judge McKeon's experience is that the iterative nature of the process gives the parties incentives to cooperate and builds trust between each party and the judge over time.
- Vigorously safeguard the confidences of each party regarding their willingness to settle. Over time, parties learn that they can entrust the judge with their "bottom line," arming the judge with the critical information necessary to move the parties toward settlement.
- Consider whether meetings with the litigants themselves (rather than only attorneys) would facilitate dispute resolution. Judge McKeon has had success meeting alone with families and patients or with providers (and their lawyers) -- after getting consent from the opposing party -- a technique that goes counter to standard courtroom process.
- Without betraying confidences made by either party, offer a frank assessment of the merits and weaknesses of their case, where it is within the judge's competence to do so and where it may help litigants evaluate the prospects for their case to succeed before a jury.
- Determine whether alternative remedies might be of interest to plaintiffs and defendants. For example, financial compensation could be complemented by an institutional commitment to undertake defined corrective actions to prevent recurrence of the error.

Periodically Judge McKeon will observe proceedings conducted by participating judges to review their technique and meet with them individually to assess results and make suggestions for improvement. Judge McKeon will report his findings regularly to Judge Kluger so that appropriate support can be provided when needed.

To enable them to evaluate the medical issues in a case in an informed way without having to rely on expert witnesses hired by the parties, who are not only partisan in their perspective but also may not submit reports until months into the litigation, judges will be supported by the neutral Medical Advisor/Program Coordinator. His/her role will be to:

(1) Research legal and clinical issues raised in the initial case filings, educate the judge on these issues, and independently assess the likelihood that the standard of care was violated, causing injury.

(2) Serve as a liaison to DOH with respect to medical findings. Cases in which a deviation from the standard of care appears likely (in the Medical Advisor/Program Coordinator's opinion or based on the outcome of the case) will be summarized (after deidentification) and forwarded to patient safety staff at DOH for analysis.

(3) Collect program data for purposes of evaluating the demonstration project. Information about the injury, litigants, and case disposition will be abstracted for each case, as described in the evaluation plan below.

A critical aspect of this Program is judge selection. Based on their knowledge of the judge pool in New York, Judge Pfau and Judge Kluger will identify, approach, and appoint the most qualified and committed judges to participate in the demonstration project, through a formal search and selection process to be coordinated by OCA. Currently, three judges adjudicate cases involving HHC hospitals. Discussions with HHC have helped to define requisite traits and characteristics, which include the judge's ability to: (1) modify his or her role from that of a distant decision-maker to an engaged negotiator; (2) develop expertise in applicable medical concepts; and (3) convey open-mindedness, neutrality, and the ability to listen and learn.

Approximately 700 lawsuits are filed against the participating hospitals in an average year; starting in Year One of the grant, all these will be directed to the Judge-Directed Negotiation Program.

D.5. Approach to Dissemination

The project's approach to dissemination is comprehensive, involving all stakeholders. It will provide multiple opportunities to disseminate the project results internally within each participating organization; across organizations; to the medical, legal, and policymaking communities on a regional, state, and national level; and to the general public.

Within each participating hospital, reports and recommendations will largely flow from three sources: the Project Safety Team, the Disclosure and Early Settlement Team, and department medical leadership (OB/GYN and/or Surgery). The Patient Safety and Disclosure and Early Settlement teams will develop a formal protocol for sharing results of their respective project components. Both teams will be responsible for providing periodic project updates and reports to relevant hospital departments, including legal counsel, risk management, patient safety, medical staff, and others. Departments participating in the proactive patient safety demonstration (i.e., OB/GYN, General Surgery) will share project information and invite physician feedback at departmental staff meetings and through presentations at Grand Rounds and at other forums within the hospitals.

All reports generated from the project will be disseminated statewide through the medical associations, including the Greater New York Hospital Association (GNYHA), Healthcare Association of New York State (HANYS), Medical Society of the State of New York (MSSNY), ACOG and the Perinatal Safety Collaborative sponsored by the GNYHA and the United Hospital Fund; and legal organizations, such as the New York State Trial Lawyers Association (NYSTLA) and the New York State Bar Association (NYSBA). Reports will also be publicly available on the DOH website, as appropriate, and project updates will be included in periodic letters from the Commissioner of Health to providers across the state. Specifically, DOH and OCA will create and disseminate reports detailing implementation barriers, solutions, and "lessons learned" for each component of the NYS Model. OCA will produce judge training modules on medicine for judges, and mediation and negotiation skills.

DOH will convene a one-day, statewide conference in 2012 to present the NYS Model and to review preliminary evaluation results, lessons learned, and options for adaptation by other hospitals. The conference will be recorded and available on the DOH's website and on CD.

OCA and DOH will report results to state policymakers. Legal reform coalitions and advocacy organizations, such as Common Good, the New York State Health Foundation and the New York State Bar Association, will also be included as part of the dissemination effort.

Harvard University School of Public Health will assist with dissemination within the scientific community. Michelle Mello, JD, PhD, Professor of Law and Public Health at Harvard, has broad contacts within the relevant community and will help publicize the New York experience through presentations and scholarly publications.

Finally, grant project reports that are filed with the Agency for Healthcare Research and Quality (AHRQ) will also be an important dissemination tool. The project investigators intend to submit the NYS Model to AHRQ for inclusion as a safety tool on their website. This will allow best practices implemented during the project to effectively reach a national audience of health care providers interested in patient safety and medical liability reform and allow all or part of the project components to be replicated by other institutions.

D.6. Evaluation Plan

Each component of the NYS Medical Liability Reform and Patient Safety Model will be formally evaluated. The Project Management Team will be responsible for coordinating the evaluation effort, utilizing the results to reach the project's objectives, and synthesizing the component evaluations. Leadership of and methods for each of the component evaluations are described below.

D.6.1. *Culture of Patient Safety Evaluation*

Each hospital will evaluate the culture of patient safety before and after implementation of the NYS Model using the AHRQ *Hospital Survey on Patient Safety Culture*²⁰ (see Appendix). The survey will be administered by each hospital's Patient Safety Team to all clinical staff to help assess the hospital's efforts. Survey results will be compared to national benchmarks from the current year's *Hospital Survey on Patient Safety Culture: Comparative Database Report*.

Each hospital's Patient Safety Team will evaluate the specific clinical interventions implemented in the institution to improve patient safety. The Team will define specific outcomes for each clinical initiative at the time of implementation and implement a process for monitoring those outcomes. Evaluation results will be analyzed to assess risk of particular adverse events, set thresholds for team intervention, identify team priorities, and develop appropriate response strategies. Evaluation metrics will include, among others: number of providers trained, success rates on simulators, response time on simulation drills, birth trauma rates, and number of adverse events referred to risk management

D.6.2. *Disclosure and Early Settlement Program Evaluation*

The Disclosure and Early Settlement Program evaluation will be led by Michelle Mello and research staff at the Harvard School of Public Health. The evaluation will proceed in 5 phases.

Phase I: Development of evaluation metrics. Dr. Mello will develop a list of evaluation metrics for each hospital in consultation with the other members of the Project Management Team, leadership of the 5 participating hospitals, and Dr. Mark Callahan, Senior Vice President and Chief Medical Officer for FOJP Services Corporation, Inc., risk management advisor for 4 of the

hospitals. Ideally, the list of metrics will be standardized across hospitals and insurers. However, differences in routine data-collection processes, extant database capabilities, willingness to collect new data fields, and willingness to share sensitive malpractice claims data across institutions may lead to some variations in the set of data fields collected. Preliminarily, the following potential metrics have been identified:

- Number of incidents reported to insurer by clinicians
- Proportion of reported incidents resolved without a claim being filed
- Proportion of reported incidents resolved without plaintiff attorney involvement
- Number of new claims filed
- Proportion of claims resolved without payment
- Proportion of claims settled
- Median and mean settlements
- Loss adjustment expenses
- Proportion of claims progressing to trial
- Time to disposition of claim (dismissal, abandonment, settlement, or verdict)
- Number of open claims
- Horizontal equity in compensation (extent of variance in payments for injuries with same severity)
- Vertical equity in compensation (degree to which more severe injuries receive greater compensation)
- Total hospital losses
- Malpractice insurance premiums in OB and General Surgery
- Patient safety interventions identified through claims data analysis

Phase II: Development of database. These metrics will be evaluated through collection of case-level data on each adverse event reported to the program. In addition to information regarding the handling and disposition of the case, data will be collected on the nature of the injury, the involved clinicians, findings concerning factors leading to the injury, and findings concerning possible corrective action to prevent injury recurrence in the institution. An Access Database will be developed for data entry at each institution. The data entry fields will be customized for each institution, but the database will be designed to facilitate data merges across institution. The database will reside on each institution's internal network so that it is accessible by all institutional claims managers and designated members of the Disclosure and Early Settlement Team.

Phase III: Data collection. Data will be collected and entered into the database by designated individuals within the Disclosure and Early Settlement Team at each hospital (and, where the insurer is organizationally separate, the hospital's insurer). We anticipate that the designated individuals are likely to be the lead risk manager or insurer claims manager assigned to investigate the adverse event; therefore, we anticipate training multiple individuals at each institution on the data entry protocol. Dr. Mello will train each of the designated individuals in the data entry protocol, and each will be assisted by a written data entry manual. The leader of the Disclosure and Early Settlement Team will be responsible for conducting monthly data quality checks to identify and locate missing data and ensure consistency in data entry across the designated individuals. In addition to the case-level, prospective data collection, which will begin at the time of implementation of the Disclosure and Early Settlement program, there will be a baseline measurement of the institution-level evaluation metrics (e.g., number of open malpractice claims, total losses) for the past 3 years to facilitate comparison to the post-intervention data. Information on malpractice insurance premiums and patient safety initiatives will be collected separately.

Phase IV: Data analysis. Data analysis will be conducted at Harvard. Individual case records will be stripped of identifying information before being sent to Harvard. Dr. Mello and the Harvard staff will merge the institutional databases and conduct descriptive analyses of the data metrics by year. Pre/post analyses will be performed using t-tests, chi-squared tests, and stratified analyses to the extent possible. Because the sample sizes of incidents cannot be estimated with precision at the outset of the demonstration, decisions about stratified analyses will be made after Year 1. Differences in the amount of change in the key metrics over time across institutions will also be examined.

Phase V: Feedback, interpretation, and reporting of findings. Findings for each institution will be presented to institutional leadership for review and comment. Interim reports will be made at the end of Years 1 and 2, with a final, cumulative report presented at the end of Year 3. The cumulative results for all institutions will be written up in the final project report and scholarly publications. Variations in results across institutions will be reported, but individual institutions will not be identified by name.

D.6.3. Judge-Directed Negotiation Evaluation

The Judge-Directed Negotiation evaluation will be led by Michelle Mello and research staff at the Harvard School of Public Health. The evaluation will proceed in 5 phases.

Phase I: Development of evaluation metrics. Dr. Mello will develop a list of evaluation metrics for each hospital in consultation with the other members of the Project Management Team, OCA, and representatives from the hospitals' insurers.

Preliminarily, the following potential metrics have been identified:

- Number of claims handled
- Mean, median, minimum, and maximum number of settlement meetings held
- Proportion of claims dropped, dismissed, or settled for zero dollars
- For settlements, the mean, median, 25th percentile and 75th percentile indemnity payment
- For verdicts, the mean, median, 25th percentile and 75th percentile indemnity payment
- Proportion of claims settled
- Proportion of claims tried
- Mean, median, 25th percentile, and 75th percentile time to disposition
- Horizontal equity in compensation (extent of variance in payments for injuries with same severity)
- Vertical equity in compensation (degree to which more severe injuries receive greater compensation)
- Litigant satisfaction with the settlement negotiation process.

Phase II: Development of database. Except for satisfaction, these metrics will be evaluated through collection of case-level data on each case referred to the program. In addition to information regarding the settlement negotiation meetings convened and the disposition of the case, data will be collected on the nature of the allegations in the case, the involved clinicians and facility, findings concerning factors leading to the injury, findings concerning whether a deviation from the standard of care occurred; and findings concerning possible corrective action to prevent injury recurrence. An electronic database will be developed by OCA for purposes of this data collection.

Phase III: Data collection. The Center for Court Innovation will be responsible for data collection and performing quality checks. The Medical Advisor/Program Manager will have lead responsibility for data collection and entry. In addition to the case-level, prospective data

collection, which will begin at the time of implementation of the Judge-Directed Negotiation program, there will be a baseline measurement of the institution-level evaluation metrics for the past 3 years to facilitate comparison to the post-intervention data.

Litigant satisfaction will be assessed through a structured survey administered to one attorney representative from each side of each case, along with one plaintiff and one defendant (for cases against a physician and a hospital, both will be surveyed). The survey will be administered by mail by OCA, with telephone follow up. The instrument will be designed to be completed in 10 minutes or less and will cover satisfaction with both the negotiation meetings and the ultimate resolution of the case. Topics and concepts to be covered include procedural fairness; fairness of the outcome, including compensation received; perceptions of timeliness and efficiency of the process; perceptions of the skill and knowledge of the judge; and changes in attitudes about the likelihood of achieving settlement over the course of the process. Surveys will be assigned an identifier number that permits data to be linked to the administrative data collected about the case.

Phase IV: Data analysis. Data analysis will be conducted at Harvard. Individual case records will be stripped of identifying information before being sent to Harvard. Dr. Mello and the Harvard staff will conduct descriptive analyses of the data metrics by year. Pre/post analyses will be performed using t-tests, chi-squared tests, and stratified analyses to the extent possible. Because the number of cases cannot be estimated with precision at the outset of the demonstration, decisions about stratified analyses will be made after Year 1. Sample size permitting, multivariate regression modeling will be used to identify characteristics of claims settled compared to those that proceeded to trial.

Survey data will be analyzed with univariate descriptive statistics. Bivariate comparisons will also be performed by defendant institution, plaintiff characteristics, time to case disposition, whether the case settled before trial, and whether compensation was paid to the plaintiff.

Phase V: Feedback, interpretation, and reporting of findings. Findings will be presented to the leadership and insurers of the participating hospitals and at end of each year of the project. The cumulative results will be written up in the final project report and scholarly publications.

D.7. Likelihood of Success

The issue of medical liability reform in New York State has been particularly difficult for all stakeholders. As a consequence, there is a strong desire to find solutions that produce positive outcomes for all parties. The Model offers this opportunity, involving all stakeholders in one or more aspects of the process, beginning with patient safety and moving along the continuum to court adjudication.

Implementation of the NYS Model will benefit from the proven strength of the participants, all of which have a demonstrated track record of achieving liability reform or patient safety improvements. As set out above, OCA has been a national leader in introducing alternative judicial programs, including the intensive settlement model introduced in New York City by the Honorable Douglas McKeon. DOH has a long record of successful patient safety initiatives, as do the five hospitals.

All participating hospitals have well-developed patient safety infrastructures that include health information technology, a comprehensive and collaborative committee structure, and incident reporting systems. The OB departments at the four FOJP hospitals pursue performance improvement collectively. Clinical leadership has already instituted several mandatory patient

safety measures (e.g., electronic fetal monitoring course for staff, use of clinical guidelines) and has implemented a sophisticated audit and feedback program that is linked to the guidelines. New York Presbyterian Hospital - Columbia Presbyterian Center has developed a comprehensive patient safety structure under the leadership of the Chief Quality and Patient Safety Officer and uses a sophisticated on-line reporting system (Medical Events Reporting System-Total Hospital) to collect data and conduct in-depth analysis of adverse events. Some level of early settlement programs exists at each hospital but will benefit from increased transparency, disclosure and communication training for providers, and a more complete and systematic approach to settling cases.

All of the participating organizations are committed to contributing significant existing and additional resources. The OCA intends to select qualified jurists that will be focused on this pilot. DOH and the hospitals will provide data bases; clinical, research and evaluation expertise; and the hospitals will build on infrastructures that already support patient safety and risk management efforts. Each participating hospital has a well-established electronic patient safety data base and access to benchmarking data.

Further, several project team members and contributors, including Judge Kluger; Judge McKeon; Dr. Morley; Michelle Mello, JD, PhD; Richard Boothman, JD; and Dr. Michael Callahan, are noted experts in this field, have extensive experience in successfully implementing related projects, and have published their research results nationally. Department chairmen from five of the nation's prominent academic institutions are leading the project teams in their respective hospitals: Dr. Irwin Merkatz of Montefiore, Dr. Howard Minkoff of Maimonides, Dr. Michael Brodman of Mount Sinai, Dr. Arnold Friedman of Beth Israel, and Dr. Eliot Lazar of New York-Presbyterian. All five hold dual appointments with leading medical schools in New York City and have published extensively. Additionally, the commitment of experienced OCA and DOH resources to manage and oversee the project is another key element of success.

D.8. Project Significance

The results produced by the evaluation of the NYS Model will be valuable to project participants, to other institutions in New York State and has the potential to serve as a model for collaborative efforts by court and health agencies in other states. The significance is highlighted by the Model's unique synthesis of all steps of a medical malpractice claim grounded, in the first instance, in patient safety. The NYS Model is generalizable to other clinical specialties and settings and can be disseminated and implemented elsewhere with minimal adaptation.

Patient safety will be improved at each hospital proactively and through responsive action. Because the NYS Model is self-informing, the results will be used to improve patient safety throughout the project period and beyond by implementing specific interventions aimed at reducing adverse events. Some specific patient safety interventions may be adopted across departments or hospital-wide, if applicable.

Additionally, the results from the evaluation of the Disclosure and Early Settlement Program will assess whether a comprehensive Disclosure and Early Settlement program can be effective in the absence of protective medical liability legislation. Similarly, the results from the evaluation of the Judge-Directed Negotiation Program will show whether it is replicable in the private sector, for institutions structured differently from HHC. These are areas of intervention that will benefit from further evaluation as they have either not been evaluated extensively or been explicitly piloted.

These results may be used to encourage hospitals in other states to implement such programs, particularly in states seeking alternatives to restrictive tort statutes. The project partners believe that demonstrating the effectiveness of a medical liability model that puts patient safety first will result in a shared culture of safety that adequately protects both patients and providers, brings consensus and continued cooperation among stakeholders, and ultimately saves scarce resources.

D.9. Work Plan

Objective	Action Steps	Person(s) Responsible	Timeframe
Goal 1: Develop a culture of patient safety			
1a. Establish/enhance a proactive approach to patient safety	<ul style="list-style-type: none"> A. Identify staff members who are active members of existing patient safety committees B. Recruit active members and other key clinical, administrative, and risk management staff to create a multidisciplinary hospital-specific Patient Safety Team (PST) C. Establish explicit proactive short-term and long-term patient safety goals for the Patient Safety Team D. Create a process by which best practices and risks related to the short-term and long-term patient safety goals are identified E. Create process by which information generated by the PST will be distributed and enhancements implemented F. Create and promote a process by which any staff member in the PST can assist with identifying potential risks 	Patient Safety Team (PST)	Months 1-3; <i>Note:</i> Particular proactive approaches have already been identified
1b. Establish/enhance a process for creating patient safety initiatives when risks are identified through an adverse event	<ul style="list-style-type: none"> A. Utilize/enhance existing comprehensive Adverse Event Reporting System whereby adverse events, near misses, and unexpected outcome are reported B. Define process by which the PST evaluates an event to determine its severity and actions needed (root cause analysis, aggregated root cause analysis, departmental review, or continued monitoring) C. Create process where analysis results are used in response planning to prevent future events D. Define process in conjunction with the Disclosure and Early Settlement Team to include information provided by the affected patient/family in the analysis and response planning, as well as, inform the affected patient/family of the results E. Create process by which response plans are disseminated and implemented in the department 	Patient Safety Team (PST)	Months 1-3
1c. Obtain staff buy-in for a culture of safety	<ul style="list-style-type: none"> A. Engage management and other influential hospital staff members in PST B. Elicit and incorporate input from staff in creating processes of reporting adverse events, conducting analysis, creating response plans, and disseminating/implementing response plans 	Patient Safety Team (PST), hospital staff	Months 1-4

Objective	Action Steps	Person(s) Responsible	Timeframe
1d. Implement measures to promote a culture of safety	<ul style="list-style-type: none"> A. Implement proactive patient safety initiatives B. Task PST for continued development of proactive patient safety initiatives C. Begin analysis, response planning, dissemination of plans, and implementation of initiatives as adverse events are identified 	Patient Safety Team (PST), hospital staff	Beginning month 5
Goal 2: Develop a hospital-wide environment that enables and promotes complete adverse event reporting			
2a. Establish/enhance an environment that promotes comprehensive reporting	<ul style="list-style-type: none"> A. Convene hospital-specific Patient Safety Team B. Patient Safety Team will receive training in creating an environment that enables adverse event reporting C. Promote a system by which behaviors (not outcomes alone) are addressed, regardless of outcome D. Create a process by which behaviors are identified, addressed, and documented 	Patient Safety Team (PST), hospital staff	Months 1-3
2b. Obtain staff buy-in in complete adverse event reporting	<ul style="list-style-type: none"> A. Engage management and other influential hospital staff members in PST B. Elicit and incorporate input from staff promoting a system of appropriate responses to identified behaviors and ensuring comprehensive events reporting 	Patient Safety Team (PST), hospital staff	Months 1-4
2c. Implement an environment conducive to uncensored adverse event reporting	<ul style="list-style-type: none"> A. Train all staff in events reporting B. Post reminders and enable staff to report all adverse, unexpected, and near miss events 	Patient Safety Team (PST), hospital staff	Beginning month 5
Goal 3: Create a Disclosure and Early Settlement Program for the OB and/or Surgery Departments			
3a. Establish/enhance a system to identify and report adverse events	<ul style="list-style-type: none"> A. Utilize/enhance existing comprehensive Adverse Event Reporting System whereby adverse events, near misses, and unexpected outcomes are reported B. Train all staff on reporting events, emphasizing that responses and actions will be commensurate with behaviors, regardless of outcome C. Educate all staff on procedures following adverse events 	Patient Safety Team (PST), hospital staff	Months 1-3
3b. Establish/enhance a Disclosure and Early Settlement process	<ul style="list-style-type: none"> A. Establish and convene a Disclosure and Early Settlement Team B. Develop policies and procedures for adverse event response and incident settlement C. Organize committee or other body to make compensation decisions in individual cases 	Disclosure and Early Settlement Team, hospital staff	Months 1-3

Objective	Action Steps	Person(s) Responsible	Timeframe
3c. Obtain staff buy-in and provide training for a Disclosure and Early Settlement Program	<ul style="list-style-type: none"> A. Engage management and other influential hospital staff members in the Disclosure and Early Settlement Team B. Convene stakeholders within each institution to consider key model design and implementation decisions C. Develop and disseminate informational materials about the program for clinical staff D. Implement disclosure training curriculum 	Disclosure and Early Settlement Team, hospital staff	Months 1-4
3d. Implement Early Disclose and Settlement Program	<ul style="list-style-type: none"> A. Implement policies and procedures outlined in Program Manual, from initial event report through final disposition of the incident. B. Analyze closed claims to identify potential areas for patient safety improvement C. Provide reports to the Patient Safety Team concerning priority areas for patient safety interventions D. Collect data for the evaluation of the Disclosure and Early Settlement program 	Disclosure and Early Settlement Team, hospital staff	Beginning month 5
Goal 4: Expand and enhance a Judge-Directed Negotiation Program			
4a. Select and train judges to participate in Program	<ul style="list-style-type: none"> A. Identify judges to participate in judge-directed negotiations B. Train judges in targeted medical knowledge C. Train judges in enhanced negotiation and mediation techniques D. Provide each participating judge with RN/JD resources to provide medical expertise 	Office of Court Administration (OCA), MSSNY, NYS DOH	Month 1-4
4b. Establish process to direct claims to Program	A. Define the process by which claims involving a participating hospital is litigant are assigned to a participating judge	OCA, Judge McKeon	Month 1-4
4c. Implement Judge-Directed Negotiation Program	<ul style="list-style-type: none"> A. Convene regular, judge-led settlement negotiation meetings beginning early in the litigation process B. Tailor judge’s intervention to the particulars of each case C. Periodically observe and provide feedback to participating judges D. Record data for the evaluation of the program 	OCA, DOH, Judge McKeon	Beginning month 5
Goal 5: Demonstrate the effectiveness of the NYS Medical Liability Reform and Patient Safety Model (“the NYS Model”)			
5a. Evaluate improvements made to culture of safety	<ul style="list-style-type: none"> A. Administer baseline culture of safety survey B. Repeat survey at end of demonstration 	Patient Safety Team (PST) NYS DOH	Beginning month 1

Objective	Action Steps	Person(s) Responsible	Timeframe
5b. Evaluate the Judge-Directed Negotiation Program process	A. Take baseline, 3-year retrospective measurement of key metrics B. Prospectively collect and analyze case-level data C. Survey litigants to assess satisfaction with process and outcome D. Create annual reports	OCA, Center for Court Innovation, Harvard SPH	Beginning month 5
5c. Evaluate Disclosure and Early Settlement program	A. Take baseline, 3-year retrospective measurement of institution-level metrics B. Prospectively collect and analyze case-level data A. Create annual reports	Disclosure and Early Settlement Team, NYS DOH	Beginning month 5
5d. Evaluate effectiveness of proactive and responsive patient safety initiatives	A. Using defined outcomes specific to each initiative, evaluate the effectiveness of each initiative in preventing injuries B. Create periodic and annual reports	NYS DOH, Patient Safety Team (PST)	Beginning month 5
Goal 6: Disseminate reports and lessons learned			
6a. Disseminate model reform reports statewide and nationally	A. Make reports generated through evaluations publicly available using the NYS DOH Patient Safety Center, websites, Commissioner letters to hospital administrators, and publications. B. Share reports directly between hospitals and judicial system C. Share reports with AHRQ, Greater NY Hospital Association, Healthcare Association of New York State, Northern Metropolitan Hospital Association, MSSNY, and legal organizations for dissemination	NYS DOH, Center for Court Innovation, OCA	Beginning month 12
6b. Disseminate reports based on analyses of NYPORTS, MMDCS, and Judge Program data statewide.	A. Disseminate statewide aggregated, de-identified case information and reports from NYS MMDCS, NYPORTS, and closed claims databases	NYS DOH, Center for Court Innovation, OCA, NYS State Insurance Department	Beginning month 10
6c. Convene a one-day state-wide conference to report project progress and	A. Establish agenda for one-day conference including lessons learned to date and adaptation options for the NYS Model B. Identify interested hospitals, academic institutions, judicial organizations, and health organization to attend the conference	NYS DOH, OCA	During calendar year 2012

Objective	Action Steps	Person(s) Responsible	Timeframe
promote NYS Medical Liability Reform	C. Convene one-day conference		
Goal 7: Expand the NYS Medical Liability Reform and Patient Safety Model			
7a. Examine the potential for including additional hospital departments and additional hospitals in the NYS Model and begin expansion	<ul style="list-style-type: none"> A. Examine reports and lesson learned from the NYS Model evaluation B. Identify other departments and other motivated hospitals C. Meet with key staff in the identified departments to discuss the potential for staff buy-in and logistic considerations 	Patient Safety Team (PST), NYS DOH, Center for Court Innovation, OCA	Beginning month 12

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¹⁹ Carol Liebman of Columbia University Law School has agreed to assist in designing this portion of the curriculum.

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