Progress Report on Creating a System to Collect Hospital Medical Errors and Related Data

Pursuant to Article IX, Section 17.78, SB 1 of the 81st Legislature

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Commissioner

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Article IX, Section 17.78(d), of SB 1, the General Appropriations Act of the 81st Legislature, provides that "the Department of State Health Services shall submit a progress report by November 1, 2010, on the progress of creating a system to collect data on hospital medical errors and related data collection to the Legislative Budget Board and the Governor."

Introduction

Healthcare-associated infections (HAI) are infections that patients acquire while receiving treatment for other medical or surgical conditions. HAI are the most common complication of hospital care, resulting in 1.7 million infections annually. Nationally, patients with HAI spend on average 6.5 additional days in the hospital, are five times more likely to be readmitted after discharge, and are twice as likely to die. It is estimated that approximately 99,000 deaths each year are caused by HAI.[1] Prolonged hospital stays and utilization of resources attributable to HAI contribute to higher health care costs. The general public has become increasingly aware of and concerned about risks associated with receipt of healthcare and hospitalization. HAI are one of the most preventable causes of death in the U.S, and the infections add a significant economic burden to the healthcare system.

Preventable adverse events (PAE) are events in the course of medical care that harm or may harm patients, which can be prevented with appropriate policies and procedures and compliance with best practices. While not as frequent as HAI, PAE cause significant added suffering and disability, death, and healthcare expense. The term PAE includes "never events" (events that should never happen), such as surgery on the wrong patient, surgery on the wrong body part, or discharge of an infant to the wrong mother. Some HAI are also considered PAE.

Mandatory reporting of HAI by healthcare facilities and publication of information regarding HAI allow members of the public to compare infection rates in different facilities and then consider that information in making health care choices. Public reporting of individual facility HAI rates also allows facilities to compare their rates with others and with their own past performance, giving additional support for prevention process improvement.

Several states, with the support of consumer advocacy groups, have developed reporting systems, primarily for HAI. PAE reporting can be approached in a similar way. The ultimate intent of such reporting systems is to protect people and improve their health and healthcare outcomes. Texas seeks to achieve similar goals for its citizens: to protect patients and improve patient outcomes.

History

In 2005, with passage of SB 872[2], the 79th Legislature created an HAI Advisory Panel. It is charged with recommending definitions and methodologies for collecting and reporting evidence-based HAI data in Texas. This panel ended after submitting a report with its findings and recommendations.

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[1] Centers for Disease Control and Prevention (CDC) 2002
[2] Appendix 1

In 2007, the 80th Texas Legislature adopted SB 288[3]. The bill added Chapter 98 (Reporting of Health Care-Associated Infections) to the Texas Health & Safety Code. This chapter requires the Department of State Health Services (DSHS) to re-establish a 16-member HAI Advisory Panel and to develop a Texas Health Care-Associated Infections Reporting System.

Chapter 98 also requires general hospitals and ambulatory surgical centers in Texas to report to DSHS the incidence of surgical site infections occurring after seven specific surgeries. Pediatric and adolescent hospitals must report the incidence of surgical site infections occurring after three specific surgeries. In addition, general hospitals are required to report the incidence of laboratory-confirmed central line-associated primary bloodstream infections occurring in any special care setting in the hospital. Reporting also includes the incidence of respiratory syncytial virus occurring in any pediatric inpatient unit in the hospital.

Chapter 98 further requires DSHS to compile and make available to the public a summary, by health care facility, of reported HAI. The DSHS summary must be risk-adjusted and include a comparison of the risk-adjusted infection rates for each health care facility. The summary must be in an easy-to-read format published at least annually and available on an Internet website. Although resources were not available at the time SB 288 was adopted to implement the Texas HAI Reporting System, the Advisory Panel was re-established, and DSHS worked with the members to begin planning for the reporting system.

In 2009, the 81st Legislature adopted SB 203[4]. The bill amended Chapter 98 by adding the requirement that general hospitals and ambulatory surgical centers report the causative pathogen of a reportable HAI. It also required the reporting of PAE. Under the provisions of SB 203, hospitals and ambulatory surgical centers must report as PAE any event included in the list of adverse events identified by the National Quality Forum (NQF). The NQF list[5] currently includes 28 "never" adverse events. Examples include: a foreign object left in a patient after surgery and transfusion with the wrong type of blood product. SB 203 also requires hospitals and ambulatory surgical centers to report healthcare-associated adverse conditions or events for which the Medicare program will not provide additional payment to the facility. Lastly, SB 203 increased the number of advisory panel members from 16 to 18 and changed the title to the Advisory Panel on HAI and PAE[6].

The 81st Legislature appropriated $2,173,451 for the state Fiscal Year 2010-2011 biennium to provide staff, information technology resources, and facility training to begin implementation of the HAI Reporting System. No resources were included specifically for PAE reporting in this appropriation.

Figure 1 summarizes legislative action during the 79th, 80th and 81st Legislatures.

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[3] Appendix 2
[4] Appendix 3
[5] Appendix 4
[6] Appendix 5

Figure 1

Year	Legislature	Bill/ Exceptional Item	Health and Safety Code Chapter	Requirement
2005	79th	SB 872	96 *(expired Jan 2007)*	Established an HAI Advisory Panel to make recommendations regarding HAI reporting in Texas. Panel ended after submitting its report.
2007	80th	SB 288	98	Reconstituted the Advisory Panel on HAI and required establishment of the HAI Reporting System.
		SB 1731	108	Expanded hospital patient data collection.
2009	81st	SB 203	98	Established PAE reporting requirements; added members to the Advisory Panel on HAI and PAE; added reporting of causative pathogen.
		General Appropriations Act		Funded certain HAI reporting activities

Centers for Medicare and Medicaid Services

Recently, the Centers for Medicare and Medicaid Services (CMS) have adopted rules requiring hospitals to report central line-associated bloodstream infections (CLABSI) and surgical site infections (SSI). CLABSI and SSI reporting requirements apply only to hospitals that receive Medicare reimbursement through the Inpatient Prospective Payment System (IPPS). Hospitals that do not report CLABSI and SSI will be subject to a reduction in their Medicare Annual Payment Update.

For CLABSI, data collection will begin with January 1, 2011 discharges, and will be reported to CMS using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN)[7] for FY 2013 Medicare payment determination. For SSIs, data collection will begin with January 2, 2012 discharges, and will be reported to CMS using the NHSN for FY 2014 Medicare payment determination. CMS will determine the specific surgical site infections to report in future rules.

Hospitals and hospital units that are specifically excluded from this rule are: rehabilitation hospitals and units; long-term care hospitals; psychiatric hospitals and units; children's hospitals; cancer hospitals; religious nonmedical health care institutions; critical access hospitals, and Department of Veterans Affairs/ Department of Defense hospitals.

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[7] The National Healthcare Safety Network (NHSN) is a voluntary, secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC.

Accomplishments to Date

In 2007, the DSHS Commissioner appointed the Texas Health Care Associated Infections Advisory Panel. The Advisory Panel, comprised of physicians, infection control professionals, hospital and ambulatory surgery center officers, quality improvement professionals, public health professionals and members of the public representing consumers, held its first meeting in February, 2008. The Advisory Panel and the DSHS HAI program jointly reviewed options for facility data reporting. The panel recommended using NHSN as the most effective way to collect HAI data.

As a result of SB 203, the panel became the Texas Advisory Panel on HAI and PAE, and the DSHS Commissioner appointed two additional members. This enlarged Advisory Panel has continued to encourage the use of NHSN as the most effective way to collect data; provided input for the development of realistic timelines for data reporting, verification, and validation; informed and updated their stakeholder networks of progress in the implementation of the legislation; and indentified factors essential to an informative, user friendly website for reporting data to the public. The Advisory Panel also recommended HAI reporting rules drafted by DSHS staff. The DSHS Health Services Council likewise recommended these rules, and they have been approved by the Texas Health and Human Services Commission. The rules were published in the *Texas Register* on October 22, 2010.[8]

The proposed Texas rules and CMS rules for reporting central line-associated bloodstream infections and surgical site infections are standardized and integrated by requiring the use of the identical reporting interface, i.e. National Healthcare Safety Network. Using the same reporting interface eliminates data inconsistencies and data entry burdens that would result if different reporting systems were used. In Texas, all licensed hospitals and surgery centers will need to report HAI data to comply with either CMS rules or Texas rules.

During the interim of the 81st Legislature, DSHS determined that the statutory language of Chapter 98 posed two obstacles to the adoption of rules that required facilities to use NHSN. Sec. 98.104 specifies that the rules adopted pursuant to Chapter 98 cannot require that the facilities report to NHSN more frequently than every quarter. Sec. 98.110 specifies the agencies to which DSHS may disclose data and for what purposes. NHSN requires reporting more frequently than quarterly and uses the data for purposes for which it is not authorized to receive data from DSHS under the statute. DSHS consulted with CDC to seek a resolution without further action by the Legislature but was told that NHSN could not conform to the existing Texas statute. It is important to note that Texas facilities can and do voluntarily report information to NHSN because they find the system useful. However, the state cannot adopt rules requiring facilities to do so because of the two provisions cited. DSHS has developed language that would modify both provisions to remedy this problem.

DSHS applied for and was awarded American Recovery and Reinvestment Act of 2009 (ARRA) funds through the CDC Epidemiology and Laboratory Capacity Grant. These funds, available through December 31, 2011, support development of an HAI reporting system, creation of HAI

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[8] Appendix 6

prevention facility collaboratives, and conducting a state wide conference on HAI. With ARRA funds, DSHS has selected a contractor to implement the HAI prevention collaboratives with between eight and 12 facilities (including two in rural areas), working together to enhance infection control and prevention. DSHS conducted the second statewide HAI conference on October 26-27, 2010.

DSHS has taken steps to involve stakeholders in the planning and implementation process for HAI/PAE reporting. In addition to conducting regular meetings of the Advisory Panel and initiating the prevention collaboratives, DSHS:
- Developed a state plan in December 2009 that was submitted to and approved by CDC. Input of the Advisory Panel and other stakeholders at the 2009 HAI Conference was solicited during the development of the plan; [9]
- Held the first statewide HAI conference in October 2009;
- Conducted more than 20 meetings across Texas since January 2010 to inform stakeholders about proposed HAI reporting; and
- Selected a contractor to develop a curriculum and offer training on the use of NHSN and specific state requirements beginning December 2010. Fifteen sessions will be conducted across the state.

The U.S. Department of Health and Human Services (DHHS) required states receiving Preventive Health and Health Services Block Grants to submit a plan to the Secretary of DHHS on HAI activities within the state. The state plan must be consistent with the DHHS HAI Action Plan and contain measurable five-year goals and interim milestones for reporting and preventing HAIs in the state. The Texas State Plan describes how Texas intends to meet the requirement to parallel the DHHS HAI Action Plan and contains sections on development, enhancements to the HAI infrastructure, surveillance, detection, and reporting. It describes functions such as evaluation, oversight, and communication. The Texas State Plan also includes actions DSHS would take to create and expand HAI prevention collaboratives, build a public health HAI workforce, and enhance the ability to assess where HAIs are occurring. The Texas State Plan specifically targets central line-associated bloodstream infections and ten surgical site infections for reporting and prevention activities.

Health Registries Improvement Project

SB 1, the General Appropriations Act of the 81st Legislature, contains a provision that directs DSHS to use $1 million to upgrade registries that "collect, analyze and disseminate" health information. In response to that provision DSHS initiated a Health Registries Improvement Project (HRIP) to improve, integrate, and modernize a number of DSHS health registry and surveillance systems, including HAI. The intent is to maximize interoperability of health information exchange in health information systems development across department programs. The HRIP was born out of the need to develop an agency registry strategy that is aligned with Federal Health Information Technology (HIT) and Health Information Exchange (HIE) standards.

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[9] Appendix 7

DSHS has selected a registry software vendor to build the EMS/Trauma Registry, one of the registries included in the HRIP assessment. DSHS will begin discussions with this vendor to use their software to build the HAI reporting system.

Next Steps —with current funding

DSHS submitted the HAI proposed rules to the *Texas Register*, where they will remain open to public comment for 30 days. Following that time period, DSHS will respond to comments and submit the rule for adoption. DSHS will communicate with the facilities, of which there are more than 1,000 that fall under the rule regarding mandatory reporting of specific HAI. DSHS will also, as needed, inform the Legislature regarding potential statutory changes to facilitate Texas' use of NHSN and to support confidential exchange of data among department programs. After the DSHS Trauma Registry contract is finalized, staff will work with the contractor to adapt the Trauma Registry system application to modify the application into a system for managing HAI data. To use a modified registry application, changes must be made. These include: a system for contact management for tracking communication with facilities for reporting compliance, downloading, managing, and verifying NHSN data, analyzing data for facility level comparisons, developing and posting the Web display, and conducting data validations. DSHS will designate NHSN as the recipient of the required data submission after action by the 82nd Legislature as described above.

Next Steps —with additional funding

The DSHS Legislative Appropriations Request for Fiscal Years 2012-13 contains a Patient Safety exceptional item to enhance the HAI reporting/data management system by adding a component to which PAE can be reported. Funds are also needed to initiate ongoing HAI data validation, to continue to develop HAI reporting capabilities to meet Chapter 98 requirements, to support ongoing HAI data validation, to create additional HAI prevention/quality improvement collaboration with facilities, and to support a public campaign to promote patient safety.

At this time NHSN accepts HAI data but not the PAE information required by Chapter 98, creating the need for an equivalent data collection system for PAE reporting. Facilities will report HAI data to NHSN and report PAE data directly to the DSHS PAE system. In anticipation of PAE reporting implementation, planning for the HAI reporting system has included efforts to create a design flexible enough that a compatible PAE reporting system can be added when resources are available. DSHS will then be able to communicate and work with healthcare facilities on data validation and other activities using the same DSHS data management/reporting system for both HAI and PAE, even though the data collection systems are different.

Exceptional Item 6, Patient Safety, requests $5,456,056 and 16 FTEs for the 2012-2013 biennium. If appropriated, this funding will be utilized to design, support, and maintain ongoing HAI system development, including the training and reporting requirements. As required by Chapter 98, DSHS will use this funding to develop a PAE reporting system for collecting and managing data on the 28 NQF "never" events and healthcare-associated adverse conditions or events for which the Medicare program will not provide additional payment. DSHS will be able

to begin planning a method for the public to report suspected HAI and PAE to the department. Since Chapter 98 requires the reporting of data defined in sources that may change (the National Quality Forum events and occurrences for which Medicare will not reimburse), it is likely that facility training will be an ongoing process. It is also necessary to enhance the existing vendor contract for the Center for Health Statistics (CHS) to accommodate statutorily required, one-time expansions of Present On Admission (POA) data and ensure interoperability of POA data with HAI and PAE data.

Development of the PAE reporting system will include the potential to gather reports from healthcare facilities on other patient safety indicators besides the healthcare-associated infections and preventable adverse events noted in Chapter 98. Analyses of data can be used to promote improvement in reporting processes and also in healthcare and healthcare outcomes. Discussions are underway to address potential future quality improvement areas. They include but are not limited to collaboration between HAI staff and the DSHS Regulatory Services Division staff regarding reporting and mitigating facility reporting issues that may affect their licensure; providing additional training on HAI reporting to facilities; and promoting or providing HAI/PAE prevention classes to ambulatory surgical centers and hospitals across the state, targeting identified opportunities for improvement.

DSHS will leverage the exceptional item funding to promote best practices, optimum utilization of electronic health records, and appropriate health information exchange. Security and confidentiality measures will be implemented to protect and prevent inappropriate disclosure of personal health information.

Figure 2 provides a graphic representation of how the components of the HAI and PAE Reporting System fit together.

Figure 2

ELECTRONIC COMPONENTS OF THE DEPARTMENT OF STATE HEALTH SERVICES PROPOSED PATIENT SAFETY SYSTEM			
Sources of Healthcare Associated Infections (HAI) and Preventable Adverse Events (PAE) Data: >600 Hospitals and >400 Ambulatory Surgical Centers (1) **Facility enrollment and communication**		Reporting by the Public*	
(2) **HAI Data Collection** thru secure web portal; facilities report HAI to CDC's NHSN; data extracted into the DSHS reporting system	(3) **PAE Data Collection*** thru secure web portal; facilities report PAE directly to the DSHS reporting system modified and/or created for PAE.	Web-based public reporting	Reports by phone, fax, letter, email.
Patient Safety Information Management (4) Database management and verification (5) Data validation		Data entry, management, verification, and	

		validation.
Patient Safety Reporting (6) Web-based Standardized Reporting for the Public		

Evidence-based Prevention Activities
Once Texas has a functional patient safety data collection and reporting system, additional quality improvement and prevention strategies can be implemented to address Texas-specific priority risk areas.

* PAE data collection and receiving reports from the public (both requirements in HSC Chapter 98) will be developed when resources become available.

Figure 3 outlines the components of the Patient Safety Exceptional Item request for the State Fiscal Year 2012-2013 Biennium.

Figure 3

Components of Patient Safety Exceptional Item: Totals for FY2012 and FY2013		
Component	**GR Funding Request**	**FTE Request**
Development of PAE reporting system and further development of HAI system (Base Option)	$3,591,426	7
Targeted Interventions - HAI Prevention Collaboratives	$ 500,000	0
Information Specialist and Patient Safety Public Information Campaign	$ 136,792	1
Patient Safety Quality Improvement Teams in Regions (4 Teams of 2)	$1,227,838	8
Total for all 4 components:	$5,456,056	* 16

* The EI includes another 0.3 FTE - Health and Human Services Commission allocation

Summary of HAI Reporting Implementation

Upon designation by DSHS of NHSN as the system to which facilities must send their HAI information, reporting will begin. The Advisory Panel has endorsed a modification to the rules that requires reporting during the quarter in which NHSN is designated as the recipient system for the data. That modification was inserted into the proposed 25 TAC §§200.1 – 200.10 rules that were published. The Infectious Disease Control Unit (IDCU) of the Prevention and Preparedness Division at DSHS will have primary responsibility for implementing and monitoring these activities. Hospitals and ambulatory surgical centers will submit data into

NHSN. DSHS will download those data into the Texas HAI Reporting System. DSHS will review and analyze the submitted data records for errors and communicate with the facility to resolve discrepancies. IDCU will perform data analysis and prepare data summaries that include two quarters of risk-adjusted infection rates for each health care facility. Prior to publication on the public website, IDCU will provide these summaries to the individual facilities for review and comment. IDCU will format the final data summaries and comments and post them semi-annually to the public website. To assure that HAI reporting is meaningful and accurate, IDCU will oversee data validation which includes ongoing reviews of corroborating medical records and facility reports.

Additional DSHS Activities:

Developing a comprehensive patient safety initiative will require collaboration among many units within DSHS, including the Division for Regulatory Services, the Center for Health Statistics (CHS), the Information Technology Section, and IDCU, as well as partners across the state. Both IDCU and CHS will work closely with the staff who develop information systems at DSHS. This will ensure that all automated components of HAI, PAE, hospital discharge and Present on Admission (POA) reporting are developed and implemented in an interoperable fashion and are compliant with HIE requirements. Additionally, IDCU will work closely with the Regulatory Licensing Unit to determine appropriate corrective action in cases of health care facility non-compliance with enrollment, reporting, or data correction. IDCU will also work with the Advisory Panel and the State Epidemiologist and other subject matter experts, as well as other partners across the state on approaches to quality improvement, consistent with the department's broader efforts to optimize health information exchange and health information technology.

Lastly, data validation could be further enhanced through data sharing with CHS which, under Chapter 108 of the Health and Safety Code, is authorized to collect POA and hospital discharge data. However, the current statute restricts CHS' data sharing with other DSHS program areas, such as IDCU. Additionally, some hospitals are exempt from reporting discharge data to CHS but are not exempt from HAI/PAE reporting. Changes in this statutory language would permit discharge and POA data collected to be uniformly compared with HAI data as part of the data validation process.