MINNESOTA STATEWIDE TRAUMA SYSTEM

MINNESOTA DEPARTMENT OF HEALTH

The following is a comprehensive model plan for trauma system performance improvement. The Minnesota Department of Health together with the State Trauma Advisory Council will collaborate with industry stakeholders to develop Minnesota's trauma system performance improvement plan and establish priorities for the implementation of its components.

**Minnesota
Trauma System
Performance Improvement Plan**

June 2, 2009

**Trauma System
Office of Rural Health and Primary Care
Minnesota Department of Health**

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EXECUTIVE SUMMARY

The Minnesota Department of Health (MDH) contracted with the National Foundation for Trauma Care (NFTC), now the Trauma Center Association of America (TCAA), and Lisa Irwin, RN, MPA:HA, Trauma Systems Advisor, to develop a comprehensive, statewide performance improvement (PI) plan to assist Minnesota (MN) in its efforts to evaluate and improve the effectiveness of trauma care throughout the state. This document was created using an information gathering process that included meeting with MDH staff, the State Trauma Advisory Council (STAC), and trauma care providers at all levels, and by reviewing best practices of other state trauma and EMS systems, as well as those recommendations currently advocated by national trauma organizations.

The purpose of this plan is to provide emergency medical services (EMS) agencies, trauma centers, trauma regions, and the State trauma program with a summary of the processes and activities required to measure, monitor, evaluate, and improve the process of trauma care and its outcome. This document is divided into sections, each representing a phase of care, and is written to stand separately as a guide for that level. The sections include prehospital treatment, hospital care, rehabilitation, regional trauma system, and the statewide trauma system. An overview of trauma system PI is provided to summarize the key points relative to the statewide system and its components.

Each section describes:
- The purpose and goals for PI,
- Structure and responsibilities,
- Patient population,
- Data collection and validation processes,
- Scope of review and key activities,
- Evaluation processes including how to identify improvement opportunities and implement corrective action, and
- How information should be documented and reported.

Te following are recommendations for implementing the MN trauma system PI plan and its components. These are listed in order of priority.

1. Establish in statute comprehensive confidentiality protection for all aspects of the statewide PI including hospitals, EMS agencies, individual patients, and state and regional trauma PI committees. The Oregon Revised Statutes, Chapter 431, and associated Administrative Rules (Appendix H), and MN EMS Statutes, Chapter 145, serve as models.
2. Revise MN Trauma Registry inclusion criteria to capture patients who are unnecessarily triaged for trauma system care and/or patients who met criteria for trauma system care but did not receive the appropriate, required level of response at the trauma center.
3. Develop a mechanism for reporting to the MN Trauma Registry, as well as

uniform statewide patient disability data (physical, functional and psychologic impairment) at the time of discharge from an acute care hospital, post acute rehabilitation facility, skilled nursing and other relevant care facilities, and at periodic intervals thereafter.

4. Continue efforts to collect, refine, and validate data variables, including data obtained though linked sources.

5. Provide education to the trauma centers, particularly rural Level III and IV facilities on effectively conducting trauma PI relevant to their hospital setting.

6. Establish a continuously evolving structure for conducting PI through the Regional Trauma Advisory Councils (RTAC) and STAC.

7. Adopt uniform methods and processes for conducting PI at the RTAC, STAC, and MDH level. This should include adopting standardized definitions for the evaluation of trauma-related mortality, morbidity, and defining expectations of care, outcomes, and other relevant aspects of the review process.

INTRODUCTION

A systems approach to trauma care provides the best means to protect the public from premature death and prolonged disability. Trauma systems reduce death and disability by identifying causes of injury and promoting activities to prevent injury from occurring, and by assuring that the resources required for optimal care are available. A major goal of trauma care systems is to provide care that is efficacious, safe, and cost-effective.

The development of a statewide system of care for the injured must include a mechanism to measure, evaluate and improve the process of care and its outcome. The process must be a continuous, multidisciplinary effort to reduce inappropriate variation in care and improve the effectiveness of the system processes and its components including prehospital care (dispatch, medical control, triage, and transport), hospital care, inter-facility management, and rehabilitative care.

Performance improvement (PI) in an organized trauma system consists of multiple layers of continuous monitoring and evaluation of care to identify opportunities for improvement. This progressive cycle of evaluation extends from the performance improvement (PI) programs of hospitals and emergency medical services (EMS) agencies to review committees established at the state and regional levels, and evaluation programs within the Minnesota Department of Health (MDH) including the Minnesota Trauma Registry (MTR).

This model emphasizes a continuous, multidisciplinary, multi-layered effort to monitor, measure, assess, and improve the process and outcome of trauma care. Regardless of the hospital, service, or region, care processes and the clinical management of trauma patients must be evaluated using an established methodology with pre-defined measures based on national or state recognized standards. This review should include comparison and benchmarking of services, hospitals, and regions with state or national data obtained through trauma registries, mortality studies, and outcomes-related research.

This manual was developed to assist and guide trauma committees responsible for PI within agencies, institutions, or regional and state systems. Each section provides PI advice for each level of responsibility and is written to stand separately as a guide for that level. As a result, there is some duplication of information throughout the manual. The appendices offer explicit examples and language for PI activities which may be adapted. Adhering to the processes described will provide a foundation for a successful trauma center and system PI program but is not considered a replacement for a consensus process under the direction of a Trauma Medical Director and Trauma Nurse Coordinator.

Other resources to consult as efforts to implement trauma PI statewide evolve include the "PIPS Reference Manual" (www.facs.org/trauma/handbook - ACS

2002) the "Resources for Optimal Care of the Injured Patient" (ACS 2006), the Advanced Trauma Life Support Manual (ACSCOT), and other entities that publish evidenced based practice guidelines or reviews such as the American College of Surgeons (www.facs.org/education/ebrs), the Eastern Association for the Surgery of Trauma (EAST; www.east.org), the US Department of Health and Human Services, Agency for Healthcare Research and Quality (Evidenced-based Practice Program; www.ahrq.gov), or the National Guideline Clearinghouse (www.guideline.gov). Together with this manual, the advice of those resources should result in activities necessary for improving trauma care locally, regionally, and state-wide. Seeking the regular advice of professionals with expertise in trauma PI is strongly recommended to assure that PI processes meet contemporary theory and comply with State law governing protection of clinical care review.

It is acknowledged that modifications and adaptations of this model will occur to allow for the unique characteristics of emergency care provision in rural areas.

TRAUMA SYSTEM PERFORMANCE IMPROVEMENT: AN OVERVIEW

PURPOSE AND GOALS

The purpose of trauma system performance improvement (PI) is to measure, evaluate, and improve the processes and outcome of care rendered by all phases and levels of the trauma care continuum from 9-1-1 dispatch through rehabilitation. A PI plan establishes lines of communication, structure, authority and accountability for monitoring system components and aspects of care, and defines standards by which performance and outcomes are measured. The primary objective of trauma system PI is to decrease unnecessary death and disability by reducing inappropriate variation in care, and assuring that system expectations, standards, and benchmarks are met. An effective PI program results in implementation of plans for corrective action or improvement when indicated and modification of practice guidelines or the trauma plan when appropriate.

The specific goals of the Minnesota trauma system PI program are to:
- Alleviate unnecessary death and disability from trauma by reducing inappropriate variation in care and improving patient care practices.
- Promote optimal trauma care by performing ongoing cycles of evaluation of trauma care delivery and system components, and implementing improvement initiatives based on optimal care practices when indicated.

STRUCTURE

The trauma system PI process consists of internal (local institution or agency) and external (system) monitoring and evaluation of care by trauma care providers (prehospital and hospital), county EMS entities, regional or area trauma advisory bodies and the lead agency with authority to oversee the trauma system. Internal monitoring and evaluation occurs within the hospital or prehospital agency, while external review occurs at the regional or state PI committee level with oversight provided by the Minnesota Department of Health (MDH).

PI review at each level is multidisciplinary, occurs at regular intervals (or soon after a sentinel event), and continuously seeks to identify opportunities for improvement. The results of analysis define improvement initiatives (if necessary) that are documented and communicated to the appropriate individual or entity for action. The effectiveness of corrective strategies is evaluated as the PI cycle repeats itself.

RESPONSIBILITIES

In an organized trauma system a mechanism for continuous, multidisciplinary review of the processes of care and its outcomes must exist for each level of care if the full benefit of performance improvement is to be realized. Review is

conducted by the ambulance service provider, the county (lead EMS entity and medical examiner/coroner), the trauma facilities and local hospitals, and the regional and state trauma boards or committees. The performance improvement activities conducted at each level should complement or build upon those performed by others and should include evaluation of:

1. Infrastructure such as system response, access to EMS, hospital, and rehabilitation resources, accessibility of services, and availability and efficient use of equipment and other resources such as air medical transport.
2. Process of care such as appropriateness of triage and transport, provider assessments, treatments and management decisions, timeliness of care, communication and documentation of treatment.
3. Outcomes such as mortality, morbidity, disability, length of stay, utilization of services, cost, and patient safety initiatives.

Responsibility for communication of performance issues must be assigned within each level of review. Procedures to ensure confidentiality of the review findings must be in place and be strictly applied. The following summarizes the scope of responsibility for each care review level.

EMS Committee

Local and/or regional EMS committees can combine their trauma PI activities with the regional trauma advisory committee (RTAC). The responsibility for response to PI issues from all sources, including the regional committee, must be assigned within each EMS service.

Regional Trauma Committee

Each trauma system region should appoint a multidisciplinary committee for the purpose of regional system planning and implementation as well as to perform ongoing PI activities for the region. The regional committee may wish to establish a subcommittee for PI (recommended) or may choose to take on the task of system monitoring and evaluation at the committee level. Regardless of the configuration, the review committee should include representation from each trauma center* (physician and trauma nurse coordinator), EMS including 9-1-1 dispatch, non-trauma hospitals, and the county medical examiner/coroner, and air medical service as appropriate. Membership should be established with specified terms of appointment and a Chair, preferably a trauma surgeon, should be appointed. A staff person, generally the trauma nurse coordinator from the lead trauma center, should be assigned to coordinate meeting activities. The suggested membership includes:

- General surgeon or trauma medical director*
- Emergency physician
- Neurosurgeon as available
- Orthopedic surgeon as available

- EMS medical director
- Trauma nurse coordinator/program manager*
- Medical examiner or coroner
- Emergency nurse
- ALS & BLS EMT
- First responder
- Communications specialist (9-1-1)
- Air medical representative (clinical)

The regional trauma PI committee is responsible for analyzing region-specific trauma data to assess the effectiveness of the regional trauma system in reducing unnecessary death, disability, and cost. In addition, the committee is responsible for addressing regional system issues or concerns and monitoring the availability and use of resources (hospital bypass or service diverts, air ambulance, inter-hospital transfers and transport, etc). Another key aspect of regional PI is the review of mortality cases to determine preventability rates, practice variation, and seek improvement opportunities.

State Trauma Committee

The role of the State Trauma Committee is to monitor and analyze regional and statewide PI data for patterns or trends in care processes, evaluate outcomes, and recommend improvement initiatives as indicated by the results. This is accomplished through a PI subcommittee, preferably chaired by a trauma surgeon and staffed by the MDH. The PI subcommittee reviews trauma data, information reported by the regional PI committees, and pertinent issues or trends that are identified during designation visits. The subcommittee may wish to conduct focused audits or studies to better understand the extent of an identified problem and its root cause.

The State PI subcommittee should be multidisciplinary with representation from various levels and specialties of providers and from specific regions or areas of the state (urban, rural, etc.). Members should be appointed for their expertise and interest in PI as well as for other professional qualities. It is the responsibility of the State PI Subcommittee to guide the MHD in disseminating summary PI results to EMS agencies, trauma centers, and regional trauma committees in a timely, informative, and confidential manner as permitted by statutes. In rare instances, the State PI Subcommittee may recommend that the MDH take emergency action to address issues that pose a significant public health risk.

The State PI Subcommittee is responsible for establishing pre-defined measures or expectations of care based on evidenced based guidelines, state policy and standards, or derived out of consensus. Review at all levels should include comparison and benchmarking of services, hospitals, and regions with state or national data obtained through injury databases and trauma registries, mortality studies, and outcomes-related research.

Lead Agency

The MDH is the lead governmental agency authorized by law to develop and oversee a comprehensive, statewide trauma system PI program. The MDH has legal authority to monitor, evaluate, and improve processes of trauma care and outcomes throughout the state. The MDH is responsible for:

- Developing a comprehensive, statewide process to monitor, evaluate, and improve trauma system performance, as a whole and by its regions.
- Establishing in conjunction with the STAC pre-defined measures or expectations of care based on evidenced based guidelines, state policy and standards, or derived out of consensus
- Providing direct oversight and administration of PI activities of the state and regional trauma committees.
- Implementing corrective action strategies or initiatives based on the PI committee's findings and recommendations. With proper oversight the lead agency may empower the regional trauma committee to implement improvement initiatives that are not regulatory in nature such as evidenced-based practice guidelines.
- Communicating problems, trends, and issues identified by the state and regional PI committees to the responsible entity such as ambulance service, healthcare organization, other agencies, county health officials, etc. Communication of PI activities may be delegated to the regional PI committee given that the MDH provides oversight.
- Initiating action required to avert a potential emergent public health risk.
- Collecting, evaluating, validating, and communicating trauma data.
- Developing and enforcing policies and procedures for data security and confidentiality protection for all aspects of the state PI program.

DATA COLLECTION AND INFORMATION SOURCES

Specific, uniform data that describes the injury incident, demographics, prehospital information, diagnosis, treatment, rehabilitation, outcomes, and cost of care should be collected by every hospital and reported to the MN Trauma Registry. It is imperative that data be collected and reported using standardized definitions as recognized by the MN Trauma Registry. Data definitions should be consistent with those of the National Trauma Data Bank. Prehospital data, if not collected and reported by the hospitals, should be linked or uploaded into the MN Trauma Registry.

Performance improvement efforts must be continuously supported by reliable, valid, and objective trauma data. Many useful sources of information are available to measure and evaluate system-wide performance and outcomes at all levels of the care continuum. The following information sources should be

considered for routine monitoring of the trauma system, including data trending, comparative analysis, and benchmarking performance:

- Minnesota Trauma Registry (MTR)
- Minnesota EMS Registry
- Minnesota Traumatic Brain Injury (TBI) Database
- National Trauma Data Bank (NTDB)
- Prehospital care records
- Public safety records (FARS); these records provide information often not included in the prehospital care record
- 9-1-1 dispatch records
- Emergency department records and hospital discharge summary
- Interhospital transfer records
- Autopsy findings
- Vital Records – Death certificate data
- Complaints from all sources
- Hospital performance improvement findings
- System plan, protocols, policies, and practice guideline
- Other National PI initiatives
- Federal agency initiatives or announcements (CDC, HHS, HS, etc.)

SCOPE OF REVIEW AND KEY ACTIVITIES

The statewide trauma PI program should be capable of objectively reviewing individual patient care as well as identify variations in the processes and outcome of groups of patients. Hospitals and EMS agencies, regions, and the state should be able to effectively monitor compliance with system standards, track variability, and document improvement using aggregate data. Examples include response times, timeliness of care, length of stay, complication and mortality rates, and cost.

The use of "audit filters" to measure the effectiveness of care processes may have limited value since most do not correlate with outcome. Developing pre-defined indicators or expectations of care (based on nationally recognized standards, practice guidelines, or consensus, etc.), however, can be used to identify individual cases that warrant further review as well as to compare and benchmark performance.

Important aspects of patient care are identified by the PI committee asking, "Which of the things we do are most important?" The committee determines relevant indicators or expectations that are objective, easily defined, and reliably available for data collection. Indicators are questions that have a yes/no answer such as, "Did the patient require an unplanned readmission to the hospital; or did the patient with a systolic blood pressure of less than 80 mm Hg have IV access established within minutes of EMS arrival." It is important that expectations and outcomes of care be uniformly defined and applied throughout the state so that

comparison and benchmark data is relevant. Differences in levels of service, capacity, and resources can be imbedded into the standards, i.e., BLS, ALS, hospital levels, etc.

This model plan contains both adult and pediatric performance expectations that the PI committee may consider when developing its own expectations of care (Appendix A*).* Ideally, the state PI Subcommittee should begin its PI efforts by developing such expectations seeking input from the MDH, regions, hospitals, and EMS providers including air medical. Each section within this plan provides examples of aspects of care to be evaluated and is followed by a list of expectations that are measurable and available to the PI committee through the information sources listed above.

EVALUATION

Performance improvement in trauma care emphasizes a continuous, multidisciplinary effort to measure, evaluate and improve the process of care and its outcome. To monitor and evaluate performance, identify opportunities for improvement, and document the effectiveness of corrective action, the PI process must be supported by reliable, valid, and objective data. Expectations or standards of care derived from evidence based guidelines, protocols, consensus of important aspects of care and associated indicators, statutes, rule or ordinance are necessary to measure the quality and consistency of care, effectiveness of process, and expected outcomes.

CONFIDENTIALITY

The MDH is responsible for ensuring that state law adequately protects from discovery, including subpoena, all aspects of the state and regional PI committee proceedings including meeting materials, oral and electronically transmitted communications, written reports, notes, findings, and records created by the review committee in its course of investigation. This includes review of both individual and institutional care. An example of confidentiality legislation for system PI activities is contained in Appendix H.

In addition to statutory protection, the MDH must ensure that appropriate measures and procedures are in place to meet the confidentiality requirements of the data and protect against threats, unauthorized uses or deliberate or inadvertent disclosures. An example of a confidentiality procedure is contained in Appendix G.

Hospitals, agencies, state and regional PI committees, and the MDH may wish to consider the following measures to protect confidential patient and provider information:

1. Use of a locked file for all relevant information.

2. Requiring a signed statement or agreement by all participants to maintain confidentiality (Appendix F).
3. Sanction for any breaches of confidentiality.
4. Shredding of all copies of PI documentation.
5. Employing security efforts at PI meetings such as numbering and collection of all meeting materials.
6. Strict security procedures for videotaping trauma resuscitations in the hospital.
7. Use of security procedures when mailing or transmitting PI documentation through a facsimile or modem
    a) Addressing all correspondence to an assigned person rather than an agency
    b) Clearly marking all letters "confidential" along with citation of statutes or regulations protection.
    c) Removing all patient identifiers, dates, and locations of scenes from information, particularly when used for education.
    d) Providing direct supervision, e.g., staff standby at the receiving facsimile when faxing PI documents such as case summaries between hospitals.
    e) Recopying all "blacked out" redacted materials so information cannot be read.

PREHOSPITAL PERFORMANCE IMPROVEMENT

PURPOSE AND GOALS

The purpose of prehospital performance improvement (PI) is to measure, evaluate, and improve the process and effectiveness of care rendered by all phases and levels of prehospital responders, including communications and dispatch. This section of the MN PI plan establishes lines of communication, authority, and accountability for monitoring aspects of prehospital care, and defines standards to measure the quality and outcome of care. The objective of trauma PI in the prehospital setting is to reduce inappropriate variation in care, enhance patient safety and outcomes, and identify opportunities for improvement.

STRUCTURE

Prehospital trauma PI may occur under any number of venues. The EMS/ambulance service will have a physician medical director who is responsible for overseeing the medical care provided by prehospital caregivers. At the local level, the EMS/ambulance agency PI committee should be comprised of providers, management, and other pertinent personnel that is directed by the physician advisor. Prehospital PI activities may also occur under the auspices of a county or regional EMS administration. Air medical services may be involved in either prehospital or hospital PI or both.

In a developed trauma system, the process of prehospital trauma care and its outcomes is monitored and evaluated by the regional trauma PI committee. This generally includes the review of selected trauma cases, analysis of trauma data, and focused audits. Case review findings and agency specific PI reports are communicated directly to the pertinent EMS agency along with recommendations for improvement if indicated. The prehospital care service is expected to review the committee findings, implement corrective action if necessary, and provide feedback to the regional trauma committee. In some remote regions of the state this may be the only avenue for prehospital trauma PI to occur.

SCOPE OF REVIEW AND KEY ACTIVITIES

The goals of prehospital care in a trauma system are to prevent further injury, initiate appropriate and timely resuscitation, and provide safe and rapid transport of the injured patient.[1] Patients are triaged and transported to the most appropriate facility equipped and staffed to manage their injuries as determined by the regional trauma plan. Prehospital personnel must be trained to recognize specific injuries or mechanisms that could result in severe injury and understand treatment, triage, and transport protocols as established by the statewide plan.

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[1] Committee on Trauma, American College of Surgeons, Resources for Optimal Care of the Injured Patient, 2006

Treatment protocols, triage criteria, transportation modes, destination hospitals, communications, bypass or divert policies, and other pertinent components of the prehospital trauma care process should be the focus of prehospital trauma PI. The following topics are trauma components of the EMS system that should be considered for routine monitoring and evaluation.

Communications

Providers of emergency medical and trauma care must be able to communicate with each other to maximize their individual and collective resources (staff, equipment, supplies, and facilities) and coordinate their responses in the shortest effective time to meet individual and mass human health emergency needs. Communications in EMS and trauma systems includes: access to the system through 9-1-1 services; pre-arrival instructions to callers, dispatch of prehospital services, direct communications with physicians for on-line medical control, and pre-notification of patients being transported to facilities.   The following key areas of EMS/trauma system communications that should be reviewed at the local (county/EMS agency) or regional level using EMS and trauma registry data, prehospital care reports, dispatch logs, public safety records, and other available pertinent information resources.   Records of non-transporting (i.e., first responder) services are critical to prehospital PI.

9-1-1 Services - Public Access to EMS and Trauma Care – 9-1-1 communications are monitored and evaluated for accuracy, completeness, and timeliness to report emergency medical situations to appropriate EMS-response organizations. This includes:

- Location of incident and description of situation including number of victims and their condition, other bystanders or responders on scene, and potential hazards on roadway or at scene including violent or armed persons
- Caller identification and location
- Compliance with time and other information standards

EMS Dispatch and Control – The detection of an emergency medical incident through 9-1-1 services elicits the dispatch of personnel and equipment to respond to the emergency scene. This response must be coordinated with other public safety services, such as law enforcement and fire services, and with other agencies involved in the emergency. The following are aspects to consider for performance review.

- EMS units dispatched according to EMS system standards, including timelines
- The resources, vehicles, equipment, and personnel dispatched are appropriate for the emergency situation

- Advice (pre-arrival instructions) to people at the emergency scene about how to take additional actions necessary to preserve life or reduce suffering is provided
- Coordination with law enforcement, fire, or other agencies is appropriate and timely
- Recognition of the need for an immediate response by EMS resources to life-threatening and serious human health emergencies is rapid
- Coordination with air medical or BLS/ALS services

Medical/Hospital Communications – Vital information regarding patient physiologic status, assessment and treatment at the scene must be transmitted to emergency medical and trauma professionals to ensure proper monitoring and decision making by the destination facility.

- The number, condition, and estimated arrival time of patients is reported to the destination facility or trauma communications center upon scene departure
- An update of the patient(s) status is communicated to the receiving hospital during transport
- Vital information regarding the patient(s) physiologic status, assessment, and treatment is complete and accurate
- Medical direction and authorization requests are appropriate and timely

Medical Direction

Medical control is an essential component of the prehospital care system. It is a method of ensuring high-quality and accountability of the prehospital care provided through the use of online medical direction and off-line treatment protocols. Online medical direction allows the Emergency medical technician (EMT) to contact a physician from the field via 2-way communication to obtain instructions on further care of a patient. This method is used when a patient is in need of care that is not authorized without medical direction under the caregiver's scope of practice. For example, an EMT treating a burn victim who has already given the maximum dose of narcotic pain medicine allowed (per treatment protocol) may contact the base station hospital to ask for further instructions to provide pain relief. Off-line medical direction is provided by treatment protocols that are developed from current, evidenced or consensus based guidelines or pre-established standards of care.

Medical direction in trauma care is continually monitored for effectiveness and compliance as part of the trauma system's PI process. Prehospital care reports, communications transcripts and tapes, and other pertinent prehospital data sources are routinely reviewed at the local or regional level to measure the quality and outcome of care based on pre-established standards defined by the trauma system and EMS plans. Aspects for review include:

- Online medical direction – qualified (per state standards), available, knowledgeable of EMS and trauma specific treatment protocols, appropriate for patient condition, etc.
- Treatment interventions – authorized, consistent with off-line treatment protocols or system policy, within the EMT scope of practice, appropriate for patient condition, timely, etc.
- Documentation of medical direction authorization requests, treatment interventions, and response is complete.

Triage

At an injury scene, EMS providers must identify those patients who are at greatest risk for severe injury and determine the most appropriate hospital to which to transport the patient to. This decision process is known as field triage and is based on an algorithm, the "Field Triage Decision Scheme", first developed by the American College of Surgeons (ACS) in 1986. The Field Triage Decision Scheme is an algorithm that guides EMS providers through four decision steps (physiologic, anatomic, mechanism of injury, and special considerations) to determine the most appropriate destination facility within the local trauma system. Variations of the ACS Field Triage Decision Scheme are used by most states across the country, including Minnesota, to triage patients at risk for serious injury to a trauma center.

The MN State Trauma Advisory Council (STAC) or PI Subcommittee should determine and evaluate acceptable rates of under-triage and over-triage. Under-triage occurs when severely injured patients (measured by ISS$\geq$ 16, death, ICU admit, major operation, or LOS > 48 hours – definition may vary) are transported to a non-trauma facility or lower level trauma center where resources may not be adequate or readily available to manage the patient. Under-triage also occurs when a patient who meets field criteria for trauma system care arrives at a trauma center and does not receive an appropriate trauma team activation or consult. Under-triage may place the patient at risk for an adverse outcome and should be a monitoring priority.

Over-triage is when minimally injured patients are transported to higher level trauma centers, unnecessarily utilizing valuable resources. Patients who are transported to a higher level trauma center who are discharged from the emergency department, briefly observed, or who do not meet the definition of major injury are considered over-triage. The acceptable under-triage rate is $\leq$5% for patients transported to a non-trauma center with an injury severity score of 15 or more, and $\leq$1% for those who died of potentially preventable causes. An acceptable over-triage rate is between 25% and 50 %.[2]. Based on the findings, triage protocols can be modified to achieve acceptable rates of under and over-

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[2] Committee on Trauma, American College of Surgeons, Resources for Optimal Care of the Injured Patient, 2006

triage. The MDH should include the rate of under and over-triage in its annual report

The sensitivity and specificity of triage criteria (single criterion and combinations) to predict major injury should be evaluated from time to time. The MDH using trauma registry, and if necessary other linked data sources, should perform multivariable statistical analysis to create and evaluate triage prediction models that predict the probability of risk for injury. This information can be used to develop or update the statewide triage criteria algorithm and/or protocols for tiered trauma team response.

As the trauma system evolves it is important that the system's PI program evaluate triage criteria to confirm that the severely inured patient has the best quality of care and that the minimally injured patient does not over utilize costly resources or unnecessarily burden higher level trauma centers.

At the local level, the appropriateness of patient triage to destination facilities should be monitored by the receiving hospitals within the region and reviewed on a case-by-case basis as needed.   Potential improvement initiatives that might result from such review include education and training, development of pocket triage tools, or new methods or processes for documentation and communication of triage information.   Trauma triage criteria protocols and the concept of over/under triage should be part of the training and re-certification of EMS personnel.

Transportation
Rapid field evaluation, treatment, and transport are vital to the overall outcome of the trauma patient. After the trauma patient's extrication, the on-scene time should be limited to *ten minutes* or less, except when there are extenuating circumstances. EMS providers should use the skills available at their level of training to stabilize the victim for an expeditious transport. The majority of patients sustaining injury will be able to receive prompt and comprehensive medical care at the nearest, local trauma care facility, however, patients with serious injury may require immediate transport to a higher level trauma center. The MDH has established in statute a statewide trauma transport protocol that details the expectations for EMS transportation of injured patients to acute care trauma facilities based on severity of injury.

PI efforts to monitor and evaluate the process of trauma patient transportation to trauma care facilities an its outcome should focus on:

- Timely assessment and identification of patient's need for trauma system care (triage criteria, gut intuition, etc).
- Timely resuscitation and stabilization of patient (10 minutes or less) with on-scene procedures limited to airway management, ventilation, hemorrhage control, fracture stabilization, and full spine

immobilization. Additional procedures should not delay transport and should be performed en route.

- Appropriateness of destination facility. This is based on the patient's need as dictated by triage and transportation protocols as well as the availability of trauma or specialty care (burn center, pediatric, etc) facilities. This means the highest level trauma center (Level I or II) within 30 minutes or as determined by MN policy, unless definitive care requires a specialty hospital.
- Prehospital communications to receiving hospital (as indicated above under Communications) includes: a description of the injury and scene
- (i.e., significant intrusion, starred windshield, prolonged extrication, etc.), vital physiologic information, interventions, estimated time of arrival, and means of transport.
- Use of air medical transport services in accordance with established guidelines. Instances of prolonged delays at the scene waiting for air medical transport, use within urban setting, unavailability of air services, and cases of air transport of patients in traumatic cardiac arrest due to blunt trauma should be reviewed locally on a case by case basis.
- Transportation of unstable injured patients using non-medical transportation resources, such as police vehicles.
- Transportation of unstable patients to non-trauma center for airway management or venous access.
- All diverts or bypasses of nearest, appropriate trauma center.
- Timeliness – EMS dispatch, arrival of first responder to scene, ALS service if available, on-scene management, and scene to hospital transport.

EMT Training and Certification

Prehospital care providers are trained at varying levels to assess a patient's condition, and to perform such emergency medical procedures as are needed to maintain a patent airway with adequate breathing and circulation until the patient can be transferred to an appropriate destination for advanced medical care. Interventions include cardiopulmonary resuscitation, defibrillation, controlling severe external bleeding, preventing shock, body immobilization to prevent spinal damage, and splinting or immobilization of bone fractures. EMS providers are certified according to their level of training and although an individual state may set its own standards of certification (or licensure), all EMT training must meet the minimum requirements as set by the National Highway Traffic Safety Administration's (NHTSA) standards for curriculum. Additional certification (ACLS, PALS, PHTLS, etc.) and training, including ongoing skills maintenance, requirements are generally defined by either state statutes or local EMS system policies.

Emergency medical provider qualifications are reviewed by prehospital agency management upon hire (or volunteer service), at the end of orientation, the end of probation, and at least annually thereafter. Qualifications are documented and records are maintained as required by MN EMS system policy. Documentation should include the following:

- All certifications required to meet state standards
- Current ACLS, PALS, BTLS, PHTLS, or equivalent certification
- Current EMT certification
- Record of skill maintenance review at least annually by physician supervisor
- Attendance at required meetings and education programs

Equipment

The goal of prehospital trauma and emergency care is to minimize further injury and manage life-threatening conditions through a series of interventions that embrace principles of rapid and safe patient care. Prehospital providers at all levels must have the appropriate equipment and supplies to optimize delivery of emergency trauma care. Supplies and equipment should be stocked on ambulances to enable care providers to provide care within the scope of their certification levels. Equipment and supplies need to be available and operational at all times.

One of the performance measures of the trauma system is the availability and effectiveness of essential adult and pediatric equipment and supplies for Basic Life Support and Advanced Life Support patient care. The effectiveness of equipment is scrutinized by asking the question, "does it do the job and is it safe in the field environment in the hands of field personnel?" The availability and effectiveness of equipment and supplies is reviewed by prehospital agency management, and that review is documented as required by the state licensing agency. Documentation should include the following:

- Pre-shift checks of all equipment and supplies on ambulance
- Reports of malfunctioning equipment returned for repair
- Routine maintenance and decontamination of equipment and vehicle(s)
- Records of product/equipment failure or recall
- Records of provider training and skill maintenance in equipment use
- Return or exchange of equipment left at the receiving hospital

Safety

Emergency medical providers have unique safety risks in the transportation aspects of pre-hospital care, and patient handling in the EMS environment. EMS providers must actively work in the back of a moving vehicle, traveling at high speeds, managing critical patients with heavy equipment or other interventions

that may be difficult to perform. They must work in an environment that is at times chaotic or unpredictable and often face challenges caused by weather, lighting, hazardous exposures, etc. Performance improvement efforts should focus on promoting a culture of safety including wearing seat belts, driving safely, securing equipment, preventing exposures, and protecting the patient from further undue harm. Prehospital personnel are also susceptible to lift injuries and need training in safe lifting.

Provider and patient safety should be regularly evaluated for any deviations from normal operations. Reports of "variances" from normal operation must be required, including exposure to known infectious diseases, injury to the patient or provider during scene management or transport, loss of or damage to personal property, or other identified areas of risk. Hospital variance reports may be adapted to the prehospital setting to provide for confidential records of variances. The following are areas to consider for routine monitoring:

- Protective clothing worn by providers to assure infection control, visibility, and identification as prehospital providers
- Employee injuries are documented for: needle stick, back injury, Haz Mat exposure, infectious diseases exposure, assault by patients, etc
- Medication errors are documented and reported
- Infection Control and Hazardous Materials handling per established policies and procedures, CDC infection control recommendations, or other pertinent guidelines for handling hazardous materials

Documentation in the Prehospital Record

Documentation is an important aspect of the patient care process and lasts long after the EMS run. The written report becomes a part of the patient's permanent medical record and remains a valuable source of data for research on trends in emergency medical care as well as a guide for continuing education and quality improvement. Prehospital reports may also used as evidence in a legal proceeding. Documentation of important information can also help the EMS provider to remember specific facts about the patient during the time of their involvement.

At the national and state levels efforts to formulate standards for prehospital documentation and data collection are underway. The purpose of these projects is to glean information necessary for research about what is done in the field, and how the process of prehospital care can improve. A clinical record of the patient's medical status and the care provided must be maintained and a copy of this record should be provided to the facility receiving the patient. Prehospital care records should be reviewed by agency management for consistency, completion, and accurate documentation. Creating a checklist may be helpful to accomplish this task. The following are important aspects to consider:

- All times related the response and care of the patient including, dispatch, en route, scene arrival, scene departure, extrication, physiologic signs, interventions, status, etc.
- All applicable trauma triage criteria and injury circumstances including type, mechanism and location
- On-scene care and all interventions including failed attempts recorded with time, justification, equipment, patient response, authorization as indicated, name of provider, etc.
- Records from all levels of prehospital providers including non-transporting personnel

CASE REVIEW

High-quality, consistent emergency care demands continuous quality improvement and is directly dependent on the effective monitoring, integration, and evaluation of all components of the patient's care. This includes a multidisciplinary effort to monitor, assess, and improve both the processes and outcomes of care provided to the injured patient. The long-term goal of prehospital PI is to intervene to prevent further injury, and thus decrease death and disability by reducing inappropriate variation in care through progressive cycles of review. Multidisciplinary case review led by physician medical directors at the agency, county, or regional level must be done routinely to assure that trauma patients receive the highest quality of care available with consideration for uncontrollable elements of distance, weather, and situation. A procedure for case review such as outlined in Appendices C and D should be established to assure fair and unbiased appraisal of care. Modification of these models may improve their application in different settings.

Population for Review

The following are trauma cases which should be considered for review:

- All injured patients who die or require CPR in the field
- All patients with prolonged extrication or scene times
- All injured patients who required on-line medical authorization
- All patients meeting physiologic or anatomic triage criteria
- All multiple patient scenes or mass casualty incidents
- All helicopter activations including standby requests
- Any case where patient, staff or bystanders are injured or exposed to hazardous or infectious materials or by inadequate scene control, i.e., struck by another vehicle
- Any patient meeting state trauma triage criteria taken to a non-trauma facility
- Complaints from any source

EVALUATION

The evaluation of prehospital trauma care should focus on the process of care and its outcome as described in the above sections. Important aspects or components of care should be reviewed to determine whether the care provided met the overall objective of prehospital trauma care: to prevent further injury by performing timely assessment, extrication, initial resuscitation and stabilization, and rapid transport of the patient to the appropriate destination facility. For instance, was resuscitative care limited to airway and ventilation management, hemorrhage control, stabilization of fractures, and immobilization of the spine? The review of care processes should also focus on whether pre-established system standards or expectations of care were reasonably attained. Outcome measures as listed in Appendix B should be evaluated to determine the overall effectiveness of prehospital treatment.

Mechanisms to provide for the flow of information necessary for comprehensive case review must be established in a manner that assures confidentiality. This includes feedback information provided by the hospital or other responding agencies. Use of a format similar to that found in Appendix C will assist the physician medical director or review committee to organize case review in an objective and systematic manner. Case discussion, findings, determinations, improvement recommendations, and actions should be documented in accordance with confidentiality procedures. The review meeting should be held in executive session and the proceedings exempt from open public meeting laws.

The following determinants of performance are suggested for adoption and adaptation to assist the review body to track and trend care related issues:

- Limitation of EMT scope of practice
- Procedure performed outside of EMT scope of practice
- Inadequate assessment
- Inadequate training or information
- Lack of pertinent protocol
- Lack of medical control authorization
- Improper technique
- Lack of or failure of equipment
- Insufficient information to the receiving facility including timeliness of notification

IMPROVEMENT OPPORTUNITIES AND CORRECTIVE ACTION

Opportunities for improvement are identified by routinely monitoring aspects of the trauma care process and its outcome. This is done by developing expectations or measures of performance and care quality based on evidenced-based practices, statewide standards, or committee consensus. Cases or data

that indicate that the expected performance or outcome was not met may be further reviewed to identify opportunities for improvement or monitored for trends.

When a consistent problem or inappropriate variation occurs, improvement actions must be taken and documented. The PI committee (local or regional) determines an action plan to reduce variation in care, improve care, or correct identified problems. The action plan includes: who or what is going to change; who is assigned responsibility for problem resolution; what action will be taken and when it will occur; and who is responsible for follow-up and when it will occur. Corrective strategies may include modification of policies and procedures, professional education for staff, counseling of involved personnel, credentialing, and delineation of privileges.

RE-MONITORING

An essential component in PI is demonstrating that a corrective action has the desired effect. The monitoring and review of care should include a method for assuring the effectiveness of corrective action through continuous cycles of evaluation. This evaluation should occur within three to six months of the corrective action depending the event, and be thoroughly documented in the PI committee minutes. Documentation should include the following aspects of follow-up and re-evaluation:

- The time frame for problem follow-up
- The assignment of indicators or a special study to review the problem
- The documentation of findings and any need for continued action
- Status of the problem until resolution is verified

DOCUMENTATION AND REPORTING

The PI review process of prehospital care and its outcome includes accurate and confidential documentation of ongoing monitoring, corrective action, progress, and re-evaluation. It is important that PI records and review proceedings be protected by MN statutes making disclosure of such information subject to civil penalties. A responsible PI program assures that information is handled in a strictly confidential manner.

The following measures are suggested to protect patient information:

- Use of a locked file for all relevant information
- Use of a confidentiality statement/agreement for all participants in PI activities such as that contained in Appendix F
- Sanction for any breaches of confidentiality
- Shredding of all copies of PI documentation

- Security efforts at PI meetings such as numbering and collection of all papers
- Notation or citation of statutory protection on all PI documents
- Use of security procedures when mailing or transmitting PI documentation including addressing all correspondence to an assigned person, clearly marking all letters "confidential", removing all patient identifiers, dates, and locations of scenes from information, particularly when used for education; providing direct supervision, e.g., staff standby at the receiving facsimile when faxing PI documents such as case summaries between hospitals

Reports need to be prepared in summary format to provide a paper-path of problem identification and resolution. The prehospital entity or agency must receive information from the PI committee in order to successfully manage the service and promote positive change. PI information should be exchanged in accordance with an established confidentiality procedure similar to that contained in Appendix G.

HOSPITAL PERFORMANCE IMPROVEMENT

PURPOSE AND GOALS

The purpose of trauma center performance improvement (PI) is to measure, evaluate, and improve critical phases of trauma care and outcomes, including on-line medical control, emergency resuscitation, definitive management, inpatient care, and inter-facility transfer. The trauma center PI plan establishes lines of communication, structure, authority and accountability for monitoring program aspects, and defines performance expectations and outcome measures. It emphasizes a continuous, multidisciplinary effort to decrease mortality and morbidity and improve care by reducing inappropriate variation in care through progressive cycles of performance review. Trauma center PI promotes a standardized process to address recurring issues and improve care.

The specific goals of the trauma center's PI program are to:
- Alleviate unnecessary death and disability from trauma by reducing inappropriate variation in care and improving patient care practices.
- Promote optimal trauma care by performing ongoing, multidisciplinary evaluation of the continuum of trauma care delivery processes and their outcomes, and implementing improvement initiatives to correct issues when indicated.

STRUCTURE

Performance improvement in a trauma center consists of internal and external monitoring and evaluation of care provided by medical, nursing, and ancillary personnel, as well as hospital departments, services, and programs. Monitoring is ongoing and systematic; opportunities to reduce inappropriate variation in care are sought, and strategies to improve care are documented in a corrective action plan. The effectiveness of corrective action is evaluated through continuous reassessment as the PI cycle repeats itself.

Trauma centers at all levels are expected to develop a clearly defined trauma PI program. The structure for accomplishing trauma PI can be organized in a number of ways depending on the hospital's level of designation, size of medical staff, availability of staff resources, and service volume. In most Level I-III trauma centers, PI review is performed by a multidisciplinary trauma committee representing all phases of care provided to the injured patient, including prehospital and air medical. In a Level IV trauma facility, the PI committee may be comprised of emergency medicine or primary care physicians, who staff the emergency department (ED), as well as the trauma nurse coordinator, ED nurse(s), and EMS personnel. Small rural trauma centers with limited resources and staff should be encouraged to find creative ways to structure their trauma PI committee.

The PI committee monitors, evaluates, and corrects care process issues including those external to the trauma program. In addition, a trauma peer review committee representing surgery, emergency medicine, anesthesia, and other appropriate physician sub-specialists is constituted for the purpose of physician peer review. In small Level III and IV trauma centers physician peer review may be accomplished through an existing hospital peer review committee, the trauma PI committee, or an appropriate external review body. For example, in Oregon, some small rural trauma centers sent their peer review cases to other trauma centers, the regional trauma PI committee, or relied on physician outreach from higher level referral centers to conduct a mortality and morbidity meeting each quarter.

TRAUMA PROGRAM RESPONSIBILITIES

Because trauma care crosses most, if not all, service disciplines, the trauma program and its medical director/advisor must be empowered by the hospital's governing body and medical staff to address performance issues that involve multiple services and departments. The trauma medical director/advisor must be granted the authority and administrative resources necessary to effectively lead the trauma PI process through problem resolution. The trauma coordinator (TNC) or program manager is an essential component of the PI process because he or she is responsible for the day-to-day collection and processing of data, monitoring care and its outcome, and coordinating the logistical aspects of the PI program. The TNC may identify adverse trends in care or processes that are not evident in the individual case review because of his/her oversight role.

The trauma nurse coordinator/manager is key to the functioning of both committees, providing coordination of action planning and documentation between the trauma program and the hospital-wide PI program. Both committees should consider meeting at least quarterly (monthly or biweekly in larger volume hospitals) to review operational or care process issues (trauma committee), and morbidity, mortality, and sentinel events (peer review committee). Larger trauma programs may also find it useful to conduct a multidisciplinary educational conference or "Grand Rounds" (weekly to monthly) to discuss interesting cases. Lower volume facilities may consider the same or on a less frequent schedule. If the trauma center cares for pediatric patients (Levels I or II) a portion of the PI meeting should be dedicated exclusively to that population with a pediatric surgeon present.

PATIENT POPULATION

To ensure consistent PI monitoring and evaluation as well as data collection throughout the state, the MDH, with advice from the STAC, must define standardized criteria for determining the trauma patient population. These criteria should be uniformly applied throughout the state for all levels of care to

identify the population to be monitored and reviewed. The following criteria are suggested:

- Injured patients who meet triage criteria for trauma system care
- Injured patients who are discharged from the hospital with an ICD-9-CM diagnosis 800.00-959.9, excluding 905-909.9, 910-924.9, and 930-939.9.
- All trauma related hospital admissions
- Any trauma related death
- Any trauma transfer either into or out of the hospital
- All complaints and high profile cases

DATA COLLECTION AND INFORMATION SOURCES

Specific, uniform data that describes the injury incident, demographics, prehospital information, diagnosis, treatment, rehabilitation, outcomes (including physical and cognitive status at hospital admission and discharge), and cost of care should be collected by every hospital and entered into a trauma database. It is important that data be collected using standardized definitions as recognized by the Minnesota Trauma Registry. Data definitions should be consistent with those of the National Trauma Data Bank.

Data is collected on a routine basis using information sources that are reliable and accessible. Many useful sources of information are available to perform monitoring and evaluate the efficacy, cost, and outcome of trauma care. The following information sources should be considered for routine or periodic monitoring of the hospital's trauma program:

- Prehospital care reports including non-transporting agency, i.e., first responder
- Hospital medical record
- Public safety records;(these records provide information that may not included in the prehospital care record)
- 9-1-1 dispatch records
- Interhospital transfer records if applicable
- Autopsy findings (these may be difficult to obtain in rural areas)
- Hospital trauma registry data and external benchmarking data (MN Trauma Registry or National Trauma Data Bank (NTDB). This information is useful for trending data, performing comparative analysis, and benchmarking.
- Checklists from review of trauma resuscitation videotapes
- Complaints from all sources
- Performance improvement findings from other review committees
- System plan, protocols, policies, procedures, guidelines, etc.

The hospital-wide performance improvement department and trauma program should establish communication channels to report their activities to each other. In addition, they should work together to coordinate and track trauma cases that are referred for review by other committees.

SCOPE OF REVIEW AND KEY ACTIVITIES

The traditional use of quality indicators to measure the effectiveness of trauma care delivery may have limited value since many do not correlate with outcome. Indicators, however, are useful for trending incidents, sentinel events, and establishing benchmarks for performance and comparative analysis. In addition, they may help to identify cases for committee review and offer an alternative for evaluating process, outcomes, and consistency of care. Indicators or expectations of care should be developed from evidence-based guidelines, critical pathways, protocols, or consensus. Appendix A contains examples of quality indicators reflective of varying aspects of the care process. The Center for Medicare Services (CMS) list of "present on arrival" or "never events" should also be included in routine reviews.

Injured patients who meet criteria for review should be screened using a pre-established list of expectations of care and reviewed for morbidity and mortality. Cases that warrant further review, such as a provider related morbidity or mortality, should be evaluated by the appropriate trauma or peer review committee using pre-defined criteria so that review is unbiased. Whenever possible, the involved are provider(s) should participate in the presentation and discussion of the case, and assist in developing an effective solution to prevent the problem from reoccurring. A "tracking form" may be useful to document concerns or the occurrence of morbidity/mortality and track the case through the review process. An example of a tracking form is contained in Appendix E.

Credentialing

An important aspect of the PI plan is the establishment and routine verification of trauma care provider credentials. Provider credentialing occurs through established channels within the hospital's medical staff, nursing, and ancillary services, and mechanisms for describing their compliance are incorporated in the PI plan. Coordinating the documentation of physician and nurse credentialing between the trauma service and the medical and nursing staff offices is an important aspect of the trauma center designation process. The requirements for trauma provider (physicians and nurses) credentialing for American College of Surgeons (ACS) verified Level I/II trauma centers are outlined by the ACS, Committee on Trauma (COT); credentialing requirements for MDH designated Level III/IV trauma facilities are outlined in the MN Trauma Hospital Resource Manual.[3]

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[3] http://www.health.state.mn.us/traumasystem/hospresources/resourcemanual

Volume Trending

The trauma patient population described above should be monitored to quantify the hospital's trauma service volume. This number will serve as a denominator and help the trauma program to measure resource and service utilization, morbidity and mortality rates, provider performance, and other relevant aspects of the service. This information can also be used to help target service needs, such as resources or staff, and establish thresholds for performance improvement. For instance, tracking the number of direct admissions from the emergency department to the operating room (OR) correlated with the time of day or day of week could help determine OR staffing needs. Likewise, tracking the incidence of complications correlated with specific population characteristics (i.e., DRG, ICD-9, or other classification systems) can establish the need to develop a practice guideline.

Process Measures

The use of process indicators to measure, evaluate, and improve system performance is an important component of the trauma PI plan. Process expectations can be developed from committee consensus, hospital policies, evidence-based practice guidelines, system protocols, or the state or regional trauma plan. There are a number of categories the trauma program may want to focus on initially, including compliance with established protocols, timeliness and availability of providers or services, availability of facilities (operating room, ICU beds, etc), delays in assessment, diagnosis, or care, appropriateness of triage decisions and transport destinations, communication issues, completeness of documentation, etc. Each performance expectation must be clearly defined, measurable, and obtainable within reason.

The following are examples of process indicators used by trauma centers; others are listed in Appendix A:

- Patients who require operative control of a brain, thoracic, or abdominal injury will be admitted to the operating room within one hour of admission to the emergency department.
- Patients who require transfer to a higher-level care facility will be transferred within two hours of admission to the emergency department.
- Patients who meet physiologic or anatomic triage criteria will be evaluated by the appropriate level of trauma team upon their arrival to the emergency department.
- Patients who require higher level care will receive airway, breathing and circulation management in accordance with priorities of ATLS.
- Patients with a GCS $\leq$ 8 will have a mechanical airway established within 5 minutes of arrival to the emergency department.
- Patients with pneumothorax or hemothorax will have an appropriate sized chest tube placed within 15 minutes of diagnosis.

- Patients with unstable physiologic parameters will have two large bore IVs established.

Outcome Measures

There are a number of variables that have traditionally been used to measure the outcome of trauma care including morbidity, mortality, length of hospital and intensive care unit stay, resource utilization, cost, functional disability, and patient satisfaction. Appendix A contains examples of both adult and pediatric process and outcome measures. Complications and injury-related deaths need to be evaluated by the trauma peer review committee or trauma committee for preventability using a pre-defined, standardized methodology that includes categorizing findings. Complications should be determined using pre-established definitions such as those defined by the American College of Surgeons, Committee on Trauma (ACSCOT), NTDB, or in the MTR manual for data abstraction and reporting. In addition, CMS present on admission, "never" or "no payment", conditions should be identified and tracked as to cause.

The trauma service should prepare an annual report describing the service's trauma patient population and performance, including outcome rates. Deaths and complication rates should be presented with a defined denominator. For example, the overall trauma mortality rate equals all trauma deaths divided by all trauma admissions. Rates for mortality or morbidity can also be calculated by service, provider, or injury. For small, low volume trauma facilities the trauma program should include information regarding the total number of trauma patients seen, number of patients transferred for higher level care, mode of transport (air versus ground), average time to transfer, mean ED length of stay, percentage of patients admitted to the hospital, number of patients who received operative control of hemorrhage, mean ISS, percentage of deaths, rate of complications, and any other pertinent data, such as utilization of resources.

EVALUATION

The evaluation of trauma care should focus on all phases of trauma care process and outcomes as previously discussed. Important aspects or components of the care process should be reviewed using pre-defined criteria to determine whether the care provided met the expectation or standard. Inconsistent or ineffective care processes, reoccurring problems (trends), and sentinel events should be identified, improved, monitored, and re-evaluated to determine the success in resolving the problem. Monitoring and evaluating care processes can be accomplished through a variety of methods including trauma registry data analysis, concurrent review (daily patient rounds), or focused audits.

Morbidities and mortalities should be evaluated to determine preventability and as to whether their occurrence is disease or provider related or resulted instead from a system failure. A disease related morbidity or death is an anticipated sequela of a disease, medical illness, or injury. A provider associated

complication results from delays and errors in the treatment provided by a health care provider. A system failure results from the unavailability or delay of a service or facility, such as a CT scanner or operating room. The case review determination methodology (adapted from the ACSCOT) described in Appendix D or a similar model can be used to categorize errors in technique, judgment, treatment, etc, and determine preventability.

IMPROVEMENT OPPORTUNITIES AND CORRECTIVE ACTION

The primary objective of trauma hospital PI is to decrease unnecessary death and disability by reducing inappropriate variation in care, and assuring that program expectations, standards, and benchmarks are met. An effective PI program results in the implementation of improvement initiatives to correct care issues that have been identified using the methods described above. .

When a reoccurring problem, sentinel event, or inappropriate variation occurs, improvement initiatives or actions are developed and documented by the trauma PI committee or peer review committee. The goal of the corrective action initiative is to reduce variation in care and improve outcome by eliminating the identified problem. The action plan should include: who or what is going to change; who is assigned responsibility for problem resolution; what action will be taken and when it will occur; and who is responsible for follow-up and when it will occur. Examples of corrective strategies include the revision of guidelines, protocols, or policies, targeted education, provider counseling, change in provider privileges

RE-MONITORING

An essential component in PI is demonstrating that a corrective action has the desired effect. The trauma program PI plan should include a method for assuring the effectiveness of corrective action by continuous re-evaluation. This evaluation usually occurs within three to six months (longer for low volume facilities) of the corrective action depending on the issue, and be thoroughly documented in the PI committee minutes. Documentation should include the following aspects of follow-up and re-evaluation:

- The time frame for problem follow-up
- The assignment of expectation indicators or a special study to review the problem
- The documentation of findings and any need for continued action
- Status of the problem until resolution is verified
- Results of re-monitoring of issue as scheduled

DOCUMENTATION AND REPORTING

The trauma hospital PI program includes complete, accurate and confidential documentation of ongoing monitoring, corrective action, progress, and re-evaluation. It is important that trauma staff understand MN law governing PI and peer review and take appropriate measures to protect PI records and review proceedings from disclosure. A responsible PI program assures that information is handled in a strictly confidential manner.

The following measures are suggested to protect patient information:

- Use of a locked file for all relevant information
- Use of a confidentiality statement/agreement for all participants in PI activities such as that contained in Appendix F
- Sanction for any breaches of confidentiality
- Shredding of all copies of PI documentation
- Security efforts at PI meetings such as numbering and collection of all papers
- Use of security procedures when mailing or transmitting PI documentation including addressing all correspondence to an assigned person, clearly marking all letters "confidential", removing all patient identifiers, dates, and locations of scenes from information, particularly when used for education; providing direct supervision, e.g., staff standby at the receiving facsimile when faxing PI documents such as case summaries between hospitals
- Notation or citation of relevant statutory protection on all printed PI materials including email.

Minutes from the review committee need to well documented including candid discussion of the problem, case determination findings, improvement actions, and a defined process for re-evaluation until the problem is resolved. A tracking form (Appendix E) or similar tool may be useful to track the problem through committee review, interdepartmental evaluation, action plan implementation, and loop closure.

The trauma program should prepare an annual report of the program's overall performance that includes benchmarking accomplishments, complication and mortality rates, preventability rates, length of stay, resource utilization, and other measures of outcome. This report should also include a description of the program's successes or failures to resolve identified problems. For small, low volume trauma facilities, this report might instead contain a simple description of the trauma population treated (as suggested above under "Outcome Measures") using measures, such ED length of stay or time to transfer, etc. to benchmark performance. This report should be shared with the hospital's medical executive

committee (MEC), key leadership responsible for program oversight, and other pertinent committees or leadership.

The reporting of trauma center performance and outcomes to the regional trauma PI committee and state agency (MDH) responsible for the trauma care system will be discussed below.

INJURY REHABILITATION PERFORMANACE IMPROVEMENT

PURPOSE AND GOALS

Traumatic injuries are a major cause of short and long-term disability. Injuries to the brain and spinal cord can result in serious, long-term physical and cognitive disability and secondary conditions such as pressure sores, depression, loss of employment and career, loss of productivity, family stress and dysfunction, etc. Injuries to the lower limbs, long bones, back, and eye can significantly impair mobility and function and have a profound impact on quality of life. Injuries can also cause a variety of psychosocial problems, such as post-traumatic stress disorder, depression, alcohol and drug abuse or dependence, and difficulty in returning to pre-injury routines and lifestyle.

Trauma systems are designed to triage the most seriously injured patients to the most appropriate acute care hospitals (trauma centers) equipped with resources for optimal trauma care. The intent of trauma systems is to decrease the risk of injury through injury prevention efforts and prevent further injury or insult by providing early, optimal treatment including rehabilitative care. Trauma systems organize and coordinate trauma care resources to provide consistent, timely care from 9-1-1 dispatch through rehabilitation. Where these systems are lacking, patients may experience adverse outcomes due to preventable problems in patient management, including missed diagnoses and treatment delays.

Although many injured patients are treated and return to their pre-injury quality of life, others require extensive, prolonged in-hospital care and post-hospital rehabilitative services. The ultimate goal of trauma care is to return the patient to his or her pre-injury state. A coordinated, multidisciplinary approach to early rehabilitative care produces the most favorable patient outcomes in restoring pre-injury status or an optimal level of functioning.

Outcome measures that quantify physical and cognitive disability and quality of life can be used to focus care in specific areas, monitor treatment progress, and assess the outcome of rehabilitated trauma patients. Applying these measures can help monitor the effectiveness of the trauma system in reducing injury-related disability and identify opportunities to improve performance. Outcome measures can also be useful in conducting special studies or research about specific clinical interventions or therapies.

The specific goals of disability and rehabilitation performance improvement are to:
- Alleviate unnecessary disability from trauma by reducing inappropriate variation in care and promoting optimal patient care practices.
- Identify opportunities to reduce the risk of injury and mitigate the effects of injuries that do occur.
- Evaluate trauma care delivery processes and interventions for reducing

disability and secondary conditions, including preventable complications associated with certain injuries.

STRUCTURE

A comprehensive systems approach to trauma care should include a mechanism for monitoring and evaluating injury related disability and rehabilitative care over prolonged periods. Methods of measuring functional status, physical and cognitive impairment, quality of life, and cost should be employed to define the benefits and costs of trauma system care, and identify opportunities for performance improvement. In all aspects of trauma care, assessing outcomes and costs can provide valuable information for developing policies and practices at the state and local levels.

Hospitals and rehabilitation centers at all levels should routinely monitor and evaluate the process of rehabilitative care and its outcomes. This includes incorporating into the trauma hospital or rehabilitation center PI program, techniques that measure the effectiveness, efficiency, and accessibility of rehabilitation services.

At the local trauma center, these efforts should be integrated into existing hospital programs or services, and be part of the routine monitoring of trauma patient status from admission to discharge. Physical and cognitive assessment information should be documented soon after admission and monitored throughout the patient's hospitalization and rehabilitation. Trends, significant findings, and outcome data should be reviewed by the multidisciplinary trauma committee that includes physiatrist representation, and used to support performance improvement initiatives as well as to benchmark against past performance and regional averages.

The Commission on Accreditation of Rehabilitation Facilities (CARF) requires accredited rehabilitation centers to collect and use information in a manner that contributes to administrative and clinical decision making. Data about functional ability, cognitive status, costs, length of stay, patient satisfaction, and discharge disposition should be collected to determine the effectiveness and efficiency of rehabilitative care services. Information about physical and cognitive ability collected upon admission and monitored through discharge is valuable to focus care, track treatment progress, and assess overall outcome. This information should be entered into a rehabilitation registry, such as the Uniform Data System for Medical Rehabilitation (UDS), and used by the PI team to track performance and identify opportunities to optimize patient outcomes.

The regional and state trauma PI committees in conjunction with the Minnesota Department of Health (MDH) should monitor and evaluate system-wide issues, such as problems with access, and outcomes of both acute and post-acute trauma care, including rehabilitation. This review should focus on determining

the effectiveness, efficiency, and accessibility of rehabilitative care from a state or region-wide perspective, and should identify aspects of the system that can be enhanced to improve patient outcomes. The likely best way to accomplish this would be to link all pertinent data sources, including the Uniform Data System (UDS) and Traumatic Brain Injury (TBI) database, with the MN trauma registry. This would provide comprehensive information about the injured patient from the injury event through rehabilitation.

PATIENT POPULATION

To ensure consistent PI monitoring and evaluation as well as data collection throughout the state, the MDH, with advice from the STAC, must define standardized criteria for identifying the trauma patient population. These criteria should be uniformly applied throughout the state, at all levels of care, to identify the population to be monitored and evaluated. The following criteria are suggested:

- Injured patients who meet state or regional criteria for trauma system care
- Injured patients who are discharged from the hospital with an ICD-9-CM diagnosis 800.00-959.9, excluding 905-909.9, 910-924.9, and 930-939.9
- All trauma related hospital admissions
- Any trauma related death
- Any trauma transfer either into or out of the hospital
- All complaints and high profile cases

DATA COLLECTION AND INFORMATION SOURCES

Specific, uniform data that describes the injury incident, demographics, prehospital information, diagnosis, treatment, rehabilitation, outcomes (including physical and cognitive status at hospital admission and discharge), and cost of care of injured patients should be collected by every hospital (prehospital data collected by EMS) and reported to the MN Trauma Registry (MTR). It is important that data be collected using standardized definitions as recognized by the Minnesota Trauma Registry. Data definitions should be consistent with those of the National Trauma Data Bank.

All pertinent injury related data collected and reported to database programs separate from the MTR should linked using a common identifier to provide comprehensive information about the patient from the injury event through rehabilitation. The MTR should ultimately be capable of providing patient-specific and aggregate data to regional and state committees responsible for evaluating system performance. The following information sources should be considered for data abstraction.

- Prehospital care reports and crash records
- Hospital medical records
- Rehabilitation medical records
- Interhospital transfer records if applicable
- Outcome and treatment data from rehabilitation centers
- Metrics about patients who meet rehabilitation criteria but cannot access treatment due to monetary reasons or scarcity of resources

SCOPE OF REVIEW AND KEY ACTIVITIES

People with injury-related disability need early, coordinated rehabilitative care if they are to return to a productive life, learn to compensate for their impairments, or achieve an optimal quality of life given the extent of their injuries. The services required by people disabled by injury are complex and often involve numerous areas of expertise including case management, continuing medical care, cognitive and physical therapies, family education, counseling and other non-clinical support services, such as social and vocational retraining, to achieve a successful outcome.

The process of rehabilitative care should be initiated as soon as possible after hospital admission to establish realistic goals and to determine the potential benefit of rehabilitation. Consultation from rehabilitation services or a physiatrist should be sought early to identify rehabilitation needs and plan for specific components of therapy, both within the hospital setting and after discharge.

A major objective of trauma systems is to reduce the incidence of injury through injury prevention efforts and prevent further injury or insult by providing early, optimal treatment, including rehabilitative care. The effectiveness of injury prevention programs, efficacy of care, access to services, early assessment, planning, and initiation of therapies, occurrence of complications and secondary conditions, and outcomes are all important aspects of the trauma system that warrant evaluation. Monitoring and assessment of these components should be incorporated as part of the local trauma center or rehabilitation center's PI program, and be included in the review of system performance at the regional and state level.

Injury Prevention
Injury prevention efforts can be very effective when they target specific high risk groups. Trauma centers, prehospital care providers, local community groups, and governmental agencies can work together to develop, coordinate, and implement strategies designed to prevent or reduce the incidence of injury-related death and disability. These endeavors include epidemiology research, surveillance monitoring, education, and legislative/regulatory enactment and enforcement.

Injury Rehabilitation Performance Improvement

Trauma registry data combined with vital statistics information should be used to characterize the frequency and patterns of injury within the local community, region, or state, and identify high-risk groups who may benefit from injury prevention interventions. These data should also be used to prioritize injury prevention efforts as well as to monitor the effectiveness of these interventions in reducing injury-related death and disability.

Trauma centers, rehabilitation facilities, and the state and regional trauma systems must seek opportunities or teachable moments to provide injury prevention services or interventions. For example, injured patients treated in the trauma unit can be screened for drug and alcohol problems and provided intervention or the parent of an injured child given instruction on the proper use of safety restraints. Specific, at-risk groups or patients should be routinely identified and provided with the appropriate injury prevention education or intervention. These injury prevention efforts should be regularly monitored by the trauma PI program. The PI tracking form should include an indicator as to whether or not an injury prevention intervention was provided to the patient who met pre-defined criteria for injury prevention services.

The trauma hospitals with guidance from the state should establish expectations for injury prevention activities. Every hospital, regardless of size, must actively participate in the effort to reduce injury-related death and disability by implementing injury prevention programs or collaborating with other groups. It is only through these efforts that the enormous personal and societal costs, both direct and indirect, of injury can be reduced.   The hospital's participation in injury prevention programs should be monitored by the MDH as part of its trauma center designation process.

Rehabilitation Services
A systems approach to trauma care involves triaging the most seriously injured to a trauma center that is best equipped to provide optimal care, including rehabilitation. The goal of trauma systems is to return patients to their pre-injury status (physical and cognitive) or an optimal level of independent functioning. This requires access to appropriate rehabilitation services on or soon after the first day of hospital admission through discharge and post-acute recovery.

Rehabilitation should be coordinated using a multidisciplinary approach with a physiatrist (if available) assuming leadership of the rehabilitation team. Every patient should be assessed for rehabilitation as soon as possible in their hospitalization to identify rehabilitation needs and establish realistic goals for optimal recovery. This assessment should include factors such as the patient's family support system. Case management should also be established early to coordinate therapies, social services, vocational needs, and discharge planning for post-acute care (skilled nursing rehabilitation, out-patient rehabilitation, in-home rehabilitation, long-term care, etc.).   Rehabilitation needs should be

prioritized to avoid secondary conditions, such as pressure ulcers, behavior changes, depression, etc.

Acute rehabilitation is a specialty that provides an intensive inpatient program to enable people who have suffered major injury the skills needed to return to the community. This type of injury often involves the central nervous system and musculoskeletal systems. Acute rehabilitation covers everything from regaining the ability to walk after an amputation, to talking after a traumatic brain injury, to being able to safely function at home.

Post-acute rehabilitation seeks to accomplish the same goals as acute rehabilitation through an integrated team approach provided in a skilled nursing facility, out-patient rehabilitation center, long-term care setting, or in the home. Specialized rehabilitation services including occupational, speech, and physical therapies are provided to restore maximum function and quality of life.

The likelihood of receiving comprehensive rehabilitation after trauma in a specialized rehabilitation facility unfortunately may depend on the patient's insurance status and ability to pay. Uninsured and lower income individuals may not be able to access the post-acute services they need. This in turn may lead to a significant individual and societal burden in terms of lost productivity, prolonged or permanent disability, and cost. Access to proper acute and subsequent rehabilitative care is essential to restore an individual to his or her pre-injury status or optimal level of functioning. This aspect of trauma care should be monitored and evaluated at the local, regional, and state level.

Data collected by the trauma registry, through focused studies or audits, daily hospital rounds, or other databases should be routinely assessed to evaluate the process of rehabilitative care and its outcomes. Indicators or expectations of performance should be established and incorporated at all levels of system evaluation (local, regional, and state). Measures of functional or cognitive ability, such as the Functional Independence Measure (FIM), Glasgow Coma Scale (GCS), Disability Rating Scale (DRS), Rancho Scale of Cognitive Functioning, etc., should be documented on admission to the hospital or rehabilitation center and at discharge to track treatment progress and outcomes. This information should ultimately be reported to the MN trauma registry for more global analysis.

Outcomes
Measuring outcomes, such as injury disability (physical and cognitive impairment), morbidity, mortality, quality of life, functional status, cost, and length of stay, will help define the benefits and costs of trauma system care. In all aspects of trauma care, evaluating outcomes will likely produce valuable information needed to develop sensible policies and practices throughout the state of Minnesota. Analyzing trauma outcome data is needed to understand the causes and frequency of injury, evaluate the process of care, and determine the effectiveness of the trauma system in reducing injury related death and disability.

Evaluating outcomes can often identify opportunities to enhance system performance to increase efficiency, effectiveness, accessibility, and patient satisfaction. Outcomes analysis is also useful in conducting special studies or research about specific injuries and clinical interventions.

There are a number of variables that have traditionally been used to measure the outcome of trauma care including morbidity, mortality, length of hospital and intensive care unit stay, resource utilization, cost, functional disability, and patient satisfaction. Appendix B contains examples of outcome measures that should be routinely collected and reported to the state trauma registry. As stated previously, measures of functional and cognitive ability, such as the Functional Independence Measure (FIM), Glasgow Coma Scale (GCS), Glasgow Outcome Score (GOS), Disability Rating Scale (DRS), Rancho Scale of Cognitive Functioning, etc., should be documented on admission to the hospital or rehabilitation center (baseline) and periodically until discharge (outcome), and if feasible at regular intervals thereafter. The purpose of this is to focus care in specific areas, track treatment progress, and assess the effectiveness of care.

Tools that can be used to assess functional status, cognitive function, quality of life, psycho-social status, etc. are listed in Appendix B. The MDH and STAC PI committee should select the most practical, feasible rehabilitation outcome measures for statewide collection and reporting to the MTR. Commonly used outcome measures of disability include:

- Functional Independence Measure (FIM) – This tool is used to measure functional abilities, such as being able to care for oneself, ambulate, respond, communicate, and remember things.
- Disability Rating Scale (DRS) – This tool measures impairment, disability, and handicap; it useful to track an individual from coma to integration back into the community.
- Rancho Scale of Cognitive Functioning – A behavioral rating scale for assessment of cognitive functioning (Hagen, Malkmus, and Durham, 1979). The Rancho levels are used to classify patients for treatment and tracking their progress throughout recovery.
- Short Form Health Survey (SF)-36 - A generic quality of life survey that measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health

EVALUATION

The evaluation of trauma care must focus on all phases of the care continuum, including rehabilitation, and outcomes. At the local level, important aspects of rehabilitative care, such as access to services, patient assessment, initiation of therapies, occurrence of secondary conditions, and outcomes should be

reviewed using pre-defined criteria (consistent with evidenced-based practices, national definitions, state standards, etc.) to determine whether the care provided met expectations. Inconsistent or ineffective care processes, reoccurring problems (trends), and sentinel events should be identified, improved, monitored, and re-evaluated until the desire change is observed. Monitoring and evaluating the process of rehabilitation care and its outcome can be accomplished through a variety of methods including analysis of trauma registry data coupled with other data sources (Vital Statistics, TBI, Hospital Discharge Index (HDI), etc.), concurrent review (daily patient rounds), or focused studies or audits.

Adverse or unexpected outcomes should be evaluated to determine their preventability and whether their occurrence is disease or provider-related, or resulted from a system failure. A disease-related morbidity or death is an anticipated sequela of a disease, medical illness, or injury. A provider-associated complication results from delays and errors in the treatment provided by a health care provider. A system failure results from the unavailability of service or facility, such as a rehabilitation service. The case review determination methodology (adapted from the ACSCOT) described in Appendix D or a similar model can be used to categorize errors in technique, judgment, treatment, etc, and determine preventability

In the trauma center or rehabilitation setting, complications, secondary conditions, and deaths need to be evaluated by the peer review committee or trauma committee for preventability using a pre-defined, standardized methodology that includes categorizing findings. Complications should be determined using pre-established definitions such as those defined by the American College of Surgeons, Committee on Trauma (ACSCOT), NTDB, or in the MTR manual for data abstraction and reporting. CMS "never" events should also be tracked and trended.

The state and regional trauma committees, in conjunction with MDH should analyze statewide and region-specific aggregate trauma data to identify patterns or trends in care, evaluate outcomes, and recommend improvement initiatives as indicated by the results. This is accomplished through a multidisciplinary PI subcommittee, preferably chaired by a trauma surgeon and staffed by the MDH.

The state PI subcommittee should establish pre-defined measures or expectations of care based on evidenced based guidelines, state policy and standards, or derived out of consensus. These measures should serve as the basis for evaluating care processes and outcomes throughout the system. All levels of review should include comparison and benchmarking of outcomes of hospitals, rehabilitation services, trauma regions, and the state using data obtained from other states, regions, or nationally.

If state level resources permit, research studies can be conducted through the lead agency with consultation or oversight provided by the state PI committee. If

a Level I trauma center with research capabilities exists in the state, the PI committee and lead agency should work in cohort with that center to conduct outcomes-related research.

IMPROVEMENT OPPORTUNITIES AND CORRECTIVE ACTION

The primary objective of trauma system PI is to decrease unnecessary death and disability by reducing inappropriate variation in care, and assuring that expectations, standards, and benchmarks are met. When a reoccurring problem, sentinel event, or inappropriate variation occurs, improvement initiatives or actions are developed to increase the effectiveness and efficiency of care, and maximize patient outcomes. The action plan should include: who or what is going to change; who is assigned responsibility for problem resolution; what action will be taken and when it will occur; and who is responsible for follow-up and when it will occur. Examples of corrective strategies include the revision of guidelines, protocols, or policies, targeted education, provider counseling, and change in privileges, accreditation, etc.

RE-MONITORING

An essential component of PI is demonstrating that a corrective action has the desired effect. A continuous pursuit to evaluate the effectiveness of corrective action should be employed until the problem is eliminated or satisfactorily reduced. This evaluation should occur within three to six months of the corrective action depending on the issue, and be thoroughly documented in the PI committee minutes. Documentation should include the following aspects of follow-up and re-evaluation:

- The time frame for problem follow-up
- The assignment of expectation indicators or a special study to review the problem
- The documentation of findings and any need for continued action
- Status of the problem until resolution is verified

DOCUMENTATION AND REPORTING

Performance improvement includes complete, accurate, and confidential documentation of ongoing monitoring, corrective action, progress, and re-evaluation. It is important that trauma staff understand MN law governing PI and peer review and take appropriate measures to protect PI records and review proceedings from disclosure or discovery. A responsible PI program assures that information is handled in a strictly confidential manner.

The following measures are suggested to protect PI information:

- Use of a locked file for all relevant information
- Use of a confidentiality statement/agreement for all participants in PI activities such as that contained in Appendix F
- Sanction for any breaches of confidentiality
- Shredding of all copies of PI documentation
- Security efforts at PI meetings such as numbering and collection of all papers
- Use of security procedures when mailing or transmitting PI documentation including addressing all correspondence to an assigned person, clearly marking all letters "confidential", removing all patient identifiers, dates, and locations of scenes from information, particularly when used for education; providing direct supervision, e.g., staff standby at the receiving facsimile when faxing PI documents such as case summaries between hospitals
- Notation or citation of relevant statutory protection on all printed PI materials including email.

Minutes from the review committee need to well documented including candid discussion of the problem, case determination findings, improvement actions, and a defined process for re-evaluation until the problem is resolved. A tracking form (Appendix E) or similar tool may be useful to track the problem through committee review, interdepartmental evaluation, action plan implementation, and problem resolution.

An annual report of the program or system's overall performance that includes benchmarking accomplishments, complication and mortality rates, disability rates, preventability rates, length of stay, resource utilization, and other measures of outcome should be prepared by the oversight entity. This report should also include a description of the program's successes or failures to resolve identified problems. This report should be shared with the appropriate organizational leadership, governmental agency, and other pertinent individuals or entities responsible for program or system oversight.

The reporting of trauma center performance and outcomes to the regional trauma PI committee and state agency (MDH) responsible for the trauma care system will be discussed below.

REGIONAL PERFORMANCE IMPROVEMENT

PURPOSE AND GOALS

The purpose of performance improvement (PI) at the regional trauma system level is to measure, evaluate, and improve the processes and outcome of trauma care delivery within the region as well as with bordering areas through the state PI process. This includes assessment of all phases and levels of the trauma care continuum from 9-1-1 dispatch through rehabilitation. The regional PI plan emphasizes a continuous multidisciplinary effort to optimize trauma care, and thus reduce unnecessary death and disability, by performing progressive cycles of performance review to assure that system expectations, standards, and benchmarks are met. Reoccurring problems and/or inappropriate variations in care are corrected by implementing improvement initiatives that are based on optimal care practices. When a reoccurring problem, sentinel event, or inappropriate variation occurs, improvement initiatives or actions are developed to increase the effectiveness and efficiency of care, and maximize patient outcomes.

The regional PI plan establishes lines of communication, structure, authority and accountability for monitoring system components and aspects of care, and defines standards by which performance and outcomes are measured.

AUTHORITY

The MDH is the lead governmental agency authorized by law to develop and oversee a comprehensive, statewide trauma system PI program. The MDH has legal authority to monitor, evaluate, and improve the process of trauma care and its outcomes throughout the state. The MDH is responsible for:

- Developing a comprehensive, statewide process to monitor, evaluate, and improve trauma system performance, as a whole and by its regions.
- Establishing, in conjunction with the STAC, pre-defined measures or expectations of care based on evidenced-based guidelines, state policy and standards, or derived out of consensus
- Providing direct oversight and administration of PI activities of the state and regional trauma committees.
- Implementing corrective action strategies or initiatives based on the PI committee's findings and recommendations. With proper oversight the lead agency may empower the regional trauma committee to implement improvement initiatives that are not regulatory in nature such as evidenced-based practice guidelines.
- Communicating problems, trends, and issues identified by the state and regional PI committees to the responsible entity such as

ambulance service and/or air medical, healthcare organization, other agencies, county health officials, etc. Communication of PI activities may be delegated to the regional PI committee given that the MDH provides oversight.

- Initiating action required to avert a potential emergent public health risk.
- Collecting, evaluating, validating, and communicating trauma data.
- Developing and enforcing statutes, rules, policies, and procedures for data security and confidentiality protection for all aspects of the state PI program.

STRUCTURE

Trauma system PI at the regional level is performed by the Regional Trauma Advisory Council (RTAC) with guidance and oversight provided by the Minnesota Department of Health (MDH). The RTAC may wish to establish a subcommittee for PI (recommended) or may choose to take on the task of monitoring, evaluating, and improving regional trauma care at the committee level in an executive session. Regardless of the configuration, the review committee should include representation from each trauma center* (physician and trauma nurse coordinator), EMS including 9-1-1 dispatch, non-trauma hospitals, and the county medical examiner/coroner, and air medical service as appropriate. Membership should be established with specified, staggered terms of appointment and a Chair, preferably a trauma surgeon, should be appointed. A staff person, usually the trauma nurse coordinator from the region's lead trauma center, should be assigned to coordinate meeting activities. The suggested membership includes:

- General surgeon or trauma medical director*
- Emergency physician
- Neurosurgeon as available
- Orthopedic surgeon as available
- EMS medical director
- Trauma nurse coordinator/program manager*
- Medical examiner or coroner
- Emergency nurse
- ALS & BLS EMT
- First responder
- Communications specialist (9-1-1)
- Air medical representative (clinical)

The regional trauma PI committee is responsible for analyzing region-specific trauma data to assess the effectiveness of the regional trauma system in reducing unnecessary death, disability, and cost. In addition, the committee is responsible for addressing regional system issues or concerns and monitoring the availability and use of resources (hospital bypass or service diverts, air

ambulance, inter-hospital transfers and transport, etc). Another key aspect of regional PI is the review of mortality cases to determine preventability rates, practice variation, and seek improvement opportunities.

Monitoring and evaluation is ongoing and systematic, opportunities to reduce inappropriate variation in care are sought, and strategies to improve care and optimize outcomes are documented in a corrective action plan. Improvement initiatives that are developed to correct issues or problems are communicated by the RTAC (or its PI subcommittee) to the appropriate individual or entity for action. The effectiveness of corrective action is evaluated through continuous re-monitoring as the PI cycle repeats itself.

RESPONSIBILITIES

Regional Trauma Advisory Council (PI Committee)

1. Convene monthly to quarterly or as directed by state statutes, local ordinance, or committee operating procedures..
2. Communicate PI-related information to the designated persons within each treatment setting. For example:
   a) Prehospital issues will be referred to EMS agency director or designee.
   b) Hospital issues will be referred to the trauma program medical director and trauma nurse coordinator/program manager.
   c) Interhospital transfer issues will be referred to the responsible persons at both the referring and receiving hospitals.
3. Provide an annual (or quarterly) report describing trends, problems, improvement opportunities, and recommendations for corrective action to the to the MDH Trauma Program and STAC PI committee.
4. Notify the MDH Trauma Program of high-risk situations where patient safety may be compromised.

Minnesota Department of Health Trauma Program

1. Provide oversight of regional performance improvement program.
2. Provide trauma registry and other pertinent data as appropriate.
3. Evaluate and implement, as appropriate, the regional committee's recommendations for corrective action and system improvement.
4. Communicate trends, problems, and outstanding issues identified by the committee to responsible entities such as ambulance services, healthcare organizations, county health officials, etc.
5. Implement action required to correct potential emergent public health risk.

6.   Oversee the confidentiality of performance improvement activities through supervision, consultation, and education.

PATIENT POPULATION

To ensure consistent PI monitoring and evaluation as well as data collection throughout the state, the MDH, with advice from the STAC, must define standardized criteria for determining the trauma patient population.   These criteria should be uniformly applied throughout the state for all levels of care to identify the population to be monitored and reviewed. The following criteria are suggested:

- Injured patients who meet state or regional criteria for trauma system care
- Injured patients who are discharged from the hospital with an ICD-9-CM diagnosis 800.00-959.9, excluding 905-909.9, 910-924.9, and 930-939.9
- All trauma related hospital admissions
- Any trauma related death
- Any trauma transfer either into or out of the hospital
- All complaints and high profile cases

DATA COLLECTION AND INFORMATION SOURCES

Performance improvement in trauma care consists of ongoing and systematic monitoring, evaluation, management, and documentation of performance.   To identify opportunities for improvement, the PI process must be supported by a valid and objective method of data collection.   Specific, uniform data that describes the injury incident, demographics, prehospital information, diagnosis, treatment, rehabilitation, outcomes, and cost of care should be collected by every hospital and reported to the MN Trauma Registry. It is imperative that data be abstracted and reported using standardized definitions as recognized by the MN Trauma Registry.   Data definitions should also be consistent with those of the National Trauma Data Bank. Prehospital data, if not collected and reported by the hospitals, should be linked or uploaded into the MN Trauma Registry. Data validation should be performed for at least five percent of the cases reported to the MTR.   A discussion of trauma registry data validation is contained in Appendix K.

Data is collected on an ongoing basis using information sources that are reliable and accessible.   Many useful sources of information are available to perform monitoring and evaluate the efficacy, cost, and outcome of trauma care.   The following information sources should be considered for routine or periodic monitoring of the hospital's trauma program:

- Prehospital care reports including non-transporting agency, i.e., first responder
- Hospital medical record
- Public safety records;(these records provide information that may not included in the prehospital care record)
- 9-1-1 dispatch records
- Interhospital transfer records if applicable
- Autopsy findings (these may be difficult to obtain in rural areas)
- Hospital trauma registry data and external benchmarking data (MN Trauma Registry or National Trauma Data Bank (NTDB). This information is useful for trending data, performing comparative analysis, and benchmarking.
- Checklists from review of trauma resuscitation videotapes
- Complaints from all sources
- Performance improvement findings from other review committees
- System plan, protocols, policies, procedures, practice guidelines, etc.

SCOPE OF REVIEW AND KEY ACTIVITIES

A major objective of trauma systems is to reduce the incidence of injury through injury prevention efforts, and minimize trauma-related death and disability by providing early, optimal care. The effectiveness of injury prevention programs, efficacy of care, timeliness of care, access to providers and services, and outcomes are all important aspects of the regional trauma care system that should be monitored and evaluated to identify opportunities for improvement.

The traditional use of quality indicators to measure the effectiveness of trauma care delivery may have limited value since many do not correlate with outcome. Indicators, however, may be useful for trending incidents, sentinel events, and establishing benchmarks for performance and comparative analysis. They can be used to identify cases for review and may offer an alternative for evaluating process, outcomes, and consistency of care. Indicators or expectations of care should be developed from evidence-based guidelines, critical pathways, protocols, or consensus. Appendix A contains examples of quality indicators reflective of varying aspects of the trauma care process.

Volume Trending

The trauma population described above or as defined by the STAC will quantify the region's trauma volume. This number will serve as a denominator enabling the RTAC to monitor injury epidemiology, resource utilization, morbidity and mortality rates, and system needs including services, provider or public education, injury prevention, etc. Using geo-coding software, this information can be mapped out to effectively demonstrate system shortcomings or problems, and point out opportunities for improvement.

Process Measures

The use of process indicators to measure, evaluate, and improve system performance is an important component of the regional trauma PI plan. Process expectations can be developed from evidence-based practice guidelines, system protocols, state or regional trauma plans, or committee consensus. There are a number of review aspects that the RTAC may want to initially focus on, including compliance with established protocols, timeliness and availability of providers or services, availability of facilities and equipment, delays in assessment, diagnosis, or treatment, appropriateness of triage decisions and transport destinations, communications, completeness of documentation, etc. Each performance expectation must be clearly defined, measurable, and obtainable within reason. The following are examples of performance measures for regional PI; others are listed in Appendix A:

- EMS with total on scene of >15 minutes, excluding patients who require prolonged extrication.
- Patients who require higher level definitive care will be transferred within 2 hours hospital arrival.
- Patients who meet physiologic trauma triage criteria will undergo evaluation and treatment by the "full" trauma team upon their arrival in the emergency department, providing that the hospital received >10 minutes pre-notification. The trauma surgeon will be present upon arrival to a Level I trauma center; within 15 minutes from notification at a Level II trauma center; within 30 minutes of notification at a Level III trauma center.
- Patients who were transported by EMS to a trauma center for management of injuries who had a length of stay (LOS) less than 6 hours.
- Patients who required endotracheal intubation within five (5) minutes of hospital arrival.
- Delay in transfer or operative procedure for hemodynamically unstable patients (transient responder, SBP<90 mmHg, etc) due to diagnostic imaging.
- Patients transferred due to lack of availability of a surgical subspecialist.

Outcome Measures

There are a number of variables that have traditionally been used to measure the outcome of trauma care including morbidity, mortality, length of hospital and intensive care unit stay, utilization of resources and services, cost, functional and cognitive disability, and patient satisfaction. Appendices A and B contain examples of process and outcome measures.

All injury-related deaths within the region need to be monitored and evaluated by the RTAC PI committee for preventability using a pre-defined, standardized methodology that includes categorizing findings. Preventable mortality rates

should be reported annually to the MDH and STAC PI along with any significant associated trends. Complications should be categorized by the trauma center's PI review process using pre-established definitions, such as those defined by the American College of Surgeons, Committee on Trauma (ACSCOT), NTDB, or in the MTR manual for data abstraction and reporting. Trauma centers and hospitals throughout the state are required to report complications for each and every injured patient who meets criteria for reporting to the MTR. The MDH, in turn, is expected to provide annual reports detailing complication and mortality rates, incidence of disability, LOS, cost of care, and other measures of outcome to each region. This information should be stratified by hospital, injury severity, injury type, age, etc. In addition, CMS "never" or "no payment", conditions should be identified and tracked by the region.

Mortality Review

All trauma-related deaths occurring within the region's catchment area should undergo at least a cursory screening evaluation using pre-defined criteria to determine preventability. Any provider related mortality, unexpected death (per probability of survival prediction modeling), or challenging or interesting cases should be presented at the regional PI committee level in a peer review format.

An alternative method to reviewing deaths is to assign each committee member 1-2 cases to review and have them present their findings to the full committee. Regardless of the methodology used, the review must be timely, objective, and include all pertinent data including autopsy findings, if available. At the completion of the case review, the committee will assign a determination that establishes judgment as to preventability of mortality using a model similar to that outlined in Appendix D.

As discussed earlier, death, complication, and other rates of outcome and preventability determinations should be reported to the MDH and/or STAC PI committee using a defined denominator. These can be calculated and trended for each trauma center and prehospital care provider within the region, and reviewed annually to determine the need for performance improvement action. Any regulatory action that is required will be implemented by the MDH responsible for oversight of the trauma system PI process.

EVALUATION

The RTAC PI committee must conduct its meetings in a manner that ensures the honest appraisal of medical care. In some regions, this may require staggered or alternate meeting times with physician or hospital related aspects of care separated from the review of prehospital care. Regardless of how the committee meetings are conducted, the review of care must be multidisciplinary and unbiased.

Expectations or standards of care developed from evidence-based guidelines, protocols, consensus of important aspects of care and associated indicators, statutes, rule or ordinance are useful in measuring the effectiveness and consistency of care, and outcomes. A standardized methodology, such as described in Appendix D or similar models, should be used to guide case review determinations.

IMPROVEMENT OPPORTUNITIES AND CORRECTIVE ACTION

The primary objective of trauma system PI is to decrease unnecessary death and disability by reducing inappropriate variation in care, and assuring that expectations, standards, and benchmarks are met. When a reoccurring problem, sentinel event, or inappropriate variation occurs, improvement initiatives or actions are developed to increase the effectiveness and efficiency of care, and maximize patient outcomes. The action plan should include: who or what is going to change; who is assigned responsibility for problem resolution; what action will be taken and when it will occur; and who is responsible for follow-up and when it will occur. Examples of corrective strategies include the revision of guidelines, protocols, or policies, targeted education, provider counseling, and change in privileges, accreditation, etc.

RE-MONITORING

An essential component of PI is demonstrating that a corrective action has the desired effect. A continuous pursuit to evaluate the effectiveness of corrective action should be employed until the problem is eliminated or satisfactorily reduced. This evaluation should occur within three to six months of the corrective action depending on the issue, and be thoroughly documented in the PI committee minutes. Documentation should include the following aspects of follow-up and re-evaluation:

- The time frame for problem follow-up
- The assignment of expectation indicators or a special study to review the problem
- The documentation of findings and any need for continued action
- Status of the problem until resolution is verified

DOCUMENTATION AND REPORTING

Performance improvement includes complete, accurate, and confidential documentation of ongoing monitoring, corrective action, progress, and re-evaluation. It is important that the RTAC PI committee members understand MN law governing PI and peer review and take appropriate measures to protect PI records and review proceedings from disclosure. A responsible PI program assures that information is handled in a strictly confidential manner.

The following measures are suggested to protect PI information:

- Use of a locked file for all relevant information
- Use of a confidentiality statement/agreement for all participants in PI activities such as that contained in Appendix F
- Sanction for any breaches of confidentiality
- Shredding of all copies of PI documentation
- Security efforts at PI meetings such as numbering and collection of all papers
- Use of security procedures when mailing or transmitting PI documentation including addressing all correspondence to an assigned person, clearly marking all letters "confidential", removing all patient identifiers, dates, and locations of scenes from information, particularly when used for education; providing direct supervision, e.g., staff standby at the receiving facsimile when faxing PI documents such as case summaries between hospitals
- Notation or citation of relevant statutory protection on all printed PI materials including email

Minutes from the review committee need to well documented including candid discussion of the problem, case determination findings, improvement actions, and a defined process for re-evaluation until the problem is resolved. A tracking form (Appendix E) or similar tool may be useful to track the problem through committee review, hospital or agency follow-up, action plan implementation, and problem resolution.

Only one copy of the case determination findings and minutes should be maintained by the committee staff person in a secure manner. Documentation of committee meeting minutes, committee findings, reports regarding mortality and morbidity rates, and any other information concerning a hospital or prehospital care provider's performance should also be maintained by the staff person in a manner which protects against discovery or disclosure using the techniques suggested above.

An annual report of the region's overall performance that includes benchmarking accomplishments, complication and mortality rates, disability rates, preventability rates, length of stay, resource utilization, and other measures of outcome should be jointly prepared by the MDH trauma program and RTAC. This report should include a description of the region's successes or failures to resolve identified problems. The annual report should be directed to the MDH leadership responsible for trauma system oversight and shared with the STAC PI committee.

STATEWIDE PERFORMANCE IMPROVEMENT

PURPOSE AND GOALS

A systems approach to trauma care provides the best means to protect the public from premature death and prolonged disability. Trauma systems reduce death and disability by identifying causes of injury and promoting activities to prevent injury from occurring, and by assuring that the resources required for optimal care are organized and accessible. The development of a statewide system of care for the injured must include a mechanism to monitor, measure, assess, and improve the processes and outcome of care. The process must be a continuous, multidisciplinary effort to reduce inappropriate variation in care and improve the effectiveness of the system and its components including prehospital care (communication, dispatch, medical control, triage, and transport), hospital care, inter-facility management, rehabilitative care, and mass casualty disaster response.

Statewide performance improvement (PI) consists of multiple layers of continuous monitoring and evaluation of treatment processes to identify opportunities to optimize care and improve outcomes. This continuous cycle of evaluation extends from the PI programs of hospitals and emergency medical services (EMS) agencies to review committees established at the state and regional levels, and evaluation programs within the Minnesota Department of Health (MDH).

The purpose and goals of the Minnesota trauma system PI program are to:

- Alleviate unnecessary death and disability from trauma by reducing inappropriate variation in care and improving patient care practices and processes.
- Promote optimal trauma care by performing ongoing cycles of evaluation of trauma care delivery and system components, and implementing improvement initiatives based on optimal care practices when indicated.

AUTHORITY

The MDH is the lead governmental agency authorized by law to develop and oversee a comprehensive, statewide trauma system PI program. The MDH has legal authority to monitor, evaluate, and improve the process of trauma care and its outcomes throughout the state. The MDH is responsible for:

- Developing a comprehensive, statewide process to monitor, evaluate, and improve trauma system performance, as a whole and by its regions, and within individual institutions or services.
- Establishing in conjunction with the STAC pre-defined measures or expectations of care based on evidenced-based guidelines, state

policy and standards, or derived out of consensus

- Providing direct oversight and administration of PI activities of the state and regional trauma committees.
- Implementing corrective action strategies or initiatives based on the PI committee's findings and recommendations. With proper oversight the lead agency may empower the regional trauma committee to implement improvement initiatives that are not regulatory in nature such as evidenced-based practice guidelines.
- Communicating problems, trends, and issues identified by the state and regional PI committees to the responsible entity such as ambulance or air medical service, healthcare organization, other agencies, county health officials, etc. Communication of PI activities may be delegated to the regional PI committee given that the MDH provides oversight.
- Initiating action required to avert a potential emergent public health risk.
- Collecting, evaluating, validating, and communicating trauma data.
- Developing and enforcing statutes, rules, policies, and procedures for data security and confidentiality protection for all aspects of the state PI program.

STRUCTURE

Statewide trauma system PI is a joint effort by the State Trauma Advisory Council (STAC) and the Minnesota Department of Health (MDH) to monitor, evaluate, and improve the processes of trauma care and outcomes. The role of the STAC is to provide expertise and advice to the MDH in its effort to analyze system components, and to recommend improvement initiatives to optimize care and improve outcomes.

To accomplish statewide PI, it is recommended that the MDH, with advice from the STAC, appoint a multidisciplinary subcommittee with representation from each of the various levels and specialties of providers and from specific regions or areas of the state, such as rural and urban. Members should be appointed for their expertise and interest in PI as well as for other professional qualities. Membership should be established with specified, staggered terms of appointment and a Chair, preferably a trauma surgeon, should be appointed. The MDH is responsible for providing staff and data for the PI committee activities, as well as direct oversight of its efforts.

RESPONSIBILITIES

State Trauma Advisory Council (PI Committee)
The state trauma PI committee is responsible for analyzing state and region-specific trauma data to assess the overall effectiveness of the statewide trauma system in reducing unnecessary death, disability, and cost. The committee is

responsible for determining patterns or trends in care processes, assessing outcomes, and recommending improvement initiatives to optimize care as indicated by the results. This review includes comparison and benchmarking of services, hospitals, and regions with state or national data obtained through injury databases and trauma registries, mortality studies, and outcomes-related research.

The STAC PI committee is responsible for establishing pre-defined measures or expectations of care developed from evidenced-based guidelines, state statutes, rule, policy, or standards, or derived out of consensus of important aspects of care. It is charged with the task of developing or adopting a standardized method for determining morbidity and mortality preventability for use by all review committees or bodies statewide.

The STAC PI committee is responsible for:

1. Convening monthly to quarterly or as directed by the STAC.
2. Communicating PI related information to the designated person within each region or treatment setting.
3. Providing oversight of research related to monitoring, assessing, and improving the MN trauma system.
4. Notifying the MDH of high-risk situations where patient safety may be compromised or that pose a significant public health risk.
5. Preparing in conjunction with the MDH an annual report describing trends, problems, improvement opportunities, and recommendations for corrective action to the to the MDH leadership.
6. Providing periodic and annual reports to the STAC suitable for public dissemination about the quality and outcome of care in the regions and state.

Minnesota Department of Health Trauma Program

The MDH is responsible for providing the STAC PI committee with trauma data and the resources necessary to effectively conduct PI activities statewide. The STAC PI committee should ideally be chaired by a general surgeon with an interest and expertise in trauma care. The chair must be capable of providing the leadership necessary to monitor, evaluate, and improve system performance and outcomes using methodologies appropriate for systems analysis and case review. The specific responsibilities of the MDH are to:

1. Provide oversight of statewide PI program.
2. Provide trauma registry and other pertinent data as appropriate to the STAC PI committee to support PI efforts and research activities.
3. Implement STAC PI committee's recommendations for corrective action and system improvement.

4. Communicate trends, problems, and outstanding issues identified by the state and regional committees to responsible entities, such as ambulance and air medical services, healthcare organizations, health officials, etc.
5. Implement action required to correct a potential emergent public health risk.
6. Oversee the confidentiality of STAC PI efforts and activities through supervision, consultation, and education.

PATIENT POPULATION

To ensure consistent PI monitoring and evaluation as well as data collection throughout the state, the MDH, with advice from the STAC, must define standardized criteria for determining the trauma patient population. These criteria should be uniformly applied throughout the state for all levels of care to identify the population to be monitored and reviewed. The following criteria are suggested:

- Injured patients who meet triage criteria for trauma system care
- Injured patients who are discharged from the hospital with an ICD-9-CM diagnosis 800.00-959.9, excluding 905-909.9, 910-924.9, and 930-939.9
- All trauma related hospital admissions
- Any trauma related death
- Any trauma transfer either into or out of the hospital
- All complaints and high profile cases

DATA COLLECTION AND INFORMATION SOURCES

Performance improvement in trauma care consists of ongoing and systematic monitoring, evaluation, management, and documentation of performance. To identify opportunities for improvement, the PI process must be supported by a valid and objective method of data collection. Specific, uniform data that describes the injury incident, demographics, prehospital information, diagnosis, treatment, rehabilitation, outcomes, and cost of care should be collected by every hospital and reported to the MN Trauma Registry. It is imperative that data be abstracted and reported using standardized definitions as recognized by the MN Trauma Registry. Data definitions should also be consistent with those of the National Trauma Data Bank. Prehospital data, if not collected and reported by the hospitals, should be linked or uploaded into the MN Trauma Registry. Data validation should be performed for at least five percent of the cases reported to the MTR. A discussion of trauma registry data validation is contained in Appendix K.

Data is collected on an ongoing basis using information sources that are reliable and accessible. Many useful sources of information are available to perform monitoring and evaluate the efficacy, cost, and outcome of trauma care. The

following information sources should be considered for routine or periodic monitoring of the hospital's trauma program:

- Prehospital care reports including non-transporting agency, i.e., first responder
- Hospital medical record
- Public safety records;(these records provide information that may not included in the prehospital care record)
- 9-1-1 dispatch records
- Interhospital transfer records, if applicable
- Autopsy findings (these may be difficult to obtain in rural areas)
- Hospital trauma registry data and external benchmarking data (MN Trauma Registry or National Trauma Data Bank (NTDB). This information is useful for trending data, performing comparative analysis, and benchmarking.
- Checklists from review of trauma resuscitation videotapes (Complaints from all sources
- Performance improvement findings from other review committees
- System plan, protocols, policies, procedures, guidelines, etc.

ASPECTS OF REVIEW AND KEY ACTIVITIES

The MDH and STAC PI committee will jointly monitor and evaluate all aspects of the MN trauma system, including the causes of injury, emergency response, medical care, cost, and outcomes. These efforts should focus on a process that continuously monitors, assesses, and improves system-wide performance and outcomes. The STAC PI committee will provide the expertise necessary to interpret data, develop performance and outcome measures, establish definitions for collecting and categorizing data (i.e., complications, etc.), and create a standardized method for determining preventability.

The STAC PI committee and MDH should not duplicate the PI efforts conducted at the regional level, but should focus on global issues that impact the system as a whole. Information obtained from the state trauma registry and other pertinent data sources can be used to objectively evaluate system parameters, track variability, and document improvements. The effectiveness of injury prevention programs, efficacy of care, timeliness of care, access to providers and services, and outcomes are all important aspects of the statewide trauma system that should be routinely monitored and evaluated to identify opportunities to improve care and maximize outcomes.

The following are examples of standardized reports that can be generated by the MN Trauma registry (with linked sources) and used for monitoring performance and outcomes. Other examples are contained in Appendix J.

- Scene time (measured from first responder scene arrival time to

transporting agency scene departure time). Scene time can be stratified by numerous variables, such as EMS agency, service level, county, region, injury severity (ISS and AIS), diagnoses, injury type, physiologic data, etc.

- EMS times (call to dispatch, dispatch to scene arrival, scene time, and transport time stratified by EMS agency, county, region, etc.
- Air medical usage, response times, scene times, transport times stratified by time of day, location, injury severity, cost, etc.
- Triage criteria independently stratified by outcomes, procedures, resource and service utilization, etc.
- Morbidity rates stratified by hospital, diagnoses, injury severity, outcome (i.e., death, LOS, disability, cost), etc.
- Mortality rates stratified by gender, age, ISS, probability of survival, injury diagnoses, LOS, cost, etc.
- Hospital readmission rates
- CMS "never" rates
- Disability stratified by injury severity, injury type, diagnoses, etc.
- Timeliness of responders including trauma surgeon and consultants
- Timeliness of diagnostic services, procedures, operative care.
- Timeliness of interhospital transfer stratified by level of care, hospital, region, etc.
- Demographics and injury characteristics (E-Code, type, etc) stratified by hospital, county, region, etc.
- Hospital discharge disposition (home, rehabilitation, SNF, etc.)

There are numerous variables collected by the MN Trauma Registry that can be queried and used to effectively measure and evaluate system performance and outcomes. The data can be used to compare and benchmark performance among EMS providers, hospitals, rehabilitation center, regions, and the state. The MN Trauma Registry is the primary tool to drive the trauma PI process throughout the state.

Trauma registry data can also be used to identify system needs, support policy and decision-making, target injury prevention, focus education, document costs, and conduct special studies and research.

Outcomes Research

To evaluate the efficacy of the MN trauma system in reducing injury-related mortality and disability, the state must conduct, at least periodically, outcomes research. If state level resources permit, research studies can be conducted through the MDH with consultation or oversight provided by the STAC PI committee. The Level I trauma facilities with research capabilities should be encouraged to conduct statewide outcomes-related research in concert with the MDH and STAC PI committee.

EVALUATION

The STAC PI committee must conduct its meetings in a manner that ensures the honest, unbiased appraisal of trauma system care. Expectations or standards of care developed from evidence-based guidelines, protocols, consensus of important aspects of care and associated indicators, statutes, rule or ordinance are useful in measuring the effectiveness and consistency of care, and outcomes. A standardized methodology, such as described in Appendix D or similar models, should be used statewide to guide preventability determinations. Most importantly, members of the PI committee at all levels must be constantly aware that they represent their profession rather than their institution or service.

IMPROVEMENT OPPORTUNITIES AND CORRECTIVE ACTION

The primary objective of trauma system PI is to decrease unnecessary death and disability by reducing inappropriate variation in care, and assuring that expectations, standards, and benchmarks are met. When a reoccurring problem, sentinel event, or inappropriate variation occurs, improvement initiatives or actions are developed to increase the effectiveness and efficiency of care, and maximize patient outcomes. The action plan should include: who or what is going to change; who is assigned responsibility for problem resolution; what action will be taken and when it will occur; and who is responsible for follow-up and when it will occur. Examples of corrective strategies include the revision of guidelines, protocols, or policies, targeted education, provider counseling, and change in privileges, accreditation, etc.

RE-MONITORING

An essential aspect of PI is demonstrating that the implemented improvement initiative has the desired effect. A continuous pursuit to evaluate the effectiveness of corrective action should be employed until the problem is eliminated or satisfactorily reduced. This evaluation should occur within three to six months of the corrective action depending on the issue, and be thoroughly documented in the PI committee minutes until resolution is satisfactorily achieved.

DOCUMENTATION AND REPORTING

The same concepts and procedures to document, yet protect, sensitive PI information noted in previous sections apply to the STAC PI committee. Documentation of committee meeting minutes, committee findings, performance reports, mortality and morbidity rates, preventability determinations, and any other information that identifies a provider or patient must be maintained in a manner which protects against discovery or disclosures.

The MDH must ensure that adequate statutory protection exists to protect from disclosure all reports, findings, minutes, etc., generated by the trauma PI committees (local, regional, and state). It is strongly advised that direct statutory protection for regional and state trauma PI activities be established as exemplified in Appendix H. MN EMS Statutes, Chapter 145 also serve as an excellent model. Without explicit protection, PI activities may not be fully protected from disclosure, particularly if strong public information or "sunshine" laws mandate open access to activities of public bodies such as regional/state trauma committees.

It is important that the STAC PI committee members understand MN law governing PI and peer review and take appropriate measures to protect PI records, reports, minutes, and other documents or information that is produced reviewed or produced from disclosure, including conversations and electronically transmitted communication. The following measures are suggested to protect PI information:

- Use of a locked file for all relevant information
- Use of a confidentiality statement/agreement for all participants in PI activities such as that contained in Appendix F
- Sanction for any breaches of confidentiality
- Shredding of all copies of PI documentation
- Security efforts at PI meetings such as numbering and collection of all papers
- Use of security procedures when mailing or transmitting PI documentation including addressing all correspondence to an assigned person, clearly marking all letters "confidential", removing all patient identifiers, dates, and locations of scenes from information, particularly when used for education; providing direct supervision, e.g., staff standby at the receiving facsimile when faxing PI documents such as case summaries between hospitals
- Notation or citation of relevant statutory protection on all printed PI materials including email.

Minutes of the review committee need to well documented and include candid discussion of the information reviewed, findings, and recommended improvement initiatives. Only one copy of the minutes should be maintained by the committee staff person using proper security measures to protect against discovery.

An annual report of the state's overall performance that includes benchmarking accomplishments, complication and mortality rates, disability rates, preventability rates, length of stay, resource utilization, and other measures of outcome should be jointly prepared by the MDH trauma program and STAC. This report should include a description of the state's successes or failures in its effort to improve care and outcomes. The report should be directed to the MDH leadership

responsible for trauma system oversight and shared with other the local and regional committees responsible for PI.

RELEASE OF INFORMATION

The MDH must develop policies and procedures for dissemination of information to assure that the information released is adequately explained, and does not identify a patient or facility. There are two venues for release of PI information. One should cover requests for public information about the quality of care rendered in the regions and state, and another that covers requests about the trauma system's performance for professional research. The two different information release considerations are defined as follows:

Public Information

When releasing PI information to the public, particularly the media, balance is needed to educate and build support for the trauma system while avoiding data misinterpretation to the detriment of the trauma system as a whole. The information released should be formatted in a manner that is interesting and readable to the general public and is unlikely to be misinterpreted.

Professional Research Information

The MDH can expect to receive requests for information about trauma care within the state or region or at a trauma center from medical researchers and government agencies. These requests must be in writing and be considered on a case-by-case basis. Ultimately, the decision to release information from the trauma registry should be governed by the benefit to trauma patients, the trauma care community, and to other agencies required to oversee trauma systems. This information is not governed by public information laws and is considered part of the trauma system PI research requirement.

The amount of work needed to provide the information requested is a consideration. When feasible, agency costs including overhead, should be assessed for the workload created by research requests. When developing research proposals, the MDH should include data retrieval and interpretation, i.e., review panel, costs in the research budget.

Researcher access to the trauma registry and PI records can be facilitated by identifying registry fields and summary documents that can be made available to those who meet requirements for medical research. Release of research level data must stipulate storage conditions, security, and specific use of data, and address confidentiality and non-disclosure regarding identifiable patients or providers. In addition, researchers should acknowledge the MDH as a data source in publications and provide agency staff and trauma system leaders with the opportunity to review proposed publications for comment prior to their submission.

APPENDICES

Process Performance Measures

These performance expectations are adapted from the Oregon trauma system performance improvement (PI) program. They were developed based on review of current trauma literature and expert opinion reflecting the clinical experience of members of the Oregon State Trauma Advisory Board (STAB). These performance measures serve as an example for other state systems to adopt or adapt.

ASPECT	INDICATOR	COMMENTS	GOAL
System Function	**EMS to Hospital Communication** Patients with physiologic or anatomic triage criteria who arrive at trauma hospital without $\geq$ 15 minutes pre-notification.	To assure that optimal trauma care resources are immediately available to the patient upon arrival to the hospital.	
	EMS Record Prehospital care report/record not left at hospital by EMS personnel		
	Under-Triage Patients not entered into the trauma system by prehospital providers or a transferring hospital for which retrospective review indicates Appropriate trauma team not activated.	ISS < 9 Major operative procedure within 6 hours ICU admission Patient death	
	Over- Triage Patients entered into the trauma system by prehospital or hospital providers for whom retrospective review indicates only minor injuries.	No mandatory trauma triage criteria met Discharged from ED LOS <6 hours with discharge to home	
	Scene Time Field personnel on scene time > 15 minutes.	This measure should not be applied to cases with prolonged extrication, multiple patients, or difficult access to the scene.	

ASPECT	INDICATOR	COMMENTS	GOAL
	Team Activation Appropriate trauma team <u>not</u> activated.	To assure that trauma team composition meets the standards set forth in state plan and/or statutes.	
	Interhospital Transfer Failure to transfer patients in less than 2 hours from hospital arrival.	Injured patients who require higher level care should be transferred within 2 hours.	
	Surgeon Evaluation Patients with significant blunt chest or multi system trauma admitted to the hospital with no general surgery evaluation.	Patients in this category initially meet requirements for a modified team response but during ED evaluation are found to have significant injuries.	
	Neurosurgical Evaluation Neurosurgical consultation not obtained for patients with GCS <13.		
Airway, Breathing & Circulation	**ABCs** Failure to follow airway, breathing, circulation priorities of patient management	This is applicable both for prehospital and hospital providers.	
	Airway Management GCS less than or equal to 8 and no intubation.	For prehospital transport of less than 5 minutes, intubation is not indicated.	
	Esophageal Intubation Unrecognized placement of the endotracheal tube in the esophagus.		

ASPECT	INDICATOR	COMMENTS	GOAL
	Needle Thoracostomy Failure to decompress the chest for obvious pneumothorax with hemodynamic and respiratory compromise.		
	Chest Tube Placement No chest tube placed for pneumothorax or hemothorax within 15 minutes of diagnosis or inappropriate size tube used.		
	Ventilation Persistent over or under ventilation within the first 12 hours (pCO_2 < 32 or > 50) in patients with airway management.	This indicator is a reflection of the precision of critical care in the first 12 hours after initial stabilization.	
	Vascular Access Inability to obtain vascular access in a patient with unstable vital signs.	Adherence to Massive Transfusion Protocol with appropriate administration of FFP/Ca$^+$	
	Hemorrhage Control Failure to control external bleeding		
Resuscitation	**Head Injury** For significantly head injured patients hypotension < 90 systolic or pCO_2 < 35 or > 40		
	Base Deficit In adults, base deficit > 8 after initial resuscitation.		

ASPECT	INDICATOR	COMMENTS	GOAL
	Hypothermia Prolonged hypothermia without adequate re-warming measures.	Attention will be given to treating patients who arrive hypothermic or to preventing hypothermia during resuscitation	
	Delay Delay in transfer or operative procedure for hemodynamically unstable patients due to diagnostic imaging studies.		
	Pediatric Fluid Administration Infusion of more than 50ml/lg crystalloid solution in the first two hours in a pediatric patient with normal initial vital signs.		
	Blood Product Utilization Failure to initiate blood product administration after 2 liters (20cc/kg pediatric) crystalloid bolus during initial resuscitation of the patient with persisting class III shock.	Class III shock (approx. 2,000 ml in an adult) is manifested by marked tachycardia, tachypnea, falling systolic pressure, and changes in mental status.	
	Shock Patient with systolic blood pressure <70 mmHg greater than two hours after hospital arrival with no definitive intervention.	Attention is given to non-reparative procedures such as CT leading to delays in definitive care.	
Skeletal Protection & Evaluation	**Spinal Immobilization** No spinal precautions initiated in the field or not maintained until adequately cleared.		

ASPECT	INDICATOR	COMMENTS	GOAL
	C-spine Clearance Cervical spine cleared radiographically in patients with altered level of consciousness.		
	Initial Radiographs AP chest, pelvis, and cervical spine films not completed following ATLS protocol for victims of blunt trauma.		
	Splinting No application of traction or splinting for long bone fractures.	This indicator is applicable for both the field and hospital setting.	
	Fracture/Dislocation Reduction Failure to attempt reduction of obvious extremity fractures or dislocations with lack of pulses.	This indicator is intended for the hospital setting.	
	Hip Dislocation Failure to attempt reduction of hip dislocation within 6 hours of hospital arrival.		
Miscellaneous	**Antibiotic Administration** Failure to administer IV antibiotics for open fractures or extensive breakdown in skin integrity.		
	Delayed Diagnosis Injury diagnosed greater than 24 hours after the initial traumatic event.		
	Progression of Initial Neurological Insult		

ASPECT	INDICATOR	COMMENTS	GOAL
	Rectal Exam No rectal exam documented prior to insertion of Foley catheter in males.		
	Unplanned Return to OR		
	Readmission Patient readmitted to the hospital due to complication or incomplete management of injuries.	This excludes patients who are scheduled to return for follow up procedures.	
	Nutritional Support For patients with ISS > 15 or ICU admission, <u>no</u> nutritional support started within 48 hours of admission.		
	Vascular Injury Failure to diagnose major vascular injury within 6 hours of hospital arrival.		
	Rehabilitation Consultation Failure to obtain consultation for rehabilitation within 48 hours.		

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Outcome Measures

There are a number of variables that have traditionally been used to measure the outcome of trauma care including mortality, morbidity, length of hospital and intensive care unit stay, resource utilization, cost, functional disability, and patient satisfaction.

Mortality
Mortality prediction rates should be calculated using population based probability of survival coefficients and compared against actual rate of morality. There are a number of mortality prediction models, such as the Trauma and Injury Severity Score (TRISS) or International Classification of Disease, Ninth Revision-based Injury Severity Score (ICISS) that have been used to calculate or predict the number expected and unexpected deaths. The TRISS determines the probability of survival (Ps) of a patient from the Injury Severity Score (ISS), Revised Trauma Score (RTS), and patient's age. The ICISS predicts the patient's survival probability by calculating a Survival Risk Ratio (SRR) for each individual injury diagnosis code. Although mortality prediction models are not perfect, it is important for the state to adopt a standardized method to compare trauma-related mortality. This information can be used to benchmark mortality among hospitals and regions, and help identify cases for PI committee or peer review. As larger national databases evolve, such as the National Trauma Data Bank (NTDB), methodologies that improve mortality prediction are likely to develop.

Mortality should be evaluated to determine preventability and as to whether its occurrence is disease or provider-related or resulted instead from a system failure. A disease related death is an anticipated sequela of a disease, medical illness, or injury. A provider associated mortality results from delays and errors in the treatment provided by a health care provider. A system failure results from the unavailability or delay of a service or facility, such as an operating room. It is also important to review cases of unanticipated survivors (i.e., Ps < .5) that live so that their care can be replicated for future patients.

Morbidity
Complications must be determined using pre-established, statewide definitions such as those defined by the American College of Surgeons, Committee on Trauma (ACSCOT), NTDB, in the Minnesota Trauma Registry (MTR) manual for data abstraction and reporting, and/or CMS "never" events..   It is imperative that tight definitions be established and applied throughout the state so that meaningful comparisons in complication rates can be made. Complications also need to be evaluated for preventability using a pre-defined, standardized methodology that includes categorizing findings. CMS present on admission, "never" or "no payment", conditions should be identified and tracked as to cause.

Length of Stay (LOS)

To examine the efficiency of trauma centers and patient care, the hospital and intensive care unit (ICU) length of stay for patients with similar characteristics can be used to monitor variances. Because inpatient length of stay may reflect different levels of intensity or acuity in a hospital's ICU and acute care floors, hospital length of stay should only be used as a gross parameter of performance. It is feasible, however, to compare the LOS of similar patients with the incidence of complication or readmission to the hospital. Another efficiency measure used by the Trauma Center Association of America (TCAA) is ICU utilization, a metric of ICU days divided by all trauma patient activations. The TCAA maintains benchmarks of these metrics.

Cost

Comparing and benchmarking the true cost of care may prove to be complicated since hospital systems may track cost differently and not focus on the clinical aspects of care. Cost accounting techniques that factor in use of resources, personnel time, supplies, overhead, etc. should be used to help define the true cost of care. Hospital charges do not reflect true cost of care and should not be used to measure performance. Use of the trauma center billing code FL14, type 5 to identify true patient cost is helpful.

Quality of life – Physical, Functional, and Psychological Impairment

Quality of life (QOL) after traumatic injury has been used to evaluate the effectiveness of care and to facilitate the development of interventions to optimize outcomes. Quality of life measures can be used to determine whether relationships exist between QOL and injury severity and types of injuries. Measuring quality of life is also useful to assess the impact of injury on patients and their families, and identify their long term needs, including the need for community resources.

There are many instruments that measure physical, functional and psychologic impairment after recovery from traumatic injury. Many of the tools listed below have been widely used and are designed to measure the QOL from the patient/family's perception. Others can be found in the literature. Whatever measure is selected, it should be uniformly reported statewide and tracked over time as part of the evaluation of the trauma system.

- Functional Independence Measure (FIM) – This tool is used to measure functional abilities, such as being able to care for oneself, ambulate, respond, communicate, and remember things.
- Disability Rating Scale (DRS) – This tool measures impairment, disability, and handicap; it useful to track an individual from coma to integration back into the community.
- Rancho Scale of Cognitive Functioning – A behavioral rating scale for assessment of cognitive functioning (Hagen, Malkmus, and Durham,

1979). The Rancho levels are used to classify patients for treatment and tracking their progress throughout recovery.

- Short Form Health Survey (SF)-36 - A generic quality of life survey that measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health

- Functional Capacity Index (FCI) – Used to measure and quantify functional limitation based on ten dimensions of physical capacity and function: (1) locomotion, (2) hand and arm manipulation, (3) bending and lifting, (4) eating, (5) elimination, (6) sexual function, (7) visual function, (8) auditory function, (9) speech, and (10) cognitive function.

- American Spinal Injury Association's (ASIA) Impairment Scale – This scale is a standardized method of assessing the neurological status of a person who has sustained a spinal cord injury.

- Health Assessment Questionnaire (HAQ) – This is a self-reported questionnaire that measures functional disability status.

- Quality of Well Being Scale - This is functional assessment of the patient's mobility, physical activity and social activity, and includes a list of symptoms and problems.

- Sickness Impact Profile (SIP) – A generic measure used to evaluate the impact of disease on both physical and emotional functioning.

- Katz Index of Independence in Activities of Daily Living (Katz ADL) – A tool to assess functional status as a measurement of the patient's ability to perform activities of daily living independently.

- Injury Impairment Scale (IIS) - Developed to evaluate the impact of traumatic injury on a patient and includes parameters of mobility and dexterity, cognitive and psychological, disfigurement, sensory, pain, and sexual/reproduction.

- Pediatric Evaluation of Disability Inventory (PEDI) – Designed for young children to measures both capability and performance of functional activities in self-care, mobility, and social function.

Patient Satisfaction

Patient satisfaction surveys are used to assess the health care delivery experience from the patient's perspective and identify ways to improve care. Many survey tools are commercially available and are utilized by hospitals and system administrators to measure patient satisfaction with the quality of care and services they received.

Check all that apply (unless otherwise indicated)
PREHOSPITAL CARE: Inappropriate:
1.   Airway Management
2.   Bleeding Control
3.   Fluid Resuscitation
4.   Fracture Stabilization
5.   Use of MAST Trousers
6.   C-Spine Protection
7.   Other Prehospital _____
8.   Documentation
9.   Not Applicable

EMERGENCY DEPARTMENT: Inappropriate:
      Stabilization Treatment:
10.   Airway Control
11.   IV Access (i.e. delayed)   53.
12.   Fluid Resuscitation
13.   Use of Vasopressors
14.   Use of MAST Trousers
15.   Chest Injury Tx
16.   Documentation
17.   Not Applicable
      Diagnosis:
18.   Failure to use X-Ray/CT/FAST
19.   Failure to use Peritoneal Lavage
20.   Failure to Recognize Injury
21.   Other ER_____

OPERATIVE
22.   Inappropriate Operation
23.   Documentation
24.   Unavailable
25.   Unanticipated Return

POST OP/POST ER CARE: Inappropriate:
26.   Treatment of Infections
27.   Treatment of Re-bleeding
28.   Fluid Management
29.   Monitoring/management of head injury
30.   Ventilatory Care
31.   Nutrition/Rehabilitation consultation
32.   Other Post OP/ER Care _____
33.   Documentation
34.   Not Applicable

TIME
35.   Delay in EMS Response
36.   Excessive Scene Time
37   .Excessive Time in ED/Radiology
38.   Delay to OR (Reason)
39.   Delay in Diagnostic test
40.   Delay in Consultation
41.   Delay in Therapeutic Procedure
42   Documentation
      Phase_____

UTILIZATION OF RESOURCES: Inappropriate:
43   Prehospital Resources
44.   Transportation Resources
45   Futile Resuscitation Effort
46.   Diagnostic Resources
47.   Surgical Resources
48.   Other_____

CAUSE OF DEATH/PREVENTABILITY
(Check one)
A. For deaths within 48 hours, the <u>Primary Cause</u> of death was:
48.   Airway/Respiratory
49.   CNS Injury
50.   Hemorrhage
51.   Other_____
52.   Indeterminable

B. For deaths after 48 hours, the <u>Primary Cause</u> of death was:
53.   Airway
54.   Hemorrhage
55.   Sepsis/Infection
56.   CNS Injury
57.   Other_____
58.   Indeterminable

C. Death was:
59.   Preventable
60.   Possibly Preventable
61.   Either
      a. Non-Preventable--Care Appropriate
      b. Non-Preventable--Care Inappropriate

D. Phase Responsible for Inappropriate Care:
62.   Prehospital_____
63.   ER_____
64.   ICU_____
65.   OR_____

TRAUMA SYSTEM
Inappropriate:
66.   Activation
              a. Full Team
              b. Alert
67.   Team Response
68.   Transfers
              a. Timeliness
              b. Next level of care
69.   Disposition
              a. Timeliness
              b. Appropriate level: rehab, SNF
70.   Cost of Care
71.   a. Appropriate for condition
              b. Inappropriate/Excessive
              c. Not documented

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Appendix C

Case Analysis Model for
Trauma Performance Improvement

Complications and injury-related deaths need to be evaluated for preventability using a pre-defined, standardized methodology that includes categorizing findings. The following model for case review was adapted from the American College of Surgeons "Resources for Optimal Care of the Injured: 2006."

This process, based on outcome, has a refined method for analyzing errors useful to the Performance Improvement (PI) Committee, and is adaptable to many situations. Further adaptation prior to use by prehospital, hospital, regional, and state PI committees may be needed, but adherence to this type of review methodology is recommended to assure a fair and unbiased process for determining preventability of outcomes and analyzing errors.

JUDGEMENT	GUIDELINES	COMMENTS
Non-preventable	Anatomic injury or combination of injuries considered non-survivable with optimum care. Expected sequela of a procedure, disease, or injury for which appropriate preventive steps had been taken.	Findings at operation or autopsy.
Potentially Preventable	Anatomic injury or combination of injuries considered very severe but survivable under optimal conditions. Event is a sequela of a procedure, disease, illness, or injury that has the potential to be prevented or substantially ameliorated	Findings at operation or autopsy.
Preventable	Anatomical injury or combination of injuries considered survivable. Event or complication is an expected or unexpected sequela of a procedure, disease, an illness, or injury that is likely to have been prevented had appropriate steps been taken.	Findings at operation or autopsy.

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Appendix D

JUDGEMENT	GUIDELINES	EXAMPLE
Delay in diagnosis or impression	Injury related diagnosis after admission resulting in minimum morbidity.	Unsu spected fracture
Error in diagnosis or impression	Injury missed because of misinterpretation or inadequacy of physical examination or diagnostic procedure.	False negative CT of the abdomen.
Error in judgment	Therapeutic or diagnostic decision made contrary to available data.	Delay in treating other severe injuries to perform laparotomy in stable patient with a history of hypotension.
Error in technique	Technical error occurring during the performance of a diagnostic or therapeutic procedure	Pneumothorax related to placement of a subclavian venous catheter.
Patient disease	Complication unavoidable, due to progression of underlying disease or process	Myocardial infarction in patient with known coronary artery disease.
System-related	Event or complication not related to provider or disease but attributed to system failure	Unavailability of OR, diagnostic test, blood, provider, service, etc.

Case Review Tracking Form

Patient Name _____   Admission Date _____

Medical Record # _____   Discharge Date _____

Trauma Registry # _____   Physician _____

Diagnosis _____

Committee Review

Meeting	Date Presented	Findings/Action
Educational Conference	_____	_____
Trauma Committee	_____	_____
Peer Review	_____	_____
Regional Committee	_____	_____

Complications

Date	Complication	Comments
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Corrective Action

None	Referred to _____
Education	Letter to/Date _____
Study	Practice Guideline _____
Trend	Provider Counseling _____
Other	Revoke/Suspend Trauma Privileges _____

Follow-up

Date/Comments_____
_____
_____
_____

NP = Non-Preventable   PR = Provider Related   DE = Diagnosis Error
PP = Potentially Preventable   DR = Disease Related   JE = Judgement Error
PRV = Preventable   SR = System Related   TE = Technique Error

**Statement of Compliance with Confidentiality Requirements for the
_____ Performance Improvement Committee**

PURPOSE

The purpose of this document is to ensure that the members of the _____Performance Improvement (PI) Committee understand and acknowledge their responsibility to maintain the confidentiality of the_____ PI Committee's proceedings.

_____ (insert Statutes citation and language) provides that data received or compiled by the PI Committee in conjunction with _____ (name of lead agency) monitoring to ensure quality of trauma patient care shall be confidential and privileged, non-discoverable, and inadmissible in any proceeding. No person serving on or communicating information to the PI Committee shall be examined as to any such communications or to the findings or recommendations of the Committee. A person serving on or communicating information to the PI Committee shall not be subject to an action for civil damages for actions taken or statements made in good faith. The confidentiality provisions of _____ shall also apply to the monitoring and performance improvement activities of the _____ PI Committee and the _____ (name of lead agency).

Disclosure by a Committee member of any investigative information or any discussion of such information with unauthorized persons is a violation of _____ (name of state) law and may expose that Committee member and/or the _____ (name of lead agency) to potential liability for unauthorized release of information.

PROCEDURES

The _____ (name of lead agency) has provided the _____ PI Committee with guidance concerning procedures for conducting PI activities. Members of the PI Committee must abide by the following:

> No information may leave the room except as assigned by the Chair and staff. All written material related to the review must be returned to the staff member to store or destroy. Members may discuss matters brought to the attention of the Committee only as official business; they may not discuss with others or disseminate in any way confidential information obtained in the course of these meetings or meeting preparation.

STATEMENT OF COMPLIANCE

I, the undersigned, have read and understand the above and agree to comply with requirements regarding confidentiality. Should I not comply with the requirement regarding confidentiality, I agree to resign immediately from the _____ PI Committee. Additionally, I understand that failure to comply with the confidentiality requirements incumbent upon me may result in my being held personally liable for unauthorized release of information provided to me in my capacity as a member of the _____ PI Committee.

SIGNED

DATED   this   _____   day   of   _____,

CONFIDENTIALITY PROCEDURE FOR PERFORMANCE REVIEW

PURPOSE

The trauma performance improvement committee will assure confidentiality for patients, healthcare providers, agencies, and organizations that provide information for trauma system performance monitoring.

CONFIDENTIALITY PROCEDURE

All members of the trauma PI committee, invited guests if permitted by the trauma PI plan, and other persons attending the meeting will sign a confidentiality agreement which will be kept on file with the committee staff person. The agreement acknowledges that they have read the plan's confidentiality procedure and that they agree not to discuss or disclose any part of the meeting proceedings.

All members of the trauma PI committee will complete an orientation to the plan and its component parts, including confidentiality.

- Disclosure by any member of a PI committee, any guest, or otherwise involved party of any trauma system quality assessment committee discussion is a violation of Minnesota law and exposes that person to liability and prosecution.

- No printed, audio or video taped, computer generated, or otherwise reproducible information will enter or leave the room where PI activities are performed except as assigned by the Chair and staff.

- All written material related to the review will be returned to the staff member to store or destroy according to procedures defined in the PI plan.

  1. All non-original documents reproduced for use in meetings (including minutes, forms, reports and notes) must be numbered sequentially, counted prior to distribution, counted upon return, and shredded. Documents will be sequentially numbered prior to distribution and counted upon collection at the end of the meeting.

  2. All documentation will be clearly marked "confidential" with citation of relevant statutory protection on all printed PI materials including email.

  3. No paper other than that distributed by the Chair and staff will be allowed in the meeting room.

- All original documents will be securely stored in a locked cabinet. Procedures describing who may have access to this cabinet and its contents must be established.

• Minutes of the meeting will be maintained by the staff person. These may be in outline form and should include discussion of the reviewed materials, findings, improvement actions, and a defined process for re-evaluation until the problem is resolved. The minutes may contain medical record or trauma registry identifiers and, therefore, are confidential.

PRODUCTS OF THE PERFORMANCE IMPROVEMENT COMMITTEE

Case review will result in a decision that a problem did or did not occur.

1. Standardized, decision support methodologies will be used to assure a consistent, fair, and unbiased process for determining preventability of outcomes and analyzing /categorizing errors.
2. There will be a "Statement of Finding" which is forwarded by the staff person only to the providers of the care under review.
   a. Ambulance service medical directors/advisors will receive a copy of prehospital case review when applicable.
   b. The assigned person responsible for prehospital agency PI activities will receive a copy of prehospital case review when applicable.
3. Case review documentation may contain patient identifiers and, therefore, is confidential.
4. PI review activities will be reported in their entirety to the lead agency.

Identification of trends, reoccurring problems, or sentinel events that can be remedied by action of the PI committee, such as provider education, protocol revision, practice guideline, etc. will be reported in writing with recommendations for action.

1. These communications will not contain confidential information or information such as dates, locations or other aspects of the case that could lead to discovery or disclosure of the patient's identification.
2. Urgent matters that potentially impact patient or public safety will be promptly communicated to the MDH Trauma Program.

Written communications of the PI committee will be clearly marked "CONFIDENTIAL" with citation of relevant statutory protection and be addressed to the person assigned responsibility within any agency or organization.

**EXAMPLES OF STATUTES APPLICABLE TO
TRAUMA SYSTEM PERFORMANCE IMPROVEMENT**

ORS 41.676

Inadmissibility of certain health care facility and training data. As used in section (2) of this section "data" means written reports, notes or records of tissue committees, governing bodies or committees of a health care facility licensed under ORS Chapter 441, medical staff committees and similar committees of professional societies in connection with training, supervision or discipline of physicians, or in connection with the grant, denial, restriction or termination of clinical privileges at a health care facility. The term also includes utilization review and professional standards review organizations.

> (2) All data shall be privileged and shall not be admissible in evidence in any judicial proceeding, but this section shall not affect the admissibility in evidence of a party's medical records dealing with a party's hospital care and treatment.
>
> (3) A person serving on or communicating information to any governing body or committee described in subsection (1) of this section shall not be examined as to any communication to that committee or the findings thereof.
>
> (4) A person serving on or communicating information to any governing body or committee described in subsection (1) of this section shall not be subject to an action for civil damages for affirmative actions taken or statements made in good faith.
>
> (5) Subsection (2) of this section shall not apply to judicial proceedings in which a health care practitioner contests the denial, restriction or termination of clinical privileges by a health care facility. However, any data so disclosed in such proceedings shall not be admissible in any other judicial proceeding.

ORS 431.140
Effect of rules.
> (1) All rules of the Health Division shall have the force and effect of law.

ORS 431.607
Health Division to develop comprehensive emergency medical services and trauma system.

ORS 431.611
Division to adopt rules (1) prior to approval and implementation of area trauma plans... which specify state trauma objectives and standards.

OAR 333-200-020
Objectives of the Trauma System to include:
> (2) Developing a statewide trauma system plan to assure timely, quality, definitive care through coordinated identification, transport and treatment of major trauma patients:
>
> (b) Each area trauma plan shall consist of the policies, procedures and protocols which coordinate at least the following components:
>
> (H) Quality Management

OAR 333-200-080
Standards for Area Plans. Area plans shall describe how each of the following standards are met or exceeded. Interpretation and implementation of the standards as set forth in OAR 333-200-080 shall be in general accordance with the guidelines of the American College of Surgeons, Committee on Trauma contained in "The Resources for Optimal Care of the Injured Patient":1999.

> (8) Quality Management
>
> (a) Provisions shall be made for at least quarterly review of medical control, prehospital care, and hospital care of all major trauma cases:
>
> (A) Area-wide criteria for identifying patient cases for audit shall be described.
>
> (B) Responsibility for identifying and reviewing all cases meeting audit criteria shall be assigned.

(C)   Quarterly reports shall be submitted to the Division by the region or its representative on confidential forms provided by the Division.

(b)   All written reports, notes, complaints, correspondence and records of quality management activity are exempt from disclosure as provided in ORS 192.500(2)(b). These data are privileged and shall not be admissible in evidence in any judicial proceeding as provided under ORS 41.675.

(c)   The ATAB, STAB, all Area and State Quality Management Committee(s) and the Division shall meet in executive session in accordance with ORS 192.660 when discussing individual patient cases as required by ORS 192.525. Quality Management

Committees may meet in executive session to discuss material exempt from public disclosure as described in subsection (b) of this section.

STATUTES APPLICABLE TO MEDICAL RECORDS

ORS 192.502

The following public records are exempt from disclosure under ORS 192.410 to 192.505:

(1) Communication within a public body or between public bodies of an advisory nature to the extent that they cover other than purely factual materials and are preliminary to any final agency determination of policy or action. This exemption shall not apply unless the public body shows that in the particular the public interest in encouraging frank communication between officials and employees of public bodies clearly outweighs the public interest in disclosure. (2) Information of a personal nature such as but not limited to that kept in a personal, medical or similar file, if the public disclosure thereof would constitute an unreasonable invasion of privacy, unless the public interest by clear and convincing evidence requires disclosure in the particular instance. The party seeking disclosure shall have the burden of showing that public disclosure would not constitute an unreasonable invasion of privacy.

(3) Information submitted in confidence and not otherwise required by law to be submitted, where such information would reasonably be considered confidential, the public body has obliged in good faith not to disclose the information, and when the public interest would suffer by the disclosure; (9) Public records or information described in this section, furnished by the public body originally compiling, preparing or receiving them to any other public officer or public body in connection with performance of duties of the recipient, of the considerations originally giving rise to the confidential or exempt nature of the public records or information remain applicable.

ORS 432.060

Records of mortality and morbidity studies confidential; exceptions; nonliability of informants.

(1) All records of interviews, reports, studies, and statements procured by or furnished to the Health Division, any federal health agency or any nonprofit health agency that is exempt from taxation under the laws of this state or procured by any agency, organization or person acting jointly with or at the request of the division or health agency, in connection with special morbidity and mortality studies, are confidential insofar as the identity of an individual patient is concerned. Such records may be used solely for the purpose of the studies.

(2) The furnishing of morbidity and mortality information to the division or health agency, to its authorized representatives or to any other agency, organization of person cooperating in a special study, does not subject any hospital ... or other organization or person furnishing such information to an action for damages.

STATUTES APPLICABLE TO PUBLIC MEETING LAW

ORS 192.610 (1)
All meetings of the governing body of a public body shall be open to the public and all persons shall be permitted to attend except as otherwise provided by ORS 192.610 to 192.690.

ORS 192.640 Public notice required; special notice for executive sessions, special or emergency meetings.

(1) The governing body of a public body shall provide for and give public notice, reasonably calculated to give actual notice to interested persons, including news media which have requested notice, of the time and place for holding regular meetings. The notice shall also include a list of the principle subjects anticipated to be considered at the meeting, but this requirement shall not limit the ability of a governing body to consider additional topics.

(2) If an executive session only will be held, the notice shall be given to the members of the governing body, to the general public and to news media, which have requested notice, stating the specific provision of law authorizing the executive session.

ORS 192.660   Executive sessions permitted on certain matters; procedures; news media representatives attendance limits.

(1)... Executive session may be held to:

(c)   Consider matters pertaining to the function of the medical staff of a public hospital licensed pursuant to ORS 441.015 to 441.063, 441.085, 441.087, 441.990 (3), 442.320 and 442.340 including but not limited to. all clinical committees, executive, credentials, utilization review, peer review committees and all other matters relating to medical competency in the hospital.

(f)   To consider records that are exempt by law from public disclosure.

(3) Representatives of the news media shall be allowed to attend executive sessions other than those held under paragraph (d) (... labor negotiations) of subsection (1) of this section... (2) but the governing body may require that specific information subject of the executive session be undisclosed.

Improvement Initiatives and Corrective Actions

The primary objective of trauma system PI is to decrease unnecessary death and disability by reducing inappropriate variation in care, and assuring that expectations, standards, and benchmarks are met. When a reoccurring problem, sentinel event, or inappropriate variation occurs, improvement initiatives or actions are developed to increase the effectiveness and efficiency of care, and optimize patient outcomes. The action plan should include: who or what is going to change; who is assigned responsibility for problem resolution; what action will be taken and when it will occur; and who is responsible for follow-up and when it will occur.

The following are examples of corrective strategies that can be implemented to address issues that have been identified through the trauma performance improvement (PI) process.

Guideline, Protocol, Clinical Pathway, or Policies – These are established to assist trauma care providers in making decisions about the care of trauma patients and to provide safeguards so that the best, most efficient care possible can be provided. These tools are often based on methods that work the majority of the time for the majority of patients and/or are supported by the current best evidence. They are designed to decrease variation in care. An example of a statewide evidenced-based practice guideline is included below.

Education – This may occur in the format of grand rounds, case presentations, newsletters, conferences, one-on-one, etc. Provision of nursing (CEU) and physician (CME) continuing education credits will improve participation in all types of education.

Enhanced Resources – Increasing the availability of resources may include increasing or staggering staff during peak hours or days, enhancing equipment location or availability, increasing bed space, dedicating an operating suite for 24-hour availability, developing contingency plans for intermittent high patient volumes, i.e., surges.

Counseling - Counseling by the trauma medical director, nursing or ancillary services management, etc., may be necessary and depending on the issue can be done in person or in a letter. Any counseling that is done should be noted in the PI minutes and the provider's personnel record.

Change in Privileges, Credentials, or Accreditation - When other corrective action methods have failed, it may be necessary to temporarily or permanently revoke staff privileges. This is usually accomplished in coordination with the hospital-wide PI process and in accordance with hospital contracts or medical staff bylaws.

Focused Study or Audit – A focused study or audit can be implemented to better understand problems that reoccur. This information can then be used to develop appropriate improvement initiatives, such revising or developing treatment guidelines to reduce variation in care.

Trauma Registry System Reports

Information obtained from the state trauma registry and other pertinent data sources can be used to objectively evaluate system parameters, track variability, and document planned or unanticipated improvements. The effectiveness of injury prevention programs, efficacy of care, timeliness of care, access to providers and services, and outcomes are all important aspects of the statewide trauma system that should be routinely monitored and evaluated to identify opportunities to improve care and maximize outcomes.

There are numerous variables collected by the MN Trauma Registry that can be queried and used to effectively measure and evaluate system performance and outcomes. The data can be used to compare and benchmark performance among EMS providers, hospitals, rehabilitation centers, regions, and the State. The MN Trauma Registry, with linked sources if necessary, should serve as the primary tool to drive the trauma PI process throughout the state.

The following are examples of standardized reports that the MN Trauma Registry and larger volume hospitals can generate to monitor system or trauma center performance and outcomes, identify system or organizational needs, support policy and decision-making, target injury prevention, focus education, and document costs.

- Scene Time - Measured from first responder scene arrival time to transporting agency scene departure time. Scene time can be stratified by numerous variables, such as EMS agency, service level, county, region, injury severity (ISS and AIS), diagnoses, injury type, physiologic data, etc.
- EMS Times - Call to dispatch, dispatch to scene arrival, scene time, and transport time stratified by EMS agency, county, region, etc.
- Air Medical - Usage, response times, scene times, transport times stratified by time of day, location and distance, injury severity, cost, outcomes, appropriateness of air vs. ground, i.e., utilization, etc.
- Triage Criteria - Independently stratified by outcomes, procedures, resource and service utilization, etc.
- Morbidity - Rates stratified by hospital or provider, diagnoses, injury severity (ISS), outcome (i.e., death, LOS, critical care utilization, disability, cost), etc.
- Mortality - Rates stratified by gender, age, ISS, probability of survival, injury diagnoses, LOS, cost, etc.
- Hospital Readmission Rates – These can be stratified by complications, age, procedures, etc
- CMS "Never" Event Rates
- Disability - Stratified by injury severity, injury type, diagnoses, etc.
- Timeliness of Responders - Trauma surgeon and consultants
- Timeliness of Diagnostic Services, Procedures, Operative care – These may be stratified by injury diagnoses, severity of injury, type of injury, provider or hospital, associated complications, outcomes, etc.
- Availability of Resources – Operating room, blood, CT scan, ICU beds, specialists, etc. stratified by injury diagnoses, severity, etc.
- Length of Stay – ED, ICU, hspital, etc.

- <u>Timeliness of Interhospital transfer</u> - Stratified by level of care, hospital, region, etc.
- <u>Hospital and ICU Length of Stay</u> – Stratified by injury severity, complications, procedures, outcomes, etc.
- <u>Demographics and Injury Characteristics</u> - E-Code, injury type, and demographic information can be stratified by hospital, county, region, and outcome. This information is useful to identify injury patterns and target injury prevention efforts.
- <u>Hospital Discharge Disposition</u> – Discharge disposition (home, rehabilitation, SNF, etc.) can be stratified by variables such as injury type, injury severity, diagnoses, etc. Lack of access to rehabilitation or SNF due to funding should be monitored as well.
- <u>Disabilities at Hospital Discharge</u> – Rancho, FIM, GOS, etc., at time of discharge from hospital or post acute care, as data permits.

Trauma registry information can be queried and modeled in many ways to answer questions that arise from the PI process and used to support policy decision making and the development of treatment protocols and evidence-based practice guidelines, etc. For example:

- Triage Criteria – As the State assesses the outcome of injured patients and utilization of resources, it may find it useful to evaluate each triage criterion or combinations of criteria to determine its sensitivity and specificity to identify severely injured patients. For example, trauma registry data can be queried to produce information about what happens to patients when their systolic blood pressure is <90 mmHg compared to >90 mmHg in the prehospital setting. In Oregon, it was found that patients with a blood pressures <90mmHg had a significantly greater probability of mortality and required emergent operation substantially more frequently that those with a systolic blood pressure >90 mmHg. This information can then be interpreted through statistical modeling and used to develop and fine-tune the state's triage decision scheme and hospital resources requirements. Triage criteria may be evaluated for special populations, e.g. pediatric, geriatric, etc., as the trauma registry data becomes more robust.

- Procedures – Higher level care facilities might find it useful to use statewide trauma registry data to support the development of evidenced- based practice guidelines for trauma patient care. For instance, one might ask the question of when is the best time to perform tracheostomy and place a feeding tube (PEG) in head injured patients. Trauma registry data can be queried to illustrate the timeframes of when these procedures are performed and relate these to length of stay, occurrence (or absence) of complications, ventilator days, bedside versus operating room, and cost. In Oregon, it was found that early placement at the time of definitive surgery (trauma hospital day 1) or in the ICU led to fewer complications, reduced ventilator days, reduced length of stay, and reduced cost.

Trauma Registry Data Validation: Essential for Quality Trauma Care

Short Title: *Trauma Registry Data Validation*

(Accepted for publication in the *Journal of Trauma*)

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ABSTRACT

Background: The main function of a trauma registry is to assess quality assurance and performance improvement (QA/PI) in an individual institution. Non-validated registry data may produce unreliable reports and QA/PI information. This study examines the following objectives: types of data entry errors in a trauma registry database; effect of errors on time variable estimates, case ascertainment and statistical measurement; dynamics of error occurrence; and data validation (DV) scheme for a trauma registry.

Methods: Query and cross-tabulation techniques were used to expose a variety of data entry errors. Conceptual aspect for each type of error in DV, especially with respect to QA/PI, is given.

Results: Findings in different errors are provided: out-of-range time values; false positive and false negative errors; errors of commission and omission; duplication errors; errors in demographics; and errors due to inconsistent and incongruent coding. Error rates were less than 3% in commonly occurring data, such as scene time, demographics, hospital discharge and transportation, and greater in less commonly occurring but important data, such as thoracic aorta injury (9.5%) and audit filter for admit Glasgow Coma Scale in emergency department (55.6%). Dynamics of error occurrence that can prevent or minimize errors is described. The main features of a data validation scheme are displayed.

Conclusions: Errors in a trauma registry database cause invalid frequencies, rates, time estimates and statistical measures and affect QA/PI in trauma care. Every functioning trauma registry should develop an on-going program for DV.

Key words: Trauma registry, data entry errors, quality assurance, performance improvement, dynamics of error occurrence, data validation scheme

INTRODUCTION

As of April 2004, over 1,200 designated or verified trauma centers were identified across the United States and 434 of these were levels I or II trauma centers. [1] According to the American College of Surgeons (ACS), a trauma registry is an essential component of any trauma program in order to provide necessary information for optimal care of the injured patient. [2] Almost every trauma center operates a trauma registry.[3] Among the functions of a trauma registry are assessing quality assurance and performance improvement (QA/PI) in the process, outcome and trend of patient care in an individual institution; developing and evaluating trauma prevention programs; and conducting outcomes research especially in levels I and II trauma centers.[2] These functions play an even more important role by submitting registry data to region and state trauma registries, and to the National Trauma Data Bank (NTDB) of the American College of Surgeons.

We can extract different reports for each type of user from trauma registry data; these include QA/PI information, general trauma statistics and trends, activity or summary reports, patient lists and research.[4] Non-validated registry data may produce unreliable reports including QA/PI information. Trauma registries compile database information using a variety of software products: TRACS®, Collect®, Cales®, Trauma One®, Trauma®, TraumaBase® and others.[5] Operations among different software may be different, but the concepts of data validation techniques should be applicable to all software. Furthermore, commonality of data fields and sections among various databases allows the NTDB to produce its annual reports. In the NTDB report for 2003, about 25% of the 731,824 records were excluded from statistical analysis due to errors of inconsistency or invalid records of age, gender and hospital length of stay. [6] In the reference manual for the same report, data entry error rates for unknown or missing information for hospital transfer, external causes of injury and admit Glasgow Coma Scale values were 76%, 34% and 19% respectively.[5] These errors were probably due to flawed data submitted from the 255 participating trauma centers. If so, the frequencies clearly indicate that each trauma center should have an appropriate and on-going validation scheme operating in its registry.

The objectives of this paper are: (1) to describe various types of data entry errors such as out-of-range time values, false positive, false negative, inconsistent and incongruent coding, inaccurate inclusion and exclusion of data, duplications, and inaccurate demographic data; (2) to show the effect of errors on time variable estimates, case ascertainment and statistical measurement; (3) to elucidate dynamics of error occurrence; and (4) to propose a data validation scheme for a trauma registry.

MATERIALS AND METHODS

Parkview Hospital

Parkview Hospital is a 450-bed facility in Fort Wayne, Indiana. The American College of Surgeons verified the hospital as a level II trauma center in 2000 and re-verified it in 2003 as an adult and pediatric level II trauma center. The trauma registry has been in effect since 1991; the medical director was appointed in 1997. A Samaritan Flight Program has operated from the hospital since 1989. Currently, the staff of the trauma center registry consists of a program manager, three trauma program nurses, one registrar, and an epidemiologist, all of whom work with the trauma team.

The Data

Over the past five years, more than 800 major trauma patient records have been entered annually to the registry. Trauma program nurses abstract and collect data from each patient on a specific form, which the registrar then enters into our computer software. We used TraumaBase® (Version 5.0) from 1991 to 2001 and have employed TraumaBase® (Version 6.0)[7] since 2002. For data validation, the latter software has automatic editing by displaying an error message on the screen while entering an inadmissible data outside the specified list of codes, or outside the range of time or date value. All trauma patients are evaluated according to ICD9-CM (International Classification of Disease, ninth revision, Clinical Modification) diagnostic injury codes (800.00 to 959.59)[8] and recorded as admitted to the hospital, dead on hospital arrival, or died in the Emergency Department. Fine-tuning and utilizing the data for reporting and research is the responsibility of the epidemiologist. We are here using data from our registry to illustrate various types of errors that have occurred in the database. However, the concepts we apply are equally valid for other software users.

Database Structure in Data Validation

Data fields in TraumaBase® are in the form of numbers (medical record number), words (patient's name), dates and times (trauma surgeon arrival date and time), texts (diagnostic description), codes (ICD-9, audit filter), and derived calculated values (injury severity score, trauma surgeon response time). An audit filter is an indicator to measure the effectiveness of the process of trauma care.[2] Data fields may be single or multi-valued fields. Ordinarily, data validation is confined to single data fields, where the data could be missing or incorrect due to entry or transcription errors. To refine our approach to data validation, we worked with groupings of data fields (Table 1). For instance, we do a significant amount of coding from text description. A text description may be considered as an internal criterion for validation of its derived code. Also, related data fields may be used to validate data within the database for corroborative or exclusionary information. Furthermore, in the admission of some types of patients, recording in certain data fields should be skipped. To prevent introduction of errors, these cases need to be recognized

upfront and dealt with before entry into the database. Finally, multi-value fields can cause case selection bias, which can be avoided by selecting well-defined subpopulations for comparing stratum-specific measures. We have described the use of multi-value fields in case ascertainment for comparison purposes elsewhere.[9]

Concepts of Detecting Specific Error in Data Validation

Out-of-Range Time Values
We can identify an out-of-range time value by calculating its resultant time value (RTV). RTV is the time difference between two sets of time and date.

Algebraically,
$$RTV = t_2 - t_1,$$
where t_2 = final time and date, and t_1 = initial time and date.
The units of measurement may be in minutes or hours with decimal points or in hh:mm (hour:minute) format. Many RTV's are important as ACS screening criteria for QA/PI information (Table 2).[10-11] RTV can disclose missing values in one or more components required for calculating it, and identify unusually large or small gaps in time values, and negative and consequently inadmissible time values. Values that fall out of the allowable range may indicate poor QA/PI. Calculation of RTV is especially valuable since it validates more than one data field or item at a time. Finding errors for several related items simultaneously as well as the RTV for a parameter of particular interest is just like killing five flies with one swat.

False positive and false negative coding errors
Eliciting false positive and false negative errors needs two items, the code for the injury and the text to which the code is assigned. For example, spleen injury from text description may be used as the reference. The correct ICD-9 three-digit code for spleen injury is 865.[8] There are four possible outcomes for the code and text diagnosis. ICD9 865 coded as spleen injury is a true positive; not coded is a true negative. ICD9 865 coded as a non-spleen injury is a false positive; not coded to a spleen injury is a false negative. What concerns us are false positive and false negative errors, which introduce bias into the data due to misclassification. False positives add incorrect cases to (inaccurate inclusion) and false negatives subtract correct cases from (inaccurate exclusion) the actual values of interest in data analysis. This is true if we use codes for case ascertainment.

Errors of Commission or Omission
An error of commission is entry of data that should not be abstracted or entry of data to a field that should be skipped for recording. An error of omission is data that is not recorded but should have been abstracted or coded. The former causes over-reporting and the latter underreporting of actual data. We generally concentrate on finding missing data and may not be aware of errors of commission.

Duplication of Data
Two or more entries may be made for one-time occurrences during the course of a hospital stay. This error wrongly counts the single occurrences as multiple occurrences.

Errors in Demographic Data

A trauma patient may be unconscious or unaccompanied by a responsible informant or personal identification documents when admitted to the hospital. Common practice substitutes '1/1/current year' for an unknown DOB (date of birth); if DOB is not subsequently corrected, the patient's age is recorded as less than 1 year, regardless of true age. Such errors corrupt reporting by age. When patient identity is incomplete or unknown, a nickname (Joe) or a generic name (John Doe) may be supplied, or an unknown residential address may be substituted with a hospital address. Such errors corrupt patient identification and origin.

Errors due to Inconsistency in Coding

These errors arise from incongruence between policy definitions and actual coding practices. Inconsistent coding at patient discharge can invalidate aspects of outcome research. For instance, when patient discharge to rehab services is defined as a discharge destination, readmission of the patient from rehab back to hospital care may create an appearance of prolonged hospital length of stay (LOS). Hospital LOS is often used for outcome assessment of acute trauma care.

Errors due to Incongruence in Coding

These errors arise when the same or similar codes in two or more related data fields are not congruent; they can cause misclassification of cases. An example for two related fields in TraumaBase® may be 'discharge disposition' and 'discharge destination'. Discharge destination is patient specific destination, e.g. moved to a specific hospital, after hospital discharge. Discharge disposition refers to broader category of patient placement after discharge e.g. moved to an unspecified or unnamed hospital. Many codes such as home, nursing care, death are common to both fields. An example for three or more related fields may be drawn from the following data fields: 'hospital transfer', 'from hospital', 'transport origin', 'transport destination' and 'procedure location code'. The common code in all these fields is related to referral of patient from outlying hospital.

Techniques and Procedures

We used query technique to detect all entry errors mentioned above. Query technique to find false positive and false negative errors has been described in detail elsewhere.[12] In addition, cross-tabulation was used to detect incongruent coding errors for the same or similar codes in two or more related fields, employing two related fields at a time. Various periods between 1996 and 2003 were selected to illustrate identification and quantification of several types of errors.

RESULTS

Out-of-Range Time Values

The query technique, applied to records entered in specific time frames, detected 23 outstanding errors for scene times, trauma surgeon arrival time from patient arrival and trauma surgeon call time from trauma team activation time (Table 3); the error rate for the recorded cases was 1% or less. Nevertheless, uncorrected, the magnitude of those individual errors of extreme time variable values (Table 4) would not only indicate any good or bad performance on the parts of responsible transport agency and trauma surgeons, but

also definitely affect the statistical measures such as mean values in aggregate analysis and thereby produce unreliable reports. Correction of the data achieved reasonable values when compared to allowable ranges.

False Positive and False Negative Coding Errors

Using patients with spleen injury as an example, the error rate was about 2.5% whether using ICD-9 vs. DIAGNOSIS or AIS vs. DIAGNOSIS as matching pairs (Table 5). The findings of false negative errors for other injuries were in the range of 7.4 and 55.6% (Table 6).

Errors of Commission and Omission

An error rate of 4.5% was found for patients with direct admit and 7.4% for patients with death at the Emergency Department; error rates for missing procedure ICD-9 codes for patients undergoing diaphragmatic surgery and tracheostomy were 10.5% and 22.2% respectively (Table 7).

Errors in Double Entry

Error rates in double entry for audit filters, such as incomplete documentation of trauma notification sheet among 512 patients, and repeated vital signs among 549 patients in Emergency Department in 1999-2000 were about 1%. The double entry rate among 7737 patient records in 1997-2001 was 0.2%.

Errors in Demographics

Error rate in patients with unknown address among 811 cases in 2000 was 2.7%; those with unknown age among 1009 cases in 2001, and unknown name among 4808 cases in 1996-2001, were less than 1%.

Errors due to Inconsistent Coding

Error rate of inconsistent coding for determining hospital LOS from 1997 to 2000 was 0.8%. When the 11 cases from 1999 data were taken into consideration, before correction mean hospital LOS was 19.27 (SD± 9.68) days; after correction mean hospital LOS was 12.00 (SD ± 5.50) days. The difference was statistically highly significant (t-value = 4.54; $P < 0.01$).

Errors due to Incongruent Coding

Table 8 is a simplified condensed table, cross-tabulating discharge disposition vs. destination. Incongruent coding errors were detected for two combinations: two cases of 'Home' (discharge to home) in the destination field vs. 'No data' in the disposition field; and two cases of 'Nursing Home' in the destination field vs. 'Home' in the disposition field.

One case of missing data was in both fields. The error rate was 0.5% (5/984). All erroneous data was corrected. In cross-tabulating transport modes for having three or more related data fields, among 2190 referral patients in 1996-2002, 58 cases that were recorded as scene either transported by ambulance or helicopter were actually referral cases, giving an error rate of 2.6%.

DISCUSSION

Errors may be due to missing entries, mistakes in transcribing or coding (false positive, false negative, inconsistent or incongruent coding), duplicate entries, redundant data unnecessarily introduced for certain selected patients (commission errors), or suppositious data temporarily substituting for unknown variables (errors in demographics). An error rate found in a given study sample over a given time period generally gives us information about the overall quality of specific types of data during that period: the lower the value, the higher the probability that the quality of data is being maintained. Higher rates identify areas where improvement in data entry is required. Current rates of error provide quantitative measures for evaluation of deterioration or improvement in data collection methods. The error rates were less than 3% in most common data items, such as scene time, demographics, hospital discharge and transportation at Parkview Hospital Level II Trauma Center. The exceptions are false negative coding errors for other injuries and conditions (Table 6) and errors of commission and omission (Table 7). How such errors can seriously affect QA/PI information is summarized in Table 9. Errors due to incorrect case ascertainment such as misclassified, over counted or undercounted cases, will result in invalid numbers e.g. frequencies, which in turn, produce invalid estimated parameters, e.g. rates. Invalid frequencies and rates if they are used for trending, will not reflect any meaningful performance improvement. On the other hand, incorrect individual time estimates and their derived statistical measures will not provide reliable QA/PI information. In our case, we were able to correct almost all identified errors by referring to the abstracted form or patient records or both.

For performance improvement in a trauma center, trauma registry data may be used to review trauma care, to identify variations in the process or outcome of care, to assess trends in performance and outcome, and to track variability and improvements of a variety of parameters in the institution and regional trauma system.[2] In addition, ACS Committee on Trauma suggests that local criteria and performance improvement be established to define conditions for level I and level II trauma centers.[2] For example, in the years from 2000-2004 at Parkview Hospital, the following findings, based on our validated trauma registry data, were recorded:
    The general trend of trauma patient admission to trauma services was more or less constant (810-850 admission cases per year) from 2001 to 2004 and relatively low (650 cases) in 2000;
    The annual rates of trauma team activation per year ranged from 95-100% for severely injured trauma patients that required immediate major resuscitation;

    Trauma surgeons, on the average, arrived at the Emergency Department before the arrival of these patients;

Annual over and under triage rate in the Emergency Department by three levels (types 1, 2 and 3) of care, as defined in our policy, ranged from 7-30% and 2-8% respectively.

Our record was considered satisfactory or acceptable in the review process.

ACS commends audit filters to assess trauma care in an institution and the trauma system. One of these is scene time longer than 20 minutes which ACS has designated ACS1 for assessment of pre-hospital care in a trauma center.[2] When we evaluated ACS1 for patient transportation by helicopter after arrival to, and departure from scene, en route to Parkview Hospital in our 2002 registry data, the percentage of ACS1 was 27.7% (31/112). In reviewing these 31 patients with corresponding data recorded by the Samaritan Flight Program, all entries were found acceptable because of the nature of landing zone for the helicopter, occurrence of extrication, multiple trauma patients, and performance of critical stabilizing procedures at the scene of injury (personal communication, Cathy Harris, RN, BS, February 2003). Reliable information from our validated data for this important audit filter was able to explain the high percentage of ACS1. There are many other examples when our validated data provided reliable information for QA/PI, among them, timeliness of care for craniotomy or laparotomy; ICU or hospital LOS; incidence of pneumonia or other complications; and comparison of observed and expected deaths based on TRISS model.

Conducting research is a function of trauma centers especially at level I and level II trauma centers.[2] Trauma registry data is often used for research at the local, state and national level. According to the 2004 NTDB report, more than 100 research projects have been carried out since its inception in 1989; these projects used the NTDB data to answer questions about surgical care and to provide hospitals with NTDB benchmarking reports as they continually evaluate and improve performance.[13] Again, without submission of valid data from participating trauma centers, the results of the NTDB research would not be reliable. One of our investigators noted that, in 48 research articles published in the Journal of Trauma: Injury, Infection and Critical Care, issued in 2004, trauma registry database was queried for case ascertainment as study subjects entirely or in part; these data were taken from institutional or statewide trauma registries in the United States. Again, the importance of validated data is indisputable.

Trauma centers request ACS to perform on-site hospital verification and periodic re-verification of compliance with trauma center standards so as to provide optimal care to trauma patients. Printed reports of data for different types of important injuries are requested from the trauma registry just before and at the time of on-site verification visits. Unreliable data could affect the verification or re-verification process.

For purposes of QA/PI, external sources of data may be used to detect and correct missing and erroneous entries in the registry database. For example, instances of missing data at Parkview Trauma Registry occurred in the earlier years of operation from 1991-1995, because of a shortage of personnel. By referring to a flight register kept at the Parkview Hospital's Samaritan Flight Program, we identified the missing data. A fixing program incorporated in the computer software repaired the missing and incorrect data of interest, and the valid and reliable data was incorporated into the current database. Thereafter, the data in the registry was able to serve QA/PI for the Flight Program from 1991-2003.[14]

Errors inevitably occur even with the most meticulous data collection efforts and with sophisticated automatic editing which is incorporated in the software system during data entry.[15] However, the trick is to prevent or minimize their occurrence. Consequently, understanding of dynamics or determinants controlling them is important. The nature of determinants influencing error occurrence in a trauma registry is shown in Fig. 1, and the components under each determinant are given in Table 10. With respect to managerial determinants, staff interaction between data collectors and registrar is especially important in the prevention of entry errors. Acquisition of knowledge on data validation techniques will facilitate sufficient data validation. Presence of service or research projects or programs will promote adequate use of data, get a better opportunity of data being validated, and thereby less errors. The role of administrative personnel is significant for provision of necessary financial and other support such as appropriate hardware, software and updates, as well as training of staff involved in registry operations and management. The role of the registrar is crucial for recognizing and minimizing errors in registry database.

The Trauma Resource Network, an official program of the National Foundation for Trauma Care (NFTC) has indicated that managing the trauma registry is a large part of the trauma service's function[4] and this management should include validation to assure trauma registry data quality to be worthy of trauma service's expenditure. The American College of Surgeons Committee on Trauma has emphasized the importance of entering valid data, of having strategies to monitor data validity, and establishing schemes for internal validation to detect errors in data entry or coding.[2] Based on our findings and experience, we have developed a data validation scheme for use at Parkview Level II Trauma Center; we display the main features in Table 11. The data validation program, as utilized in this study, can be adapted by other trauma centers to minimize error occurrence in their registries.

ACS recommends that 5 to 10% of all patients be validated to compare the data abstracted and entered into the trauma registry with the information observed in the medical record.[2] This approach is time consuming and could be expensive, and may not be feasible for many trauma centers, including our trauma center at this moment. However, we believe that, using our approaches and methods, and suggestions in data validation, registry data quality can be satisfactorily assured. Only when registry data is valid and reliable will it be an effective tool for performance improvement for hospitals, emergency medical services, and regional trauma systems and will it allow comparisons to benchmarks across systems of care.

CONCLUSIONS

Our findings indicate that errors in a trauma registry database cause invalid frequencies, rates, time estimates and statistical measures and affect QA/PI in trauma care; furthermore, validated trauma registry data are required for other uses to have reliable results. In order to prevent errors, the manager of a trauma registry should know

and understand the structure of the database in use, the kinds of errors possible in the database, the techniques available for search and selection within the database software and the dynamics of error occurrence. We believe that validation of a trauma registry database is crucial, especially for QA/PI information for trauma care, before producing any reports, research findings or participating in projects at local, regional or national level. Finally, we believe that data validation techniques available in various types of registry software should be fully discussed and standardized so that a scheme is available to operate and validate the content of the database in every functioning trauma registry.

ACKNOWLEDGEMENTS

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Table 1   Use of Groupings of Data Fields in Data Validation

Grouping of Data Fields	Examples
Codes and related description fields for their derived codes	Diagnostic ICD-9 Procedure ICD-9 AIS E-codes Complication Audit filters Co-morbidity

Related data fields	Two-related data fields:
	    Admit GCS vs. audit filter for admit
	    GCS
	Three or more related data fields:
	    Hospital transfer vs. referring hospital vs.
	    transport origin vs. transport destination

Data fields to be skipped for recording	Patients with direct admit should not have
	    Emergency Department related data.
	Patients who died at Emergency Department
	    should not have hospital admission date.

Multi-value data fields	ICD-9 AIS codes Body region of injury Procedures

ICD-9, international classification of diseases, ninth revision codes; AIS, abbreviated injury scale; E-codes, external cause-of-injury codes; GCS, Glasgow Coma Scale

Table 2   Resultant Time Values to Evaluate Timeliness for Trauma System Effectiveness and Patient Care

Area	Examples
Trauma system	Field time (time from injury to hospital arrival) Scene time Time spent at outlying hospital
Patient care process Sub-specialist response	Anesthesiologist response time Trauma surgeon response time Neurosurgeon response time
Time spent in performing procedures	Time to head CT Time to OR by anesthesiologist Time to OR for abdominal, orthopedic, thoracic, vascular or cranial surgery
Patient care outcome	ICU LOS Hospital LOS

Head CT, computed tomography of the head; OR, operation room;

ICU LOS, intensive care unit length of stay; hospital LOS, hospital length of stay.

Table 3   Error Rate for Unusually High or Low Resultant Time Values

Resultant Time Value (Minutes)	Time Period	Number of Cases	Number of Errors	Rate (%)
Scene time	1996-1999	1028[a]	10	1.0
Trauma surgeon arrival time from patient arrival	1999- 2000	1095[b]	4	0.4
Trauma surgeon call time from trauma team activation	2001	821[c]	9	1.1

[a]   Patients from scene.

[b] Levels 1 and 2 trauma cases. Level 2 cases were patients that need trauma team

   activation and attendance by trauma surgeons besides other health care providers.

   Level 1 cases were patients that need major resuscitation in addition to criteria for
         level 2 cases.

[c] Trauma Service admit cases.

Table 4   Unusually High or Low Individual Resultant Time Values

Individual Value (Minutes)		Allowable Range (Minutes)
Before Correction	After Correction	
Scene Time		
-4908	12	
-592	8	0-20
-1190	10	
-165	15	(Upper limit may be
-571	29	prolonged if extrication
-165	15	occurred)
44,656	16	
779	59	
610	10	
242	26	
Trauma Surgeon Arrival Time from Patient Arrival		
61[a]	-19	Level 1 = 0-15
-1352[b]	88	Level 2 = 0-60
-1137[b]	303	(Minus sign indicates
-1349[b]	7	surgeon arrived at ED
		before the patient.)
Trauma Surgeon Call Time from Trauma Team Activation		
527,055	15	
527,047	7	0-15
525,599	-1	
525,596	-4	(Minus signs indicate
527,040	0	surgeons arrived at
525,614	14	ED before trauma team
527,008	-32	activation)
525,600	0	
1,441	1	

ED, Emergency Department

[a] Level 1 trauma case. (See definition in Table 3.)

[b] Level 2 trauma case. (See definition in Table 3.)

Table 5   False Positive and False Negative Coding Errors for Spleen Injury in 3,144 Trauma Patients, 1997-2000

Matching pair of data Field	Initial # of spleen injury patients (Before matching)	Coding errors		Final # of spleen injury patients (After matching and correction)	Error Rate (%)
		False positive	False negative		
ICD-9 vs. DIAGNOSIS	238	1	5	242	2.5
AIS vs. DIAGNOSIS	236	0	6	242	2.5

ICD-9, international classification of diseases, ninth revision codes; AIS, abbreviated

injury scale.

Table 6   False Negative Coding Errors in Other Injuries or Conditions

Trauma	Time Period	Number of Cases	Number of Errors	Error Rate (%)
Thoracic aorta injury	1997-2001	21	2	9.5
Fat emboli complication	1997-2001	8	1	12.5
Carotid artery injury	1997-2003	27	2	7.4
Audit filter for admit GCS	2002	18[a]	10[b]	55.6

GCS, Glasgow Coma Scale.

[a]   Cases with missing admit GCS values in the Emergency Department.

[b]   Cases for failure to monitor the missing admit GCS values in the Department.

Table 7   Errors of Commission and Omission

Trauma	Time Period	Number of Cases	Number of Errors	Error Rate (%)
Patients admitted to Trauma Registry				
Patients with direct admit	1999-2001	44	2 (ED LOS recorded)	4.5
Patients died at ED	1997-2003	27	2 (Hospital admission date recorded)	7.4

Patients with surgical intervention

Patients with diaphragmatic surgery	1997-2001	38	4 (ICD-9 missing)	10.5
Tracheotomy patients	1996-1997	18	4 (ICD-9 missing)	22.2

ED LOS, Emergency Department length of stay; ICD-9, international classification of

diseases, ninth revision codes.

Table 8 Incongruent Coding Errors in Two-related Data Fields, 2003

Disposition / Destination	Death	Home	Hospital	Nursing Home	Other	No Data	Total
Death	93						93
Home		655				2[a]	657
Hospital 1			3				3
Hospital 2			4				4
Nursing Home		2[a]		51			53
Other					173		173
No Data						1[b]	1
Total	93	657	7	51	173	3	984

[a] Incongruent coding errors.

[b] Missing error.

Table 9   Type of Data, Type of Error, and Effect of Error

Type of data	Type of Error	Effect of Error
Demographics	Temporary substitution for unknown variables	Misclassification of cases
Codes and related description	False positive and false negative coding errors	
Two or more related fields	Errors due to incongruent coding	
Certain type of admitting patients	Errors of commission	Over counting of cases
Items with one time occurrence during hospital stay	Double or more entries	
Codes and related description	Errors of omission (of codes)	Undercounting of cases (if codes are used for data retrieval)
Resultant Time Values	Unusually high or low, or inadmissible negative values	Incorrect individual estimated values
Hospital outcome	Errors due to inconsistent coding	

Table 10   Components of Dynamics of Error Occurrence

Determinant	Component
Operational	Incorrect or missed entry (out-of-range values, errors of commission, errors of omission) Improper coding (false positive, false negative errors) Inconsistent coding (hospital length of stay) Incongruent coding (related data fields) Double or more entry Neglecting to correct temporary demographic assignments when they become known or verified
Managerial	Inappropriate supervision (lack of staff interaction) Insufficient data validation (lack of acquisition of techniques) Inadequate use of data (lack of projects/programs)
Administrative	Improper training of staff (lack of experience in coding skill and data validation techniques) Insufficient support from hospital administration

Table 11   An Outline of a Data Validation Scheme for a Trauma Registry

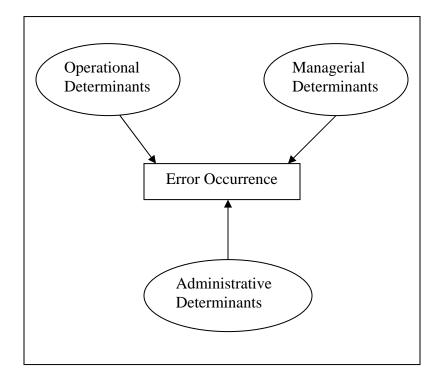| Component	Examples
Analysis of a case record by section	Demographics, pre-hospital
Selection of fields to be validated	Admitting service, surgeon response time, audit filters
Techniques to be employed	Query, cross-tabulation
Types of error to be detected	Missing or absurd values, false positives, false negatives, double entries
Correction of errors	Detected errors that can be corrected
Schedule for performing validation process	Monthly, quarterly, yearly or ad hoc

Fig. 1. *Dynamics of Error Occurrence in a Trauma Registry.*