Virginia Joint Commission on Health Care

Various Responses to Medical Errors

HJR 101 (2008) (Patron: Delegate O'Bannon)

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House Joint Resolution 101

- Directs the Joint Commission on Health Care (JCHC) to study, in the case of medical errors and adverse medical outcomes:
  - The use of:
    - disclosure
    - apologies
    - alternative dispute resolution and
    - other measures.
  - The impact of such measures on:
    - the cost and quality of care
    - patient confidence and
    - the medical malpractice system.

Study Process

- Formed a Study Committee consisting of representative stakeholders and individuals with expertise in the subject area.
  - Virginia Bar Association, Office of the Attorney General, a plaintiff's attorney, physicians, hospitals, insurers, mediators and defense attorneys.
- The Study Committee formed a Steering Committee to manage the work, and also broke into two workgroups: Disclosure and Resolution.
- Held a total of 10 meetings.

Study Committee Membership

- Ellen M. Brock, M, MD, MPH
  Associate Professor
  Director, General Obstetrics and Gynecology
  Medical Director, Center for Human Stimulation and Patient Safety, VCU
- Patrick C. Devine, Jr., Esq.
  Williams Mullen
- Jeanne F. Franklin, Co-Chairman
  Mediator and Attorney at Law
- Larry Hoover, Co-Chairman
  Of Counsel, Hoover Penrod PLC
- Heman A. Marshall, III, Esq
  Woods Rogers PLC
- Malcolm "Mic" McConnell, III, Esq.
  Allen Allen Allen & Allen
- Susan C. Ward, Esq.
  Vice President and General Counsel, VHHA
- Virginia Blair
  Vice President, Performance Improvement, Prince William Health System
- Thomas C. Brown, Jr. Esq.
  McGuireWoods LLP
- Michael L. Goodman, Esq.
  Goodman, Allen & Filetti PLLC
- W. Scott Johnson, Esq.
  Medical Society of Virginia
- Amy Marschean, Esq.
  Office of the Attorney General
- Devin C. Price, CPCU, CIC
  Colony Group, Allied Medical Division
- Arnie Snukals
  Duane & Shannon
- Rebecca W. West
  Piedmont Liability Trust

Background

- An estimated 44,000-98,000 people die unnecessarily in hospitals each year as a result of allegedly preventable medical errors.
- Besides loss of life or serious injury, annual costs of medical errors, including the expense of additional care, lost income and disability are estimated to be between $17 and $29 billion.
- Furthermore, health care providers (HCPs) face increasing malpractice insurance costs.

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When there is medical error, needs and concerns arise for both the patient and the HCP

- The injured patient may need, but not receive:
  - An explanation of what happened or an apology from the person or persons responsible for the injury;
  - Adequate compensation; or
  - Reassurance that steps have been taken to assure that the error is not repeated.
- The HCP may feel:
  - Powerless to talk openly with the injured patient about what happened and to express an apology;
  - Torn between ethical responsibilities and fear of the negative consequences of disclosing inaccurate or incomplete information;
  - It is difficult to determine how to balance their ethical and legal responsibilities, as well as their personal, professional and financial liability when they decide what and how to disclose; and
  - Disclosure does not always meet the expectations of patients.
- Fear of lawsuits and loss of reputation remain the biggest barriers to disclosure of medical errors.

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Medical Error and Medical Malpractice Lawsuits

- Studies suggest that a majority of patients sue, not because of injury but because they believe:
  - they are not treated with respect,
  - not told the truth,
  - the HCP has not taken responsibility for his/her actions,
- The silence of the "deny and defend" culture breeds anger, and is the major determining factor in a patient's decision to sue.
- About 25% of patient complaints reported to the Virginia Board of Medicine (BoM) are motivated by a patient's lack of knowledge concerning his/her treatment and poor communication by physicians.

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Disclosure of Adverse Medical Events

- Currently, there are a variety of federal and state authorities requiring HCPs to disclose.
  - The AMA states that physicians have a fundamental ethical duty to communicate openly and honestly with patients and to keep the patient informed.
  - The Joint Commission requires disclosure of medical errors and unanticipated outcomes to patients and their family members.
  - Virginia BoM regulations require practitioners keep their patients accurately informed.
  - 8 states mandate disclosure of serious adverse events and Pennsylvania and Rhode Island require written notification to the patient.

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Disincentives for Disclosure

- Federal and state reporting requirements which can trigger government investigations;
- Raised premiums and discontinued malpractice coverage if the cooperation clause is triggered;
- Possible waiver of peer review privileges;
- Possibility that defense costs could actually rise due to an increased number of claims;
- Loss of professional reputation; and
- Fear of a lawsuit.

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Incentives for Disclosure

- Disclosure rebuilds trust and solidifies the provider/patient relationship, thereby decreasing malpractice litigation and reducing overall costs.
- A culture of transparency and accountability fosters an environment where medical errors are identified and corrected, thereby buttressing the patient safety movement.
  - Acknowledging an error gives an institution the freedom to correct the mistakes and theoretically prevent future harm and improve patient safety.
- Patients gain increased confidence in the integrity of the health care system.
- Focus of attention returns to the patient, encouraging care to be patient-centered, not based on the protection of the organization.

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Disclosure and Disclosure Programs

- A movement promoting disclosure programs in the medical setting is taking root nationwide.
- Generally, disclosure and disclosure programs involve reconstructing the events that led up to an adverse outcome and relating those events to the patient.
- There are no universal standards applicable to disclosure programs.
- There are varying definitions of the event that should trigger disclosure.
  - Disclosure can be triggered by preventable or non-preventable harm or no harm at all, such as a near-miss.
  - Some programs determine the need for disclosure based on the severity of the harm.
  - It can be triggered by medical error, or simply an adverse event, that was the fault of no one.

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Disclosure and Apology

- Full disclosure includes an apology.
- As with disclosure itself, the definition of apology varies, and physicians and patients often have differing views as to what constitutes an apology.
- Many disclosure programs, as well as many state laws, define apology as an expression of benevolence, remorse or sorrow.
  - This more narrow definition differs from one more commonly understood by the general population – patients.
  - Patients define apology as an expression of remorse and sorrow coupled with an admission of wrongdoing and taking of responsibility.
- This variation highlights the lack of communication and conflicting expectations between patient and physician at the heart of the problem at issue.

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"Apology" Laws

- In an effort to encourage disclosure conversations and apology, 35 states have adopted apology laws to create an evidentiary privilege in any subsequent judicial or administrative proceeding.
  - 25, including Virginia, create a privilege for an "expression of benevolence, remorse or sorrow" only
  - 6 states protect such an expression plus an explanation, and
  - 4 states protect the entire disclosure statement, which would also include an acceptance of responsibility.

Resolution

- There are various processes currently used for resolving medical error conflict, including litigation:
  - Mediation
  - Early, interest-based mediation
  - Collaborative law
  - Malpractice Review Panels
- The most frequently used voluntary process is mediation.

Examples of Disclosure/Early Resolution Programs

- Across the country, including in Virginia, hospitals have been voluntarily implementing disclosure/early resolution programs.
  - Each program has a unique approach but some consistent characteristics include:
    - Focusing on early resolution (pre-claim) of the issues.
    - Having transparency and accountability as the intended purpose for implementation, not a decrease in medial malpractice costs.
    - Having procedures in place to determine, before a disclosure conversation is initiated, if and how an adverse event occurred.
    - Having clear policies as to who makes the initial disclosure, as well as future disclosure conversations.
    - Employing a strong education/training/support element for all involved.
  - In most instances, educational outreach began with the stakeholders before any programs were implemented.

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Veterans Administration Hospital in Kentucky

- Involves full disclosure and apology.
- If it is determined that disclosure is necessary, a meeting with the patient and family is convened and staff members make disclosure and apologize, take full responsibility, and describe steps being taken to prevent reoccurrence, and fair compensation is offered.
- Less risk for an individual physician to take part in a disclosure program at this hospital because he can not be held personally liable. In any suit against the VA, the United States is the only named defendant.
- Results have been positive:
  - Between 1987-2000, negotiated more than 170 settlements, going to trial only 3 times.
  - Largest payout was $341,000 for a wrongful death, and the average settlement was $16,000.

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The University of Michigan Health System

- Michigan has a compulsory 6-month pre-suit notice period.
  - Before a malpractice suit may be filed against any health care practitioner or facility in Michigan, the patient or patient's family is required, by law, to present details of the claims in writing. Once this notice is served, a suit cannot be filed for 182 days.
  - This pre-suit notice period allows prospective defendants time to investigate the claim, gives them the opportunity to meet with the patient or family, and offers patients and families time to reconsider their decision to sue.
- The University of Michigan Health System's Full Disclosure Program:
  - Was developed as a result of state law.
  - Each case undergoes internal and sometimes external expert reviews.
  - The patient care at issue is submitted to the Medical Liability Review Committee, which determines reasonableness of care and impact on the patient's outcome.
    - This Committee also considers every submitted case for peer review, clinical quality improvement, and educational opportunities. Furthermore, they study all adverse events to determine how procedures could be improved.

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The University of Michigan Health System

- Once the issues are clarified:
  - Hospital policy requires staff to disclose cases of harmful error, and open discussion with the patient and his lawyer ensues.
  - Physicians provide factual information of the outcome that occurred.
  - If it has been determined that the University of Michigan Health System provided unreasonable care, they compensate patients quickly and fairly.
  - If the hospital determines that the care was reasonable and the case is without merit, it will aggressively defend against any claims.
- The program has had positive results in the 5 years since implementing the program, including:
  - Annual litigation costs decreased from $3 million to $1 million.
  - Annual number of claims and lawsuits decreased from 262 to 114.
  - Average time to resolution of claims declined from 20.7 to 9.5 months.
  - The disclosure/early resolution program has led to an unprecedented exchange and flow of information, where staff reports more close calls and patient injuries.
  - Physicians in this program may be individually named in a malpractice suit, but the University will wholly indemnify all its doctors for damages.

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Disclosure Programs in Virginia

- Some hospitals in Virginia currently have disclosure programs in place.
- One example is the Prince William Hospital:
  - Has a disclosure policy that includes apology.
  - Since implementation of the program they have seen no increase in claims.
  - They have shared stories of the positive response with their Board of Trustees, which has been helping to move the hospital and providers from a culture of silence to a culture of transparency.
  - The Board reviews random chart audits for harm and identifies ways to decrease harm from medical error.
  - The Board and medical staff leaders continue to collaborate on best practice strategies.

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Pilot Programs in Other States

- Whereas some states have provided a fertile environment for hospitals to implement their own disclosure programs, other states have instituted pilot programs.
- Vermont's pilot program:
  - Requires an oral apology or explanation of how medical error occurred, made within 30 days. This oral apology and explanation may not be used to prove liability, is not admissible, and cannot serve as the subject of questioning in administrative or civil proceedings. Of course, information obtained through other channels is not barred from use.
- This pilot establishes a voluntary program run by the Vermont Department of Banking, Insurance, Securities & Health Care Administration (BISHCA), in which physicians and hospitals promptly acknowledge and apologize for mistakes in patient care that result in harm and promptly offer fair settlements.
- Negotiations under the program are confidential, and the statute of limitations is tolled during negotiations.
- Settlement bars further litigation.
- If settlement is not reached, the patient still may bring a civil action, having the same options as he did prior to entering into the disclosure program.
- Additionally, as part of the program, hospitals will report medical malpractice costs to BISHCA for the department to analyze any cost savings resulting from use of the program.
- They will report to the general assembly in January 2009, and the program will sunset.

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Pilot Programs in Other States

- Pennsylvania passed the Medical Care Availability and Reduction of Error (MCARE) Act, which states that "A person who has sustained injury or death as a result of medical negligence by a health care provider must be afforded a prompt determination and fair compensation. Every effort must be made to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety."
- Pennsylvania also implemented a pilot program for early resolution of medical malpractice cases, at the urging of the State Supreme Court.
- Once the county (Montgomery) was identified, a task force was established of county leaders including physicians, lawyers, and hospital representatives to develop a model for Disclosure/Early Resolution. The model:
  - Includes a first level of disclosure/early resolution which focuses on facilitating direct communication with patients about the patients' care and attempts to resolve matters to everyone's satisfaction and includes possible patient compensation.
    - Patients are told about this first level program upon admission to the hospital including whom the patient can contact within the hospital in order to initiate the first level of resolution.
  - Is an ombuds-type program within the hospital that works with a patient safety committee. If the HCP decides to offer compensation, the committee or Ombudsmen discusses arrangements or compensation with the patient after advising the patient of the right to counsel.
  - If the first level of resolution does not satisfy the parties, the model elevates to the offer of an early mediation process in which lawyers would be involved. The mediators would be a specially trained lawyer/physician team. A panel of trained mediators has been created.

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Pennsylvania Pilot Program (cont.)

- The hospital staff is a mixed staff so that some physicians do have their own insurers.
- The hospital group(s) is covered by the hospital policy.
- The hospital plan is to try to create a culture around this program so that the medical staff can buy into it.
- Pennsylvania law might provide an advantage: if the hospital pays the settlement – as a kind of global settlement – on the physician's behalf, there is no duty for the physician or hospital to report the settlement to the Board of Medicine.

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Study Committee Recommendation

- **The JCHC should convene a Task Force consisting of representatives of the primary stakeholders in this subject area – to include the Medical Society of Virginia, The Virginia Hospital and Healthcare Association, The Department of Health, Department of Health Professions, Board of Medicine, the Virginia Trial Lawyers Association, the Virginia Association of Defense Attorneys, the medical malpractice insurance industry, broader physician and health care provider and consumer representations. We recommend that the JCHC charge this task force with:**
  - **building upon the work already done by the 101 Study Committee;**
  - **developing agreed-upon working definitions of key terms such as adverse outcome, medical error, and disclosures, to facilitate discussions in Virginia of the issues;**
  - **tracking results and developments in disclosure and resolution programs now operational in Virginia and other states, and federal developments in this area;**
  - **crafting a model or models for disclosure and early resolution programs that could be offered to Virginia health care providers, insurers and attorneys for their use;**
    - **should such a model or models be developed, considering ways to incentivize health care providers to try use of such models and to report outcomes of their use with regard to several factors, including cost, impact on quality/patient safety efforts and reported patient/provider satisfaction;**
    - **should the Task Force decide not to offer such model(s), explaining the reasons.**

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Summary of the Rationale for the Study Committee's Recommendation

- Reflects the strong interest of the Committee in finding ways to resolve the tension between patient and provider needs and interests and the reasons why those needs are not consistently met.
- Argument was advanced that the current system works well enough, and that educating the professions about possible collaborative solutions and ethical obligations will provide an adequate enhancement of it.

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Rationale for the Study Committee's Recommendation

- Considering that the status quo might work well enough, the Committee was hesitant to make a stronger recommendation for the following reasons:
  - Uncertainty about the future sustainability of cost outcomes when more patients are fairly compensated.
  - More data will be available in the future.
  - Most data supporting claims of cost reduction were from programs that are self-insured.
  - Need consensus of all stakeholders.
  - Need more input from insurers as medical practitioners cannot risk rising premiums, discontinued coverage, or refusal by the insurer to defend a claim following a disclosure.
  - Change in interpretations of Virginia's peer review privilege has created an uncertain environment that is exacerbating the tension noted in this report and serves as a disincentive to embracing voluntary disclosure and early resolution programs.
  - Virginia reporting requirements and BoM procedures can be seen as possibly inspiring understandable fear and reluctance rather than open self-examination and correction in cases of medical error.
  - The polarization of attitudes about the medical error issue and the need for reform support the status quo.

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Options

- **Option 1:** Take no action.
- **Option 2:** Adopt the recommendation of the Study Committee.

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Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on November 10, 2008.
- Comments may be submitted via:
  - E-mail: sareid@leg.state.va.us
  - Fax: 804-786-5538
  - Mail: Joint Commission on Health Care
    P.O. Box 1322
    Richmond, Virginia 23218
- Comments will be summarized and presented to JCHC during its November 24th meeting.

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