FACILITATING IMPLEMENTATION OF EVIDENCE-BASED GUIDELINES IN HOSPITAL SETTINGS: LEARNING FROM TRAUMA CENTERS

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Commissioned by the Brain Trauma Foundation

June 2006

ABSTRACT: This study examines issues contributing to slow and partial compliance with evidence-based clinical guidelines. It focuses on guidelines for management of severe traumatic brain injury (TBI). Because severe head trauma enlists so many providers and often involves injury to multiple body systems, it maximizes the challenges of delivering timely, consistent, and coordinated care. Management of TBI thus offers a valuable perspective on the structural problems that impede the delivery of care and the implementation of clinical guidelines. The study identifies barriers to compliance with TBI guidelines, describes how three trauma centers lowered or overcame such barriers, and identifies common threads in their approaches. Based on this analysis, the study presents a model for implementing clinical guidelines to achieve consistency, continuity, and coordination of patient care.

Support for this research was provided by The Commonwealth Fund. The views presented here are those of the author and not necessarily those of The Commonwealth Fund or its directors, officers, or staff. This and other Fund publications are online at www.cmwf.org. To learn more about new publications when they become available, visit the Fund's Web site and register to receive e-mail alerts. Commonwealth Fund pub. no. 930.

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EXECUTIVE SUMMARY

This study examines a complex interplay of issues contributing to slow and partial compliance with evidence-based clinical guidelines. It focuses on guidelines for management of severe traumatic brain injury (TBI), which were first issued a decade ago and are revised every five years. Because severe head trauma enlists so many providers and often involves injury to multiple body systems, it maximizes the challenges of delivering timely, consistent, and coordinated care across the boundaries of disciplines, departments, hospital units, and lines of authority. Management of TBI thus offers a valuable perspective on the structural problems that impede the delivery of care and the implementation of clinical guidelines.

This is not a clinical study, but rather a study about change processes in complex clinical environments. Based on case studies and interviews with many physicians and nurses as well as a few academics, policymakers, and consultants, it identifies barriers to compliance with TBI guidelines, describes how three trauma centers lowered or overcame such barriers, and identifies common threads in their approaches.

Barriers to TBI Guidelines Implementation

Three types of barriers hinder implementation of TBI Guidelines: the macro-environment of trauma care, structural and organizational factors, and professional and personal factors.

Macro-Environmental Factors. The macro-environment—the financial, regulatory, and organizational context of trauma care—does not support trauma centers' investment in guidelines implementation. The trauma system itself and many of its trauma centers face significant financial challenges, putting their viability into question and impeding the reforms needed to implement the TBI Guidelines.

- Payment structures and levels do not match the costs of trauma care.
- Low volume plagues many centers, making it difficult to cover the high standby costs.
- At other centers, high volumes of uninsured trauma patients justify the standby costs but still generate losses for the center overall.

Structural and Organizational Factors. The management of TBI is embedded in the structures of medical practice through which trauma care in general and TBI care in particular is delivered. Guidelines are introduced into clinical environments that are

organized by medical specializations and the territorial issues that grow up around the various specializations.

- The segmentation of trauma care—with different providers making treatment decisions at different stages of care—is resistant and even antithetical to achievement of integrated TBI care consistent with the Guidelines.
- At every boundary between units, disciplines, and departments, there is potential for breakdowns in the continuity of care and barriers to implementation of the Guidelines.

Professional and Personal Factors. Although some physicians have taken leadership roles in aligning clinical practice with TBI Guidelines, physicians are, by all accounts, the primary locus of resistance. They are the point through which professional traditions, the imperatives of private practice, and structural barriers converge. Certain of their choices and behaviors are at the heart of what must change for TBI Guidelines to be effectively implemented.

- Treatment for trauma is becoming less rooted in surgery and thus—given the bias of payment codes toward surgery—less well reimbursed. Therefore, physicians are reluctant to take trauma calls and residents are turning away from trauma specialization.
- Physicians experience conflicts between treating trauma patients and conducting the rest of their professional lives. Further, treating trauma patients impinges on physicians' private lives.

Learning from Successful Implementation

Guidelines implementation requires organizational changes in clinical settings. Changes in clinical practice among the network of clinicians treating TBI patients are necessary but not sufficient. Clinicians from different specialties and different professions must also work together to improve communication, collaboration, and coordination of care.

The fragmented structure of trauma care must be counterbalanced by an equally powerful set of forces for integration. This requires investing in nursing and physician roles that have strong integration, coordination, and communication dimensions. Effective implementation requires several forms of leadership: physician champions, administrative and high-level medical support, and hands-on change agents.

- At least one leader from neurosurgery or trauma must be committed and persistent, and they must enlist at least one key ally from the other discipline.
- Although it is possible to implement the Guidelines without a clinical nurse specialist as the empowered change agent orchestrating the process on a daily basis, it is more difficult and appears to take much more time.

Key strategies for overcoming structural and organizational barriers as well as various forms of resistance include:

- limiting the number of people in the trauma network;
- translating each recommendation into protocols detailing how they are to be enacted;
- designing pathways and protocols with providers as well as patients in mind;
- redeploying staff to leverage their contributions;
- making changes in critical care units and/or management of such units;
- framing implementation as a research and learning opportunity; and
- enlisting, managing, and leveraging the scarce, often reluctant, neurosurgical resources.

Other factors in successful implementation include: increasing the degree of organizational readiness for change; undertaking a comprehensive change process that is both systematic and systemic; implementing an educational process that is comprehensive, ongoing, and tailored to individuals in the course of their work; and having mechanisms in place and enough resources available to sustain the changes and continue to improve.

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BACKGROUND AND POSITIONING OF THE STUDY

Many advocates seek to apply a principle that American manufacturers began to adopt in the 1980s to health care: if you want to improve the quality of your product (i.e., patient outcomes), you must reduce variability in the processes (i.e., treatments). Evidence-based clinical guidelines, protocols, and pathways are based on this principle.

Clinical guidelines aim to bring care to a consistently higher level of quality and thereby improve patient outcomes by: 1) reducing variability through standardization of many components of care delivery, and 2) codifying the optimal or best clinical choices suggested by the evidence to date. As a byproduct of this process, the resources and costs of caring for that patient population could be substantially reduced.

Nonetheless, guideline adoption has tended to be slow and uneven. What gets in the way of adopting evidence-based guidelines? When hospitals succeed in implementing guidelines, how do they do it? What can we learn from them?

Study Focus

This study tackles these questions by examining the challenges of translating guidelines for management of severe traumatic brain injury (TBI) into practice and showing how some trauma centers have overcome them. Under the leadership of the Brain Trauma Foundation (BTF), *Guidelines for the Management and Prognosis of Severe Traumatic Brain Injury* (hereafter, the TBI Guidelines, or the Guidelines, capitalized, to distinguish them from guidelines in general) were codified from the best data available by a panel of nationally recognized physicians in 1995, revised in 2000 and again in 2005 (to be published in the *Journal of Neurotrauma* in 2006).

Although some of the Guidelines are controversial and the 14 topics currently addressed have varying degrees of evidentiary support, they have made it possible for everyone involved in brain trauma care to pay attention to the same critical issues, cease practices now known to be harmful, reduce variability in treatment, and adopt best practices. It appears that following the Guidelines can contribute to significant declines in mortality, fewer complications among survivors, and higher neurological functionality at discharge—thus increasing the potential for TBI patients to experience an enhanced quality of life and more independent living.

If so, the impact could be considerable. Every year, 50,000 people die from TBI. In trauma centers that have not implemented the Guidelines, survivors might spend 10 to 20 days or more in critical care, followed by equal lengths of stays in hospitals.[1] Hospitalization is followed by long periods of rehabilitation and variable degrees of recovery. Each year, 70,000 to 90,000 relatively young people are neurologically disabled to varying degrees by TBI. The total annual TBI bill for society is estimated at $40 to $48 billion.[2]

Nonetheless, compliance with the guidelines has been slow and variable.[3] The fieldwork conducted for this study suggests that becoming compliant requires trauma centers to overcome numerous barriers and takes years. With support from The Commonwealth Fund, the Brain Trauma Foundation commissioned this study to identify barriers to implementation of TBI Guidelines and lessons from those who have overcome or lowered them.

The analysis focuses on treatment of severe TBI in its own right and as a window into how health care systems currently operate and how change in provider behavior can be brought about at the local level. If practices that produce inconsistent and fragmented care can be overcome in such an intense and complex area as trauma care, then there are lessons to be learned from this experience that go beyond this arena.

Study Design

This is not a clinical study, but a study about change processes in complex clinical environments. It does not address the relative efficacy of treatments or examine the benefits of TBI Guidelines or guidelines in general. It does proceed from the premise that reducing variability in clinical practice, drawing on the best evidence for clinical decisions, and coordinating care are generally good for the health system.

The study draws on dozens of confidential interviews, mostly with physicians and nurses but also with academics, policymakers, and consultants. Its goal is to develop an in-depth understanding of issues and barriers in Guidelines compliance and how some trauma centers have found ways to overcome them.

Accordingly, candor and frankness are essential. Interviewees were promised anonymity unless they agreed to be named. The quotations included in this report illustrate general themes or perceptions emerging from the interviews. These comments and other interview material ground this study in real life—raising issues related to power and perception that are often left out of peer-reviewed studies.

An interview-based study is not intended to address questions that require data analysis (such as the role of resource constraints) or judge the methods used in peer-

reviewed studies. Findings derived from surveys are mentioned from time to time only as a check on the salience of the field-based narrative.

The study focuses on the relationships between the Guidelines and the clinical environments in which they are introduced. It is based on the premises that:

- Notwithstanding the structural and financial constraints of the health care system and misalignment of its financial incentives, much improvement can be effected at the local level. Resistance—and overcoming it—are best observed on the ground floor.
- Understanding how people overcome barriers at the local level is best captured through case studies that convey the interdependent factors underlying success and situate readers in concrete situations.

Study Organization

Part I focuses on barriers to Guidelines implementation. It examines the mismatches between the macro-environment of the trauma centers and implementation of the Guidelines, the clinical environments through which trauma care is delivered, the primary locus of resistance (physicians), and the factors that mediate nurses' embrace of the Guidelines.

Part II presents case studies of three trauma centers that have implemented the Guidelines. They were chosen because each has published accounts about their change efforts, including data comparing their situation before and after they became compliant. Their published accounts, like most accounts in professional journals, tell us what they did. By contrast, the case studies describe how they did it and provide a glimpse into how the process unfolded.

Part III extracts learning from these case studies as well as from the challenges and frustrations described by interviewees from several other trauma centers. It identifies fundamental themes in overcoming structural and organizational barriers and key strategies for reducing professional, personal, and organizational resistance.

Part IV synthesizes the case studies and other fieldwork by creating a model of what trauma centers are really trying to achieve when they implement the Guidelines. This model applies to other health care contexts.

I. BARRIERS TO TRAUMATIC BRAIN INJURY (TBI) GUIDELINE IMPLEMENTATION

Despite the potential benefits of TBI Guidelines to patients and clinicians, there are several barriers to their implementation. Particular forms of resistance do not fit neatly into any one category or operate only at one level. They can, however, be roughly grouped as shown in Table 1.

Table 1. Barriers to Implementation of TBI Guidelines

Type of Barrier	Primary Level of Operation
Macro-Environmental	Financial/System
Organizational/Structural	Trauma Center/Hospital
Professional/Personal	Individual Clinicians

The macro-environment in which trauma centers operate—the financial, regulatory, and organizational context of trauma care—organizes the system for delivering trauma care in suboptimal ways. That system and many of its constituent centers face significant and growing financial challenges, putting their viability into question and impeding the reforms needed to implement the Guidelines.

Because trauma involves injury to multiple body systems and requires so many diverse players to work seamlessly in a time-critical situation, it maximizes the challenges of delivering timely, consistent, and coordinated care across the boundaries of disciplines, departments, hospital units, and lines of authority.

Although some physicians have taken leadership roles in aligning clinical practice with the Guidelines, physicians are, by all accounts, the primary locus of resistance. They are the point at which professional traditions, imperatives of private practice, and personal preferences converge. By contrast, nurses and numerous ancillary professions involved in trauma care are empowered by the Guidelines. Although Guidelines-based care cannot be practiced without nurses and other health care providers, they do not control whether the Guidelines are implemented.

Mismatches Between Macro-Environment and Guidelines Implementation

The macro-environment does not support efforts to implement Guidelines and imposes imbalances among centers.

Variability Among Designated Trauma Centers. The existing organization of trauma care is a patchwork of American College of Surgeons Committee on Trauma (ACS-

COT)–certified centers, state-certified centers, and self-designated trauma centers. The resulting variability is hardly the ideal environment in which to attempt to achieve consistency of TBI care through the Guidelines.

Financial Imbalances Among Centers. The trauma system as a whole is precarious financially and stretched professionally, and promises to get worse. The National Foundation for Trauma Care (NFTC) estimates total trauma center costs at $10 billion and losses at $1 billion annually—an average loss of 14 percent of operating expenses.[4] These losses do not include the unbilled and uncollected fees of physicians who wind up donating their time.

The financial problems of the system are not spread uniformly across trauma centers. Some centers are doing well, some are struggling, some have closed, and some are on the verge of closing. Interactions among three structural factors appear to contribute to the financial jeopardy of many centers: payer mix, standby costs, and volume of trauma patients.

Patients in three payer classes—commercial insurance, auto insurance, and workers' compensation—constitute half of the costs of trauma care, and they each generate surpluses. Medicare, Medicaid, and uninsured patients generate losses that, in total, exceed the surpluses.[5] Payer mix varies considerably among trauma centers. Suburban centers often have a large proportion of insured patients as well as a significant volume of patients, and may operate in the black. Urban centers often have a high and/or disproportionate volume of uninsured and Medicaid patients.

Standby costs are incurred by paying physicians to be on call and fulfilling a wide range of program requirements. Up to 200 physicians in 16 specialties are needed to support a Level I trauma center and, increasingly, physicians expect compensation for being on call. Physician stipends averaged $2.1 million per hospital in a recent study, half of which went to the "big three" of general/trauma surgeons, neurosurgeons, and orthopedic surgeons.[6] A Level I or II trauma center must support several full-time professionals in a formal trauma program, have an operating room (OR) on standby, and have anesthesiology and radiology services available around-the-clock. In addition, centers must meet numerous other requirements for their emergency departments (EDs), ORs, intensive care units (ICUs), respiratory therapy services, and radiology services and participate in many registries, databases, and performance improvement programs.

How do standby costs, payer mix, and patient volume interact? Patient volume is too low in many centers to support the heavy standby costs and provide staff with the

continuous practice that underwrites excellence. In rural centers, low volume is a major issue. While many urban trauma centers have high volumes that justify high standby costs, the volume is often offset by payer mix, since patients tend to be disproportionately uninsured. If volume increased in these centers, it would only increase their losses—unless reimbursement policies are changed to counteract these inequities.

When centers are struggling with the problems generated by interactions among volume, payer mix, and standby costs, they will be hard pressed to invest the necessary time, resources, and concentration needed to translate Guidelines into standard practice.

Mismatch Between Payment Structures and Costs of Trauma Care

Trauma centers also face mismatches between their high costs and the payment structures through which they are only partially reimbursed. These mismatches affect all trauma centers, but the degree of impact is mediated by payer mix, the contracts that centers negotiate, and the business sophistication of their financial staff. In addition to uncompensated care, three major factors lead to hospitals and physicians being underpaid for trauma work:

- Medicare and Medicaid do not cover standby costs and their rates for reimbursed services tend to be low.
- Managed care plans do not pay their fair share of trauma costs because they usually bundle trauma care into the same discounted rate structure as regular or elective care. By and large, managed care plans haves resisted negotiating carve-outs for trauma.
- Physician billing codes are biased in favor of performing procedures, and many physicians engaged in trauma work do not know how to use existing codes to get full credit for their work.[7] According to the 2004 NFTC report, billing codes:

> do not reflect the time and skill required to resuscitate and care for seriously injured patients. The payment system rewards performing procedures above the time-consuming critical care and monitoring that is the majority of a trauma surgeon's practice. Emergent, night, and weekend care are paid at the same rate as routine, scheduled care despite the disruptive nature of trauma care to elective practices.

Inability to See Cost Impact Clearly. Hospital accounting systems obscure the very things we need to know to assess the true costs of TBI care and begin to construct business cases that could strengthen arguments for Guidelines-based practice. For example:

- Hospital billing systems are set up to capture delivery costs on a patient-by-patient basis. That makes them a particularly poor match for trauma care, because they are not set up to capture the enormous standby costs of always being ready to deliver.
- Like any enterprise, a hospital assigns to each unit (i.e., each patient) a share of the fixed and indirect costs needed to keep the doors open and lights on. Traditional accounting methods use formulas to assign fixed and indirect costs that rarely give operating managers what they really need to know to understand actual costs under various conditions and thereby optimize or at least improve resource use, or make reliable comparisons before and after the Guidelines.
- Accounting systems do not facilitate even the most basic comparisons to measure resource use before and after Guidelines compliance. Apart from pharmaceuticals and purchased supplies, actual costs are difficult to calculate. "Charges" are a hospital's equivalent of the "retail price" of its services and do not reveal true costs. Nursing time is typically bundled into bed charges, for example, and nursing time is calculated from staffing ratios. When Guidelines compliance reduces length of stay, the components of the "savings" are likely to be estimated indirectly and crudely through lower bed charges. But does that have any real effect on what the hospital pays out to salaried nurses on contracts? Does another patient—perhaps a paying patient—occupy the bed during those freed-up days?

Difficulties in Making Business Cases. Are there business cases to be made for implementing TBI Guidelines? Probably there are. Have data been collected and organized in ways to build such cases? No one interviewed for this study knew of any such work. Not only have business cases not been built, but the data to build such cases either do not exist or cannot be extracted easily if at all from traditional accounting systems. The state of building business cases for Guidelines care is embryonic at best.

The few trauma centers that have collected historical data prior to Guidelines adoption and compared it with prospective data since the Guidelines became the basis of TBI care consider their work primitive and unavoidably composed of best "guesstimates." They compare physical use of certain resources that can be counted and readily assigned to a patient before and after implementation and then convert them to constant dollars to generate the "savings" to the hospital. These "variable costs" are actually charges, however, whose conversion to "real" savings is complex and problematic. Nonetheless, with these front-end "savings" ranging from $9,000 to $15,000 per patient, the potential savings for a trauma center could be substantial.

Trauma centers that have attempted to compare results before and after the use of Guidelines have produced findings that, on the surface, appear inconsistent. In the three centers discussed in Part II, one center improved patient outcomes while reducing charges, another had equivalent outcomes for fewer resources, and a third saw its costs increase significantly along with dramatic improvements in outcomes. Rather than assuming these findings are inconsistent or imposing a premature synthesis, it's possible to see these results as three different views of a complex situation, in which many aspects are unknown or unrepresented. It might turn out that each of these cases is a partial representation of a larger untold and as yet untellable story.

Before-and-after comparisons could become the first step in more sophisticated and dynamic analyses of business cases for Guidelines. We could ask, under what conditions do the paper savings of using fewer resources or shortening length of stay translate into real-world savings? If, for example, all of a center's contracts are per diem and it has a lot of empty beds, then the ability to move TBI patients out faster could mean loss of income. If, on the other hand, it has a mix of payer methods and is running closer to capacity, then faster throughput could mean fewer deficit days and the ability to take in more insured patients. To understand the business impact of using fewer resources to produce equivalent or better outcomes, one would need to examine the mix of methods or contract types and payer mix at different capacity levels, as well as other factors such as staffing levels and contracts.

Another challenging but instructive avenue of approach might be to estimate the value created by investing in advanced practice nurses to effect, ensure, and enforce Guidelines implementation. The combined value of potentially fewer resources per TBI patient, faster throughput, improved outcomes, better working relationships and communication, enhanced hospital reputation and ratings, and reduced likelihood of litigation might represent many multiples of their salaries.

Might it be possible to demonstrate that physicians are in fact called in less often when the Guidelines are fully implemented? Could investments in physician extenders, as discussed in Part III, reduce disruptions and the need for specialists, particularly neurosurgeons, to come to the hospital? Even if the benefits cannot be quantified, might trauma call be made less unattractive by being less disruptive?

Organizational and Structural Barriers in Delivering TBI Care

In the United States, trauma care is delivered through certified or self-designated trauma centers operating within hospitals. There are more than 1,200 trauma centers, of which at least 455 are Level I through Level III centers that treat severe TBI.[8] Certification does

not, however, mandate TBI Guidelines compliance. A trauma center is a way of practicing by members of a trauma network in an ED, OR, or ICU.

Patient's Path. A TBI patient is likely to be seen, triaged, and to some extent treated by Emergency Medical Services (EMS) and ED staff. Yet—contrary to the impression generated by television dramas—trauma care is not usually directed by ER staff but by trauma teams, or subsets of trauma networks, led by a trauma service. If the patient has an isolated head injury requiring a craniotomy, neurosurgery might be in charge.[9] About one-third of severe TBI patients need a craniotomy for removal of a blood clot. Many patients with severe TBI have other significant injuries and require general surgery during their hospitalization.

Once a patient is resuscitated and stabilized, most of their care takes place in a critical care unit (or ICU; the two terms are used synonymously). During the acute and critical care phase, the TBI patient also draws on many ancillary services, including pharmacy, radiology, nutrition, and respiratory therapy. Social services also might begin working right away, and the various rehabilitation therapies become engaged as warranted.

> In order to change the treatment of trauma patients in general and TBI patients in particular, certain behaviors and treatment decisions of EMS technicians, ED staff, anesthesiologists, the trauma team, the specialists consulted, critical care staff, and ancillary services must become consistent with each other and with the best practice treatment behaviors being advocated (such as the TBI Guidelines).

Structural Tensions and Discontinuities. Guidelines are introduced into clinical environments organized by medical specializations and the territorial issues that grow up around them. At every boundary between units, disciplines, and departments, there is potential for discontinuity in care and barriers to implementation of the Guidelines throughout the entire trauma network.

The large numbers of clinicians in a trauma network mean that the composition and variability of the trauma team for any given patient or day can be considerable, which can significantly affect consistency and compliance. Although medical residents stay on site, they vary in their skill and experience and rotate in and out of trauma care. Attending physicians and private-practice physicians take turns being on call for trauma patients. Other specialists might be called in for consultations. Attending physicians, residents, and specialists make decisions about a patient's care, and do not necessarily coordinate with the treatment plans of others. Any one of them might still use methods that have been discredited, such as prophylactic hyperventilation or steroid administration.

The potential for problems begins at the scene of the injury. Each EMS has its own set of protocols for handling different situations. These protocols may or may not be integrated with a hospital's protocols, or aligned with the in-hospital TBI Guidelines. There is consistency across BTF's Guidelines for the Prehospital Management of Severe Traumatic Brain Injury and the hospital TBI Guidelines, but often the EMS or hospital is not in compliance with them.

Relationships between the emergency department and trauma service vary widely. One trauma program manager reported, "We have good rapport, they are good at triage, they don't hold the patients for hours and then call trauma. Most of their residents have rotated with us, and that helps." Despite policies specifying under what conditions and how quickly the ED should call trauma to assess the patient, they are not always followed. One nurse said, "In most institutions, it can be a bear to get these two teams to work together and agree on how to take care of patients."

The service that admits the TBI patient and/or coordinated their acute care might not "own" the ICU or control the way it operates even thought it "owns" patients housed there. One clinician said, "They see the ICU as *their* unit. When we say we want this patient fed by day one or two, they react, 'Who is trauma to tell us how to take care of patients?'"

In addition to territorial divisions, differing clinical orientations affect whether providers follow Guidelines. Perhaps the most basic difference is whether a physician is rooted in internal medicine or surgical/critical care; the former tends to take less aggressive approaches.

The challenges for a trauma network in working across a segmented structure were summarized by one trauma program manager:

> We don't own any area but we need all the areas of the hospital to take care of our patients. We don't own the ED and it has many other kinds of patients. We don't own the ICU, the OR, the lab. We have to work the boundaries. Boundary management cannot be underestimated.

"Working the boundaries" is necessitated by segmentation of the horizontal flow of care delivery processes. As found in these case study interviews and research, clinical providers may go their own way, often persist in practices that the literature now deems harmful or practice in inconsistent and sometimes incompatible ways, may not be accountable to one another, may inherit each other's mistakes, and may not communicate effectively or even at all.

Hierarchies related to gender and medical culture also present barriers to Guidelines implementation. For example, Guidelines enforcement at the bedside depends in no small measure on proactive nurses who can educate residents and nursing staff on Guidelines practices and feel free to speak up when residents or attending physicians are not complying. This is problematic in some cultures in which, as one nurse manager put it, "nurses are taught to follow doctors, do as they are told, and not trained to think on their own or to challenge doctors or men." She continued, "When we do an in-service training and I ask, 'What would you do in this situation?,' they give me a weird look and say, 'I wouldn't *do* anything.'" These largely unacknowledged and unaddressed problems are further intensified when male residents come from countries or cultures where men do not even give lip service to taking advice or orders from women.

> Trauma care and ICU care require integration of various disciplines into one focused plan, but the structure of medical practice is resistant and even antithetical to such integration, cohesion, and patient-centeredness.

Professional and Personal Barriers Among Physicians

Some physicians are Guidelines champions and early adopters, but many are resistant to Guidelines implementation. Even though physicians are likely to benefit from implementation, they might not perceive the benefits or see them as secondary to other pressures and considerations. Physician resistance to TBI Guidelines implementation takes numerous forms, and is not easy to distinguish from reluctance to take trauma calls and general resistance to change. It can be intertwined with issues of turf and prestige and might reflect the orientations of their specialties or departments.

Benefits of Guidelines for Physicians. When the TBI Guidelines are well implemented, neurosurgeons are called upon more frequently to insert intracranial pressure (ICP) monitors. However, in other respects, the protocols can be designed so that neurosurgeons have less work to do and are disrupted less often. The work eliminated or delegated by the new protocols would previously have encroached on neurosurgeons' higher-priority, higher-skill, and higher-paying activities.

Protocolized Guidelines, or Guidelines translated into protocols, provide physicians with: a clear understanding of their own and others' responsibilities, advance knowledge of the approach colleagues from their own or other disciplines can be expected to take, and assurance that those interventions will not conflict with their own. Standardized orders and checklists ensure that steps are not forgotten and are performed in a timely manner. This can reduce delays, which can be costly and increase the risk of complications.

Physicians and Trauma Care. Many physicians are reluctant to take trauma calls because doing so can play havoc with their private and professional lives. Being on call can disrupt personal plans and interrupt sleep—which can have serious consequences for physicians' performance and patients' safety. Taking time to respond to trauma calls means that physicians might forfeit income from their own private or elective practice. Often, physicians receive little or no compensation from trauma patients who are uninsured or underinsured. Hospitals and physicians absorb the losses.[10]

Physicians' resistance to adopting the TBI Guidelines might be rooted in their dislike of trauma and trauma patients, and more broadly, in their perceived resistance to change and/or to being told what to do. Trauma patients are typically young and male, often uninsured or underinsured, and might have engaged in reckless behavior (e.g., drunk driving, speeding, or fights) that produced the trauma. For some physicians, the Guidelines might be experienced as adding insult to injury by telling physicians how to do what they don't want to be doing in the first place.

Trauma Surgeons and Trauma Care. A vocal subset of trauma surgeons are pressing for a more active role in neurotrauma care, largely because of the limited availability of many neurosurgeons. The long-term outlook for trauma surgeons themselves, however, and thus for TBI care is problematic. Younger physicians are reportedly much less willing than previous generations to make the personal and lifestyle sacrifices that trauma care entails.[11] Our interviewees concur; one stated, "The students who come here love this rotation, but they say, 'We don't want to live like you.' We did it because it was the right thing to do, but this is not the attitude of the young people I work with. This is huge."

Young surgeons are turning away from trauma care not only because of the lifestyle sacrifices, but because there is not that much trauma surgery to do. Trauma care is increasingly non-surgical, and advertised positions for trauma surgeons far exceed those willing and able to fill them.[12]

Neurosurgeons and Brain Trauma. Neurosurgeons wrote the Guidelines, and their colleagues' compliance is essential to their implementation. Some neurosurgeons have taken a strong leadership role in advocating TBI Guideline practice, but many have not. Five years after the Guidelines were first published, a survey by the Brain Trauma Foundation concluded that compliance was low and that the Guidelines by themselves have had only limited effect on changing physician behavior.[13]

Neurotrauma is usually a small part of a neurosurgeon's practice and—even with call pay—entails a net loss of income when opportunity costs are factored in. According to

interviewees, many neurosurgeons seem to be uninterested in brain trauma and resistant to change.[14] Removing hematomas for trauma patients is seen as low on the prestige ladder for those who graduated at the top of their class and revel in complex surgeries, and "protocols seem to insult their intelligence," as one clinician put it.

Interviewees observed some differences between neurosurgeons in private practice and those holding academic appointments and practicing in university hospitals. The former might be required to take trauma call as a condition of having access to hospital privileges. By contrast, neuroscience departments claim the study of the brain—and thus the effects of injury to the brain—as their primary subject matter for research and publishing. For neurosurgeons with academic appointments, participating in neurotrauma and training residents goes with the territory. These impressions are consistent with findings in the 2000 BTF study and other work.[15] Interviewees also note, however, that some academic centers have little interest in TBI, while some Level II and non-academic centers are keenly interested. This should be taken into account in any reorganization of the neurotrauma system.

Professional and Personal Barriers Mediating Nursing Empowerment

Because practicing according to TBI Guidelines and protocols is empowering to nurses and reduces work-related stress, nurses rarely oppose their adoption. It has been said that nurses are the natural adopters of guidelines. The extent to which nurses actually become champions of the Guidelines or realize the benefits of working in accordance with them appears to be mediated by numerous factors beyond their direct control.

Benefits for Nurses. Nurses are empowered by TBI Guidelines, especially when they are fleshed out by detailed protocols. By setting numerical parameters that need to be achieved or maintained, the protocols provide standards against which to calibrate care and progress. For example, nurses receive feedback even when a patient is still comatose, and thus the satisfaction of feeling efficacious. They have greater scope for action in accordance with the protocols and can often correct a situation that is slipping. Nurses know in detail what to do for patients day by day and phase by phase, and understand the conditions under which other intervention is called for and when a phone call needs to be made. Overall, nurses need to make fewer calls to residents, attending physicians, or specialists. As a program manager summarized:

> The Guidelines make it easier to understand when patients are doing well and not doing well. Nurses see patients in a different way than they did before they were educated about these standards. "If I can maintain blood pressure and oxygenation, the patient has a better

> chance of living, so that's my goal today." The Guidelines and protocols make it easier for staff—both nurses and residents—to take care of patients.

When a set of Guidelines-based protocols is firmly in place, nurses are less likely to be caught in the middle of disagreements between services or subjected to competing or conflicting orders from different residents, attending physicians, or specialists. Patients and families are reported by interviewees to be less likely to be angry and vent their anger on nurses.

Mediating Factors. To be empowered by the Guidelines, nurses have to take action, and some are more confident and proactive than others. Interviewees reported that nurses tend to be more proactive when an organization supports use of their expertise and when attending physicians and department chiefs back them. A nurse manager described her days as a trauma staff nurse:

> We had more clinical expertise and experience than residents with this type of patient, so we would stop a lot of bad things from happening. "I don't think you should do this, let's do that." You had to really know your stuff to challenge them. You had to be confident to know when to call and not call attendings. How do you get that confidence? By focused education and daily experience in your specialty.

If nurses are treated as interchangeable from a scheduling standpoint, they cannot support quality or consistency of care because they know less about what is missing or going wrong. If they are not expected to operate with some degree of autonomy—to identify problems or potential problems—problematic situations are likely to remain uncorrected. One nurse lamented:

> The bar for hiring nurses is low because what they expect them to do is low. If you only expect them to check vital signs, measure output, and do basic assessment, you can hire any RN and put them into almost any situation. But the demands of trauma care are complex and getting more so.

Such comments suggest that recruitment, hiring, deployment, scheduling, and retention of nurses as well as performance expectations affect the relationship that nurses develop with the Guidelines.

II. CHANGING PARADIGMS OF TBI PRACTICE: THREE CASE STUDIES

"Guidelines implementation" sounds relatively straightforward, but this phrase greatly understates the challenges. Implementation requires working across boundaries that can impede the flow of consistent and coordinated care. It entails working with a large number of diversely situated providers, changing behaviors, neutralizing resistance, and/or limiting the number of providers in the network.

The following case studies demonstrate some of the barriers to TBI Guideline implementation and show how some centers have managed to overcome them. The case studies highlight different challenges and approaches to solving them, such as:

- getting the ever-changing cast of residents to practice in the same way (University of Louisville Hospital);
- using clinical nurse specialists to drive and sustain the Guidelines implementation process (Mission Hospital and University of Louisville Hospital);
- using trauma nurses to achieve continuity and consistency of care (Mission Hospital);
- creating a culture of learning and continuous improvement (Mission Hospital and Inova Fairfax Hospital); and
- controlling how care is delivered in the ICU and shifting to an intensivist model of care (Inova Fairfax Hospital).

As the case studies indicate, some barriers are related to factors beyond the control of any one trauma center, such as the overall organization of the trauma system or reimbursement policies. Yet, many can be overcome at the local level by expending a great deal of energy, patience, and persistence. It should not have to be this way, but in the current medical system guidelines implementation is often hard, uphill work.

Mission Hospital

Located in Mission Viejo, California, Mission Hospital is a community hospital that was owned privately by physicians until its acquisition, in 1994, by the Sisters of St. Joseph, a Catholic hospital network. The Sisters of St. Joseph network considers having a trauma center part of its commitment to serving the community and the indigent. Mission sees about 1,000 trauma patients a year, half of whom require a neurosurgical consultation. Of that number, about 10 percent are diagnosed as severe TBI patients.

Change Agents in Relation to Environment. Like most trauma centers in the pre-Guidelines era, Mission Hospital used steroids, dehydrated patients, hyperventilated them, experienced high variation in treatment and practice, and was unaware of the importance of avoiding even brief episodes of hypotension or hypoxia. Then in 1997, Mission's Level II trauma center "turned its TBI practice upside down," according to Mary Kay Bader, R.N., M.S.N.

The center's clinical redirection was mobilized by Tom Shaver, M.D., a trauma surgeon and medical director of trauma at Mission since 1980. Shaver recognized a great disparity between current practices and Guidelines recommendations. He and Sylvain Palmer, M.D., chief of neurosurgery, became physician champions for change. When Palmer recruited Bader, an experienced trauma nurse, as neuro/critical care clinical nurse specialist (CNS), Shaver gave her the mandate of working with the trauma team to translate the Guidelines into standard hospital practice and to make the changes stick.

The trauma center's operating philosophy had been in place for a long time. Only a subset of each specialty (e.g., neurosurgery or plastic surgery) was and is allowed to take trauma calls. Those who do must have expertise, interest, and pass muster with trauma colleagues. Palmer explained, "You can't involve everyone. We don't want any more people taking calls than are necessary. If they don't mesh, we drop them. We can do that because trauma is a private service owned by trauma surgeons who can call or not call whomever they want." As a result, he observed, "we already had the elements of a trauma team in place. What we did not have was neurosurgical care consistent with the Guidelines."

Guidelines implementation was approached in the spirit of trying to improve performance and outcomes. This climate had been well established by Shaver and the trauma surgeons. As described by Bader, "People are not afraid to ask questions in this unit or to change. Dr. Shaver is always asking everyone, 'How can we do it better?' That has been the philosophy of our trauma center for 25 years, and it was ingrained in me as a young nurse in everything from what is done at the bedside to overall team management."

The openness and performance improvement orientation of the trauma center was situated in a broader context in which all improvement activities are reviewed, prioritized, approved, and overseen by the Quality Leadership Council (QLC). The QLC draws its members from the Board of Trustees, executive management, and hospital staff and is co-chaired by the CEO and chief of the medical staff. A clear reporting structure leading up to the Board was in place for improvement activities as was a methodology: FOCUS-PDCA, or Find a process to improve; Organize a team; Clarify current understanding of the process; Understand sources of variation; Select a process to improve; and then Plan it, Do it, Check the results, and Act to sustain the goals.

Changing TBI Practice. With the support of the physician champions and QLC, Bader drew together physicians (including trauma, neurosurgery, anesthesiology, and intensivist physicians), nurses (including advanced practice nurses, nursing managers, staff from adult and pediatric ICUs), and representatives from pharmacy, respiratory therapy, nutrition, social services, rehabilitation, and pastoral care into a multidisciplinary team to improve the process of treating TBI. She herself had reviewed about 50 key articles and conducted a retrospective audit of 2,000 records, and now she handed out assignments: "You need to study the Guidelines, read this list of articles, and we need to come to consensus on how we are going to change our practice."

In meetings within and across disciplines, participants examined current practice and sources of variation and discussed TBI Guidelines, their supporting evidence, and their own reading. They agreed to practice as a team using the new Guidelines as their backbone and develop protocols to flesh out how treatment is delivered and by whom. Bader synthesized the recommendations from all the disciplines into a coherent set of protocols and algorithms. She recalled, "It required a lot of education, clinical support, and continuous dialogue with all the specialties."

After the protocols were reviewed and approved, Bader led an education process with all affected departments. Within two months, implementation was launched by a "Trauma Nurse Education Day" attended by all ICU and trauma nurses as well as members of the prehospital care team to drive home the importance of avoiding hypoxia and hypotension before reaching the hospital. Dressed in black suits and dark sunglasses like the characters in the film "Men in Black," Bader and two colleagues brought in a big beacon light and told the nurses to stare into it while they chanted: "You will forget everything you ever knew about head injury. We are going to start fresh." Nurses still remember this event, and it marked a dramatic shift in practice.

Bader's implementation style is hands-on. During the early years, she was highly visible in the ED, operating room, and at the bedside to make sure everyone understood the Guidelines and followed the protocols. "We started with a core group of nurses and expanded. To support the trauma nurses, get new trauma surgeons and new neurosurgeons on board, and see that our protocols were followed, I went to every head trauma resuscitation for the first two years, and still go to some," she said. "There's a lot of one-on-one time and time on the floor." Nurses quickly became champions and advocates of the protocols.

Shaver and Palmer worked to bring their partners on board. Palmer recalled, "One day we said, 'today we are changing our practice. We will all do it this way.' It was not that easy getting uniformity among practitioners, and not everyone wanted to do it. Because we are a private service, we could eliminate some people from call coverage. When we had a new person, it was always a struggle to get them to agree to practice parameters, but eventually they did." Bader found that the observable difference in outcomes became the strongest selling point:

> Many thought, "This is not a survivable patient so we don't need to do all this." We said, "Yes, we do, there is a chance this patient will survive." When skeptics saw people who would previously have died but now talked and then walked out of here, it was like a revelation. They took it on themselves to talk to their peers and the new guy on the block.

After the first year, the multidisciplinary team reviewed all trauma cases, received updates on the literature, examined problem areas, and made adjustments to protocols to improve consistency and reduce variation. It also differentiated the processes of care into three phases: resuscitation and stabilization, OR, and ICU.

The improvements in outcomes observed during the first year were sustained and even slightly better after 24 months and have been sustained thereafter. Not only does Mission report a dramatic reduction in mortality, but also that survivors have achieved a higher level of functioning. Six months after the implementation of the Guidelines, 72 percent of TBI patients had a good outcome or only moderate impairment, whereas before the Guidelines, 73 percent died or had a severe disability. The resources expended to achieve these outcomes increased by nearly 50 percent, from a mean of $196,000 per patient to $293,065.[16]

In 2000, Mission's trauma center won the Joint Commission on the Accreditation of Healthcare Organization's Codman Award for excellence in performance improvement

related to TBI, and it has won several awards for nursing excellence and collaborative, multidisciplinary teamwork from the American Association of Critical Care Nurses. From 1997 to 2004, trauma center staff published 12 articles in the nursing and medical literatures and gave lectures at 50 national and 26 regional conferences.

Hallmarks of the Approach. One of the most critical factors in Mission's success has been having a neuro/critical care CNS. Bader's emphasis is clinical practice and her interpretation of her role is as the leading change agent for evidence-based clinical practice. "I work collaboratively with physicians and the nursing team to make sure we are practicing according to evidence-based protocols," she explains. "My job is to make sure everyone understands the Guidelines and follows them." Achieving consistency of care and bringing new people into the process is an ongoing part of her work.

Mission's trauma team did not attempt to get every physician on board. It began with core groups of doctors who were willing to abide by the protocols. Palmer observed, "Most people don't want to take trauma call, so getting the ones who don't want to comply not to take calls is not a problem. We have enough who are willing most of the time. If necessary, the chief of staff or chief of a department can require someone to take calls or lose their staff privileges."

The core figure in the resuscitation and stabilization process is a trauma nurse who stays with the patient throughout the acute phase, accompanying them to testing, the operating room (if surgery is necessary), and the ICU. The trauma nurse ensures that the Guidelines-based protocols are followed and is, as Palmer assesses it, "very, very effective for guaranteeing quality of care. Doctors come and go—trauma surgeons, anesthesiologists, radiologists—but the trauma nurse stays with them the whole time. That's the way to get quality control."

The anesthesiology department believed it should decide what it does in the operating room, even if it conflicted with the TBI protocols. The trauma team conducted educational sessions with the anesthesiologists, took them on grand rounds, presented its paradigms and their scientific rationales as to why, for example, blood pressure cannot be too low. Bader reports, "It took a lot of work to get them on board." The presence of the trauma nurse in the OR was a significant persuasive factor. If a protocol was not being followed, she brought it up on the spot, or called Bader who stood there with her reminding the anesthesiologist of how TBI patients are to be managed at Mission. If compliance was still not achieved, the situation had to be reviewed. At monthly review meetings, the Trauma Committee examines every deviation from protocols, providing a structure for considering changes. Of Shaver's role, Bader commented, "Dr. Shaver

demands accountability. He reviews every case, dissecting it with the Trauma Committee, and always wants to know how we can do it better."

Mission's nurses have observed that some physicians behave differently in the surgical/trauma ICU than in other parts of the hospital. The nurses attribute this difference in part to the "expectations of nurses. Nurses here expect respect. If they encounter disrespect, the nurse manager or the CNS will step in to make sure that kind of behavior is not tolerated." How is this culture replicated and sustained? Bader reports, "Trauma surgeons are very good about being collaborative, collegial, respectful. The trauma nurses work closely with the trauma surgeons, there is a lot of give and take during rounds, and our mutual respect gets reinforced." Turnover and vacancy rates in the surgical intensive case unit (SICU) are less than 2 percent. In a survey of staff, 90 percent gave the hospital good ratings on teamwork and agreed that employees were in line with the organization's values.

Mission's TBI treatment is resource-intensive. Trauma leaders negotiated an adjustment to the one nurse to two patients ICU staffing standard, so that one nurse per-patient staffing was established for TBI care, and even two-to-one staffing when needed. While patient outcomes have improved dramatically, charges have also increased dramatically. Several factors account for the increases: greater use of expensive medications and cutting-edge technologies; a high ratio of nursing time; a protocol recommending an additional day on the intracranial pressure monitor (ICP) on a ventilator and in the ICU; and the fact that surviving patients cost a lot more than patients who die along the way. The level of TBI care has also been supported by CEO Peter Bastone, described by Bader as "a visionary who wants this hospital to be the very best. He champions trauma within the larger health system. I could not do this without him."

Deepening and Sustaining Improvement. Bader is proactive in the development and ongoing revision of protocols and introduction of new technologies and equipment. Even before TBI practice was turned upside down by the Guidelines, the trauma center was routinely using ICP monitors, and it was one of the first 10 U.S. hospitals to adopt monitors for brain oxygenation. Shaver, according to Bader, "is an early adopter—unusual in a community trauma center—and makes sure we have the resources." Bader generates dialogue, brings people together, and facilitates their developing consensus around revisions and changes. "Every six to nine months our protocols change based on experience, research, and literature. They are an evolving, living document."

Grateful families have donated over three million dollars to the center. This has funded sophisticated equipment for managing and monitoring TBI, a nurses' education fund,

and facilities to support families, such as sleep chairs and lockers. One family earmarked their money to enable the CNS, a neurosurgeon, and a nurse manager to go out and help other trauma centers. The trauma team has carefully selected 20 centers, where they spend two days with surgeons, ED physicians, anesthesiologists, nurses, and pharmacists giving presentations and sharing their protocols. After that, two nurses come to Mission Hospital for a week. The recipient hospitals must have doctors who are willing to change practice and an advanced practice nurse to be the leading mentor and change agent.

University of Louisville Hospital

The Level I trauma center at the University of Louisville Hospital is located at one of three downtown hospitals in Louisville, Kentucky, affiliated with the university and staffed by its residents. The trauma center sees about 2,000 trauma patients yearly; 20 percent of these have head injuries, of which 20 to 25 percent are considered severe. Motor vehicle crashes and farm accidents are the major source of trauma.

Change Agent in Relation to Environment. In the spring of 1995, Laura Mcilvoy, R.N., M.S.N., a SICU staff nurse, proposed to the nursing department that they restructure the care of neurotrauma patients to improve outcomes and costs. As clinical nurse specialist (CNS) for neurosurgery, she could facilitate a multidisciplinary team's creation of clinical pathways, beginning with severe TBI. Her proposal was well received because the Joint Commission on the Accreditation of Healthcare Organization was advocating collaborative care, the hospital's quality improvement director favored a multidisciplinary approach, and the hospital wanted to improve performance. Nursing secured approval to move forward with critical care and medical/surgical performance improvement teams. Being co-chair of the Critical Care Performance Improvement (CCPI) team became part of Mcilvoy's new CNS position.

Changing Practice: Round One. Mcilvoy drove several, interacting processes: getting the CCPI team together and educating them about pathways and their objectives; enrolling key physicians to define the medical components of the pathway, recruiting and leading a smaller team to build the pathway; conducting literature reviews; and gathering data to define the current situation. Three months later, the severe TBI pathway was developed and approved.

The CCPI team included about 20 people: medical directors and nurse managers of all four ICUs, chairs of hospital departments, and other key staff. Mcilvoy enlisted the chief of trauma surgery, long an advocate of collaborative care for trauma patients, to serve as co-chair of the CCPI team.

Attending physicians from trauma and neurosurgery became its physician champions. They drew on the literature and their practice patterns to establish the medical parts of the pathway. The attending physician from trauma, David Spain, M.D., then director of the trauma ICU, recalled, "We had a fairly stable and like-minded neurosurgical staff who agreed on the principles. The differences were in the time frame: when do you start doing x or stop doing y? We took what we were already doing and put it on a pathway with milestones."

Spain broke with tradition, however, to advocate for the new and controversial practice of early tracheostomies (within 72 hours) and early placement of percutaneous feeding tubes (PEG). As a resident, Spain had done research showing that "for every day you delayed trach, the patient stays on a ventilator two additional days." Early "trach and peg" was incorporated into the pathway with minor resistance from other attending physicians. Spain noted, "The trauma service made the decision, and we controlled the patients in our ICU, which I directed. The neurosurgeons did not feel strongly one way or another."

Mcilvoy got her own social worker and assembled a working team of nurses from all of the ICUs, a pharmacist, a dietician, occupational therapists, physical therapists, and rehabilitation specialists from a nearby rehabilitation hospital that specialized in brain injuries. They met frequently, went on rounds, worked together to flesh out the medical components, built the overall pathway, and built protocols specific to an area (e.g., airway management or nutrition). Early and integrated involvement of all ancillary services in TBI care is a hallmark of the pathway.

Retrospective data on an historical control group were used to document current practice and provide a basis for identifying treatment parameters to compare with data collected prospectively on pathway patients. This analysis revealed wide variability and sobering data. Todd Vitaz, a neurosurgical resident at the time and now director of neurosurgical oncology and co-director of the neuroscience ICU, recalled, "We found patients who had not been fed for 10 or 12 days, but no one knew it because everyone thought someone else was doing it." In his view:

> Too many doctors was the biggest problem. The neurosurgeon says one thing, the trauma surgeon says another. The nurse caught in the middle, the family is confused. Who is in charge? The second big issue was delay in treatment. Who is looking at spinal x-rays? Doing the DVT prophylaxis? With the pathway, we decided such things in advance.

The primary resistance came from medical residents. Mcilvoy recalled, "the residents had nothing to do with building the pathway but they were the ones it would affect most. Some of the chief residents were very resistant that first year. In retrospect, not including residents was a mistake. We corrected that when we revised the severe TBI pathway and developed pathways for moderate TBI and spinal cord injury."

Mcilvoy observed that senior residents feared that the pathway meant losing their ability to use clinical judgment and make decisions on their own. In particular, many were resistant to early feeding, which ran counter to their practice. Spain concurred, "You

always get resistance with fourth-, fifth-, and sixth-year residents, so it always takes two or three years to get a change in practice. The senior guys want to do it the way they were taught, they don't want 'cookbook medicine' or anything that impinges on their independence."

The TBI pathway was designed to define responsibility and coordinate care while retaining physician autonomy. Not only has this approach reduced provider resistance, but it has also targeted the major culprits behind variability, delays, complications, extended lengths of stay, and excess costs. Problems began to be solved and momentum grew for change and, as one CCPI member recalled, "no one wanted to be left out." Even though the pathway made few changes in practice apart from early "trach and peg," Spain noted, "we got this big decrease in length of stay and got patients through faster."

Residents began to appreciate reductions in workload. Instead of having to write pages of orders, they checked boxes and filled in blanks on standardized order sheets. If a patient did not have standard orders, Mcilvoy was empowered by the CCPI team to put them on the chart. As elaborated by Kim Meyer, R.N., M.S.N., neurosurgery's research nurse and later nurse practitioner, "it was very helpful to have the chief of trauma surgery co-chairing our development committee and the weight of the two attendings behind us. When Laura ran into resistant residents, she went to the attending and the attending spoke directly to the resident."

Hallmarks of the Approach. At Louisville, the TBI pathway standardizes many treatment decisions and serves as a platform from which further decisions are derived. It operates as a detailed, yet open, framework that defines who is responsible for what and spells out what is to be done and how to do it. As was the case at Mission Hospital, care is better coordinated because providers have a clear understanding of their own and others' responsibilities and what approaches others will be using. The pathway reduces redundancy, variability in treatment, incompatibility among specialists and treatments, and workload for attending physicians and residents. Checklists mean, according to Vitaz, "We don't have to worry about something being forgotten and we minimize transport of patients for various tests."

Physical therapy and occupational therapy providers now see patients much earlier and a dedicated social worker begins paperwork for insurance coverage and discharge planning on the first day of hospitalization. Previously, many patients who were ready for discharge were held up because of paperwork and insurance delays. Early involvement of all affected services helped cut lengths of stay and costs.

A balance between standardization and autonomy was achieved by standardizing mundane yet critical activities while leaving space for physicians to make decisions in response to unfolding situations. Thus, the protocol standardizes basic testing, treatments (e.g., feeding, dosing, and ventilator weaning), and monitoring activities. Vitaz underscores their importance for outcomes, "It is the basic things that are mandated, and it is doing the basic things that prevent delays and complications."

For example, before the pathways, questions about which formula to use for feeding, how much to use, and how to start its administration were decided from scratch every time, with predictable variability. Pathways state which formula to use, how to start the process, how much to use, and whose job it is to revise the approach if the patient does not tolerate that formula. The physician retains autonomy about when to start the feeding but after that he or she hands off responsibility to the nutritionists and nurses who feed and monitor patients.

Incorporating Guidelines: Round Two. The trauma center adopted the TBI Guidelines as a package in 1997. Mcilvoy stated, "There was no discussion about whether we were going to adopt them. Neurosurgery, trauma, and I all said the same things and we said them strongly: 'These are national guidelines put out by the Brain Trauma Foundation and we will follow them.' At that point, the pathway was revised in accordance with the Guidelines. Phases of care were more clearly demarcated, and the pacing of patients was pegged to their progression through four phases: admission to the ICU, acute critical care (patient on ventilator, trached and pegged, ICU closely monitored), mobility and weaning from ventilator, and pre-rehabilitation.

The Guidelines significantly changed or reversed several modes of treatment, yet they were adopted with relative ease. Four factors seem to be responsible. The clinical changes involved neurosurgical care, and so, according to Mcilvoy, the trauma service did not have a problem with them. The other three reasons are: the power of Louisville's departments and attending physicians to mandate compliance; the limited numbers of physicians and disciplines taking care of brain trauma patients; and a drug study in which neurosurgery wished to participate shortly after the Guidelines were issued. Meyer elaborated on the first two:

> We had a few physicians who still wanted to hyperventilate or dehydrate patients. Our vice-chairman said "no," and that was the end of that. Neurosurgery is in charge of head injury, and since the late 90s, neurotrauma patients are admitted on our service. Critical care management is done by second- or third-year general surgery residents (usually two at a time) who are overseen by a chief resident and by a trauma attending. So at Louisville there are not a lot of doctors taking care of the TBI patients.

A requirement of the drug study was that patients receive standardized treatment across participating hospitals by adopting and strictly adhering to the Guidelines. As Spain noted, "If you have wild variation in care, how can they show the drug made the difference? By the time the drug study was over, practicing according to Guidelines had become the way they did things."

A great deal of education was conducted, especially in the ER, according to Mcilvoy, "to get them to understand about hyperventilation, use of fluids, and sedation. Then we went to the critical care units and implemented it." Because of their constant rotations (30 days for trauma, three months for neurosurgery), residents continued to pose the biggest challenge for the educational effort that had begun with the original pathway. Meyer recalled, "As soon as we got a resident working really well with us, he would rotate to another hospital or service and I would get a new neurosurgery resident and a new batch of trauma guys, and we would have to start all over with the pathways and Guidelines."

These educational efforts were reinforced by attending physicians on rounds, by Vitaz becoming a chief resident and enforcing their practice, and by the yearly accrual of pathway experience by those moving up the residency hierarchy. Each successive year got easier because returning residents taught more junior residents, and new residents thought the new way was how it had always had been. After five years of such cycles, the mindset among residents had shifted to pathways that had become informed by the TBI guidelines. One of the most significant factors in this process was the drop in phone calls and change in their quality, as Spain elaborated:

> Residents began to notice the dramatic difference in the phone calls they get because the nurses can manage so much more. Instead of eight calls a day, there are only two. When the nurse does call, it is something more serious. Whereas before she might have said, "the ICP is up," now she says, "the ICP is up and I did x, y, and z, and none of it worked." Now the nurse and the resident are having a much more focused discussion.

Resistance was also lowered through the use of comparative data. With the revised severe TBI pathway, there was a small improvement in mortality, and survivors were more likely to go to rehabilitation than to nursing homes when discharged. Patients spent 4.4 fewer days in the ICU, 2.9 fewer days on a ventilator, and the incidence of pneumonia was a little lower. The charge reduction per patient was calculated at $14,550 (1999 dollars) per patient; this estimate does not include medications, radiography, or laboratory costs.[17]

Deepening and Sustaining Improvement. Protocols have been solidified or modified, and thresholds shifted. The CNS continued to follow each patient from the perspective of how well the pathway was working as a system and how it could be improved. The CNS and nurse specialist have brokered communication so that neurosurgery and trauma attending physicians now talk directly to one another. Working relationships between these services have become more collaborative and the trauma teams communicate with each other more. The CNS and nurse practitioner roles converge in communication activities—being the glue that prevents situations from deteriorating or important steps from falling through the cracks. As Mcilvoy explains, the CNS and nurse practitioner roles are complementary:

> Kim sees everyone who comes in, talks to families, teaches medical students. When needed, she spends time at the bedside. She writes prescriptions, helps out in surgery, and like a resident, takes call one night a week. She works patient by patient while a CNS takes the patient population as her focus. How are they treated in the hospital? Did they all get the same treatment? What orders did they have? What are the system problems being revealed? How can we rearrange care to maximize outcomes?

Inova Fairfax Hospital

Inova Fairfax Hospital is a private, nonprofit, community hospital in Northern Virginia that trains medical residents. Fairfax became a regional branch campus of the Virginia Commonwealth University School of Medicine in August 2005, but it is not a university hospital. First designated as a Level I trauma center in 1983, the Inova regional trauma center now sees almost 3,500 patients annually, a fivefold increase in the last 15 years. About 45 percent of these patients have a brain injury, 16 percent of which are considered severe.

Change Agent in Relation to Environment. When Arthur Trask, M.D., joined Fairfax Hospital as its trauma chief and only full-time trauma surgeon in 1990, he brought his perspective that, "Someone must look after the patient as a total human being and understand their whole physiology, and not just treat lungs, bones, or seizures in isolation." He advocated a model that had been successful in his previous work. According to the model, a team of full-time intensivists coordinate care and "captain" the trauma ship in the form of a surgical ICU, which they manage. While Trask believes an intensivist or a trauma surgeon is likely to be the most appropriate captain, the most critical thing in his view is that there is a designated individual to lead. "The worst thing that happens—and the reason you need a critical care *team*—is having six or seven consultants seeing trauma patients and not reading each other's notes and orders," he says. "No one is coordinating and you can have pandemonium." (By "team," Trask refers to a group of like-minded partners who act as intensivists and manage the ICU and its patients.)

Fairfax relied on consultants, each of whom wrote their own orders. General surgeons and neurosurgeons who took trauma calls were in private practice. One or two were board-certified in critical care, but they had all gained extensive experience in managing trauma patients during their residencies and thereafter. Trauma patients were admitted by the trauma service (Trask or the general surgeon who was on call), and the trauma service supervised the general surgery residents in managing their care.

In his role as trauma chief, Trask elected to see all the trauma service patients in the trauma ICU and to make suggestions about care and management of individual patients. Although his advocacy of an intensivist model did not find receptive ears for several years—he was not able to hire another full-time trauma surgeon until 1996—he held to his vision and persisted in its advocacy.

Changing Practice: Round One. Trask soon discovered that the trauma diagnosis most frequently seen at Inova Fairfax was TBI and so knew that "we needed to get really good at it." He plunged into the literature on the management of head injury and, by 1993, had recruited two of the hospital's leading neurosurgeons and a couple of key general surgeons to work together to develop protocols for treatment of brain trauma. It took two years to reach a fair degree of consensus and develop a pathway, protocols, and a set of standard orders. Although the TBI Guidelines were not published until 1995, Trask knew some of the authors and the conclusions they had reached, and those recommendations formed the basis of the Fairfax protocols.

The small development team approached the clinical changes from a research perspective: Would evidence-based, guideline-driven care really make a difference in patient outcomes? Nurses and residents were trained on the protocols, but during the first year virtually the only ones using them were the physicians who had developed them and the residents, nurses, and allied professionals serving on their watch. Compliance (measured by the presence of TBI order sheets on the chart) was in the 35 to 45 percent range, but for those on the protocols, "We were getting indications of significant improvement. Death rates were significantly lower, and that began to get people's attention."

Over the next two years, more and better quality data indicated that the protocols did indeed reduce mortality, degree of disability, length of stay, and charges. Training continued and more symposia with outside experts were held. There were changes in hospital administration, a few key physician departures, and one neurosurgeon was asked to step down from the trauma call roster. Compliance rose to 85 to 90 percent. Even so, it took longer to get some practices, such as prophylactic hyperventilation, to stop. Maureen Waller, R.N., M.S.N., administrator for the trauma service, recalls the years that it took to see change:

> Art Trask ran into a brick wall for a long time. The critical care concept of a coordinated service managing patient care was new. In the early days, the medical doctors were in charge of all aspects of patient care, including the critical care units. We had an outstanding critical care physician who championed the concept of a critical care service for managing care in the ICUs. Ultimately he left because of the resistance. Eventually it became obvious that coordinated critical care was better care and the environment became more open to also having a *surgical* critical care service.

Changing Practice: Round Two. When Trask partially retired in 1997, he was succeeded as chief by Samir Fakhry, M.D., who shared his vision of an intensive and coordinated model of care. At the time, there were three full-time trauma surgeons on the teaching staff and nine in private practice. The teaching group of trauma surgeons (Trask and his two partners) admitted 30 to 35 percent of patients, while the remaining patients were admitted by the private practice surgeons who were not in the hospital most of the time. Before joining Fairfax, Fakhry had noticed on his visits that, "Art was one of the few people who provided ICU care to his own patients." As a result, for two-thirds of patients, as Fakhry explained:

> No one was managing total patient care in the ICU. Each physician did their own thing. The infectious disease physician gave antibiotics, the pulmonary doctor put patients on a ventilator and weaned them off of it, the nephrologist checked urine output, someone else monitored the heart. No one coordinated care and consultants communicated poorly because they were not there at the same time. Each consultant looked at their own organ, and their orders could conflict or might be inconsistent with the TBI guidelines.

Fakhry drew the conclusion that, "for me to integrate and optimize the care of trauma patients and influence the general direction of things, most of the patients had to be admitted on my service. When you admit, you are the attending of record and you have the final say. You have authority to decide many things, including who sees your patient, who consults, and how much authority you give them." Not only did most trauma patients need to be on the trauma service, but their care needed to be centralized in one location over which that service had authority, and there had to be enough partners to work as surgical intensivists and manage their care.

In his contract, Fakhry asked for two things. The first was to hire more partners so there would be enough physicians to deploy the surgical intensivist group model for trauma patients. Fakhry thinks the minimum number is five, but seven is better, and Fairfax now has seven. The second condition was that he become medical director of a critical care unit that would be focused on trauma patients. He did not, however, insist that this happen immediately because it would have engendered too much resistance in a private hospital. It took three years to effect all of these changes, and another two to consolidate them.

Instead of making a frontal assault on ICU control, Fakhry began by getting more of the patients on the trauma service. He and his partners did that by taking more and more trauma calls, which enabled them to make the trauma schedule, which in turn

allowed them to put themselves on call. They did not rely on consultants because as surgical intensivists they could do most of the work the specialists did. When they did contact a specialist, it was not to ask the specialist to oversee the care of a single organ but to perform a major procedure or intervention on an as-needed basis. In addition, consultants no longer wrote independent orders, but instead made recommendations that were coordinated and integrated by intensivists.

Staffed by a gradually increasing number of surgical intensivists who were also the attending physicians of record, the trauma service took on the care for 85 to 90 percent of the trauma patients and put them in the neuro/trauma ICU. The surgical intensivists argued that this ICU needed to be separated into the Trauma ICU (TICU) and the Neuro ICU, and the TICU managed by the trauma service. This argument was backed by the position of the American College of Surgeons Committee on Trauma, which says that the trauma director should be in charge of the unit where most trauma patients go.

By 2002, enough intensivists were on board to take care of all trauma patients around the clock, working in 12-hour shifts, and to fully deploy the surgical intensivist model. This replaced the old model in which an attending was present from 8:00 a.m. until 5:00 p.m., and residents covered the rest of the time. Fakhry and colleagues built their case that all trauma patients admitted to the TICU (not just the 85 to 90 percent admitted on the trauma service) should come under the care of the TICU surgical intensivist team. Because their model had established its ability to provide strong and consistent care for less time and money, and because an intensivist was in-house at all times and could respond immediately, it was, they argued, now possible to have a single level of care at all times. Waller reports:

> The nurses love having a doctor there to support them. Before, when a nurse saw the ICP going up and this or that intervention wasn't working according to the protocol, she had to call the ICU surgical resident first. The resident, depending on their experience and skill level, might or might not be helpful. The attending physician was next in line for a call, and was at home if it was after hours. Meanwhile the nurse was waiting and worrying about getting an appropriate and timely response for the patient. Now we have a trauma intensivist in the unit at all times. You can say, "Come and see this, what do you think?" Or, "This patient is having an airway problem," and the surgical critical care attending can jump in and take care of the problem right away.

Since 2004, Fairfax has had a neuroscience ICU for patients whose brain conditions do not have a traumatic source (e.g., those who have had aneurysms, brain tumors, or strokes). Neurotrauma patients, on the other hand, are cared for in the TICU. Fakhry says, "I decided if you are a trauma patient, you are a trauma patient." In Fakhry's view, "two things determine success in treating brain trauma: getting the neurosurgeons on board, and getting control of the ICU. We have done it one way, but whatever you do, you must be the ones who manage it. Most of what happens in brain trauma happens in the ICU."

Fairfax has achieved Trask and Fakhry's vision: standardizing nonoperative critical care under a trauma service that manages the TICU to which all trauma patients are admitted, where patients can be managed according to protocols and by intensivists who are board-certified, surgical critical care specialists, and where all staff members are on the same page. The trauma service physicians write the orders, act as intensivists managing care in the ICU, and coordinate care of all specialties. The protocols have decreased variance in care delivery, empowered those at bedside to intervene in a timely way when the situation warrants, and nearly eliminated delays in contacting physicians and obtaining orders.

Deepening and Sustaining Improvement. In the fall of 2004, Fairfax undertook a process orchestrated by Trask of revising its TBI protocols based on the most current literature and in tandem with the 2005 Guidelines then in development. Every issue was hammered out with a core group of trauma surgeons, neurosurgeons, and an advanced practice nurse. Trask says, "We spent months with neurosurgery going over these plans, modifying things like threshold levels. To go through a process like this and get approvals takes a year." Trask convinced the neurosurgical section chief to make protocol revision a process improvement project for neurosurgery, thus bringing all parties to the table. This time around, the goal was as much the process as the product. Trask noted, "The goal is to get everyone to have ownership in the process and have it be the basis for team activity."

Fakhry encourages his team not only to be current with the literature, but also to generate research. The trauma center is always involved in research projects, and frequently presents and publishes its work. Fine-tuning Guidelines-based practice has meant finding an optimal balance between following Guidelines and having flexibility for good cause. Fakhry explains:

> Our protocols do not say do a, b, c, d. They plot out the course in which you can manipulate this or that variable, but only these two.

> You can also deviate if you have a reason. What we are moving toward is setting boundaries of care for people. We agree on boundaries of care acceptable to you and to me and consistent with the Guidelines. You can function at a specified level of responsibility within these boundaries, but when you get to this edge, you need to talk to someone else.

Sustaining compliance and improving performance are supported by daily follow-up and watchdog activity by its champions. Waller commented, "We look at complications and events, anything we think that needs to be discussed, anything that impacts care, outcomes, costs, length of stay. Dr. Fakhry is always looking for the best way to manage our patients, which protocols to develop or update, and opportunities for studies that might help us to improve care. Now he's looking at improving the prehospital management of TBI and how to better coordinate that with the hospital phase."

III. STRATEGIES FOR SUCCESSFUL IMPLEMENTATION

What do you have to do in order to implement the Guidelines? Primarily, change the behavior of physicians. For brain trauma, this means getting the neurosurgeons on board, getting other physicians to change their behavior in relation to TBI patients, and getting all of the hospital and prehospital players on the same page. The question of how to implement the TBI Guidelines can be specified more precisely as, "How do you change the behavior of physicians and get everyone on the same page, despite the fragmented context of TBI care?"

The Guidelines pose a challenge not merely to clinical decisions and the tradition of making them autonomously, but also and more broadly to the manner of delivering trauma care. "Alignment with the Guidelines" really means realignment of clinicians with each other through the vehicle of Guidelines. Much of the work of implementation involves listening, dialogue, strategizing, and negotiating among clinicians from different specialties and professions in order to come to agreement about protocols, coordination, and management of care. Guidelines implementation requires organizational changes in clinical settings.

This section draws out 14 strategies for successful implementation from the case studies as well as from interviews with other clinicians and a few academics, policymakers, and consultants. Virtually all of these strategies address problems in Guidelines implementation by: counteracting the fragmented structure of trauma care; reducing resistance to trauma care, behavioral changes, and/or the Guidelines themselves; and getting all players to practice in a consistent and coordinated way.

1. Timing and Organizational Readiness. If a hospital environment is hostile or indifferent and/or a change agent is well ahead of the curve, change is likely to be slow and partial—as seen in the case study of Inova Fairfax Hospital. Something will have to change: key defenders of the status quo retire or leave, a new administration is more receptive and willing, a crisis forces the situation open, the external environment moves in the direction advocated by the change agent, and/or accrediting agencies begin to exert pressure on a hospital to change.

2. Comprehensive Change: Systemic and Systematic. A comprehensive change effort is both systemic and systematic. Systemic change alters the system itself (e.g., the routine workings of the trauma network). Systematic change is an organized method or process for effecting change. Altering TBI practice requires both systemic and

systematic change to get providers from many disciplines on the same page; it is an organizational as well as individual change process.

Effective implementation processes pull together working groups from all disciplines that affect neurotrauma patients to acknowledge and identify problems, analyze and understand their sources, develop motivation to change, and figure out how to do so. The working groups need to be multidisciplinary to get broad-based inputs, ownership in the process, and commitment to its realization. The groups need to develop a working consensus about all key decision points in treatment, and agree on which can be standardized and translated into protocols. A key product, if not the key product, of this process will be a set of protocols aligned with the Guidelines that spells out precisely how treatment decisions will be executed, who will do what, and under what conditions alternative interventions are needed.

Implementation might go more smoothly if there is an existing context and even method for effecting change (e.g., as part of performance improvement or patient safety efforts). It is enhanced by a culture in which people ask questions, are open to new ideas, and are always trying to learn and improve.

3. Leadership and Change Agents. Instigation for Guidelines compliance can come from trauma or neurosurgery, physicians or nurses, or somewhere else. For effective implementation, several forms of leadership need to be engaged at three or more levels: nurses, physicians, and higher-level administrators and clinicians (e.g., chiefs, department heads, and medical directors).

There must be powerful and credible physician champions from at least two services. If the lead instigator/champion comes from trauma, they need neurosurgical allies, and vice-versa. As a program manager put it, "You have to have a champion in a specialty outside your realm of control." Champions try to influence partners and colleagues, and build critical mass. They teach residents during rounds through the kinds of questions they ask, and back up nurses vis-à-vis residents and other attending physicians who are not on board with the Guidelines. The need for cross-disciplinary and higher-level support was addressed by a trauma surgeon, "You need one good administrator or department chair—not a trauma person—who allies with you because it is right. You work under the banners of safety, or quality of care, and they help you find a way to exert pressure on recalcitrant physicians within the rules of the organization."

As used here, the "change agent" is the hands-on leader who drives the implementation process on a daily basis. Their authority comes primarily from being

deputized, condoned, and supported from above as well as across disciplines. They must also have their own credibility that comes from clinical experience, and they need to be imbued with self-confidence, perseverance, a thick skin, and strong interpersonal skills.

4. Clinical Nurse Specialist as Hands-On Change Agent. Although it is possible to implement the TBI Guidelines without a CNS orchestrating the players and doing the hands-on work, it is more difficult and appears to take much more time. The process of hammering out agreements and translating the Guidelines into protocols took two to three months in the two cases where a CNS was empowered to do this, and two years where there was no advanced practice nurse whose job it was to do this. A hands-on change agent who drives the process on a daily basis could be a physician or another kind of advanced practice nurse. But the six dimensions of the CNS role are a near-perfect match for translating evidence-based guidelines into standard practice and ensuring compliance. A CNS is:

- an expert clinician who goes on rounds to check on neuropatients and communicates with everyone;
- a taskmaster of the process of developing protocols related to neuro/critical care;
- a change agent for improving system performance;
- a researcher and author of research articles;
- a teacher and mentor for neuro/clinical care practice; and
- an enforcer who ensures that protocols are followed.

5. Integrators, Coordinators, and Communicators. Given the fragmented structure of TBI care and the number of clinical disciplines in a trauma network, strong countervailing forces are needed to integrate and coordinate care. This requires effective communication at every juncture, handoff, and potential gap as well as efforts to build relationships among various providers. Certain integrator and coordinator roles are mandated simply by being a trauma center (such as the medical director of trauma and program manager), while others are elective.

The program manager works with the medical director to make everything click. She pulls information together for regulatory and review bodies, gets policies and procedures in place for patients, and manages databases for quality improvement. She coordinates and sometimes conducts education on trauma care and performance improvement. Depending on which other roles are filled, she is either a key liaison or the

key liaison with trauma's nursing staff, dealing with everyone who comes into contact with trauma patients. A program manager explained:

> Trauma deals with so many departments and so many personalities, all with their own issues. We work with prehospital, the ER, the OR, the ICU, people on the floor, rehab, the blood bank, nutrition, the therapies. It's not the care of the patient that is difficult, but the orchestration of all these departments to work in synergy with each other. I move my patients through the system by working with each department.

Given administrative demands, the amount of time that program managers and directors are able to spend with patients is often more limited than incumbents would like. Having other clinicians play integrating, communicating roles strengthens the coordination of trauma care. Advance practice nurses can be enormously effective in this regard, and are arguably essential.

6. Limiting the network. All three trauma centers limited the number of people in the trauma network as part of their strategy for getting an optimally sized network.

- Those committed to Guidelines implementation did not try to convert everyone.
- They aimed for an optimally sized trauma network by working from both ends: starting with a core of committed nurses and physicians and expanding to build critical mass, while peeling off those who lacked commitment or wouldn't make necessary changes in their practice.

7. Protocol Development. Guidelines implementation not only means aligning clinical decisions with most or all of its key directives, but also developing protocols that spell out how a hospital will execute them.

- Guidelines implementation means much more than deciding to adopt some or all of the Guidelines. It is shorthand for what it takes to translate a set of recommendations into standard, everyday practice for a network of quasi-independent clinicians.
- Developing protocols requires extensive multidisciplinary discussion and dialogue.

8. Pathway and Protocol Design. The three centers consciously designed pathways and protocols with providers as well as patients in mind to achieve balance and reduce workload:

- Pathways and protocols were designed to standardize routine matters while allowing flexibility where judgment is needed, or to give clinicians zones of latitude while clearly marking boundaries where consultation is needed.
- In general, protocols and pathways aimed to reduce the workload for physicians, especially for neurosurgeons but also other attending physicians and residents. When physicians are called, they have more focused and higher-level conversations with empowered nurses, who have already tried interventions that are not working for this patient.

9. Staff Redeployment. The three centers redeployed some of their staff to leverage their contributions and give ancillary services direct contact with patients.

- Pharmacists and/or nutritionists go on rounds, observe patients directly, build relationships with the trauma network, suggest alternative drugs or see how the formula is working, and help to contain the costs of medications.
- A trauma nurse is sent to meet the patient and stay with them throughout the acute and resuscitative phase until they are admitted to the critical care unit. She acts as advocate for the patient and the Guidelines, ensuring consistency across boundaries and venues.

10. Research Framing. The three trauma centers framed Guidelines implementation as an opportunity to compare a new approach with their historical approach and assess, as one clinician said, "whether this really is best practice that makes a significant difference." The before-and-after data comparisons of outcomes and charges were important tools through which to inform themselves, get skeptics on board, and validate differences in outcomes that had been observed.

- Trauma centers studied the literature and generated their own data. They gathered historical data from chart audits as a basis for understanding their current outcomes and the practices leading to them.
- They gathered information prospectively for comparison and to guide improvement.

11. Organization and Management of ICUs. Once a trauma patient is resuscitated and makes it through the first 24 hours after the incident, most of their progress (or lack thereof) depends on managing secondary brain trauma and its complications in the critical care unit. Virtually all of the clinicians interviewed for this

study reported some tensions if not clashes in terms of how neurotrauma patients are managed in the ICU. The issues clinicians raised include: On whose service was the patient admitted? To which ICU were they admitted? Who manages it? Are they more medically or surgically oriented? Do they respond like a critical care person or a non–critical care person? How receptive are they to the Guidelines?

To make ICU care consistent with the Guidelines, informants spoke of the need to make changes in the ICUs themselves or in their management. Changes desired, attempted, or effected include:

- changing the service on which neurotrauma patients are admitted;
- bringing ICU managers, residents, and nurses on board with the Guidelines;
- rearranging the ICU constellation so that there is a better fit among neurotrauma patients, the Guidelines, and the ICU management;
- developing a new ICU (a neuro ICU or a trauma ICU);
- gaining control of the management of an existing unit; and
- developing a critical care intensivist model.

The latter is a growing trend in which an intensivist is on site most of the time, actively managing the ICU and coordinating the care of all of its patients, whatever service the patient is on.

12. Leveraging the Neurosurgical Resource. Neurosurgical expertise is a scarce, essential, and often reluctant resource in neurotrauma care. There are not enough committed neurosurgeons to go around. To deal with this, the three case study centers used Guidelines to increase neurosurgical commitment to TBI care and/or limit participation. At the University of Louisville Hospital, several neurosurgeons stepped up to the plate to take the lead in TBI care. At Mission Hospital, a subset of neurosurgeons committed to trauma call; those who were not interested were excluded from the trauma roster. At Inova Fairfax Hospital, surgical intensivists took on the critical care for all trauma patients, including TBI patients, thereby minimizing the amount of time neurosurgeons have to spend on trauma.

Interviewees noted three other strategies for leveraging the neurosurgical resource: physician extenders, telemedicine, and reorganization of the neurotrauma system itself. Many neurosurgeons believe that other providers could be trained to perform less invasive procedures (such as putting in ICP or oxygen monitors). As one argued, "We can stretch

our resources through physician extenders—qualified RNs, physician assistants, nurse practitioners—as well as residents. Physician extenders are key." Not only could teleconferencing, teleradiography, and other telemedicine tools be integral to education and training, but such tools could link surgeons in remote, low-volume centers to centers of concentrated neurosurgical expertise.

Physician extenders, telemedicine, and other strategies could help facilitate the much larger undertaking of reorganizing the neurotrauma system itself. Some neurosurgeons have suggested greatly reducing the number of regional neurotrauma centers while ensuring they are linked in a much more structured way to improved neurotrauma care delivery in satellite centers.[18] Such a reorganization might support more consistent, higher-level care delivery and reduce pressure on neurosurgeons who do not want to be involved in trauma care. It also might produce "centers of neurotrauma excellence" that perform a high volume of cases and include a critical mass of colleagues conducting research and clinical trials. Transport and funding would be the two major challenges to this model.

Interestingly, this kind of reorganization would parallel, on a large scale, the local strategy observed among the cases study sites: limiting the size of the trauma network to those who are truly committed by allowing them to self-select for neurotrauma. While it is anticipated that many university centers would be among those meeting rigorous criteria for certification under such a reorganization, outstanding non-university Level I and Level II centers could also make the grade.

13. Comprehensive and Tailored Education Process. The educational process needs to be comprehensive, beginning with core team members and spreading among all of those who participate in TBI care. The process should be both hands-on and based on research and discussion. It needs to be tailored to the situation, the person, and the moment. A clinical nurse specialist captures what an effective education process looks like in a clinical setting:

> "Education" is not a lecture, not a classroom, not a one-time thing. It is a comprehensive and ongoing process. It means literature searches, encouraging people to bring stuff in, sit in small groups, talk about what works and doesn't. Education is what is asked and said on rounds. It is nurses being able to correct residents. It is working with every new resident, every new attending, and every new nurse. It is coaching. It is not embarrassing people. It can be hard to convince a neurosurgeon to stop using cortico steroids for TBI patients. So you say, "let's go over the research." You have to be willing to be a learner as well as a

> teacher. You go out to each constituency group—the neurosurgeons, the emergency docs, the ER nurses, the trauma/ICU nurses, the residents, the respiratory therapists, nutrition. You say, "I'd like you to identify someone who can sit on the Task Force who will review data and come up with recommendations," or you pick the person, an early adopter type, and they go back and educate the others.

14. Organizing for Continuous Improvement. All three case studies illustrate that the work of clinical improvement is never done and can never be taken for granted. There need to be mechanisms in place and enough resources available to sustain changes to align practice with the Guidelines and continue to improve. A monthly review process by a trauma committee can go beyond reviewing mortality and morbidity to function as a significant force in continuous learning. By continuing to invest in a designated change agent, a center empowers a change agent to stay on top of the situation and orchestrate successive iterations of improvement. Change agents can play a strong role in bringing new people on board and ensuring that everyone is still on the same page, and that they are empowered to police outliers. Periodically, a change agent will have to lead a process of revising and updating the protocols and ensure that everyone shifts from the old way to the new way at the same time. Ideally, sustaining and institutionalizing change becomes a way of life, part of leadership, part of everyone's job—an idea that is traditionally not taught in medical and nursing schools.

IV. SYNTHESIS: THE 3Cs OF SEAMLESS CARE

Let us now step back from the particular challenges and common ingredients in successful Guidelines implementation to consider: what *are* the TBI Guidelines? Indeed, what are clinical guidelines, protocols, or pathways in general? They are ever-evolving tools, means to an end. What are these ends?

Missing from the conversation about guidelines, pathways, and their protocolization is a conscious understanding of the relationship among these three tools, among the caregiving goals they are trying to achieve, and between these tools and their goals. By asking, "What are we really trying to achieve through implementation of the Guidelines?," we can generate a model that is flexible and transportable across health care contexts.

Relationship Among Tools

The TBI guidelines are put forward as 14 high-level recommendations about *what* to do. They form a skeleton that needs to be fleshed out by protocols that define detailed processes and procedures describing *how* to do it at a particular hospital. Such protocols empower nurses and residents at the bedside. Although hospitals always have protocols, often they are separate, disconnected bits. Here I am speaking of a *set* of protocols built around a guideline spine or skeleton and *linked to each other through that skeleton*.

But is the multidisciplinary process of developing protocols to flesh out the Guidelines enough? If we extend the skeleton/flesh metaphor, we also need a brain to run and coordinate everyone's activities and orders. Clinical pathways can serve this function.

Clinical pathways provide an overall road map or framework for the entire process of care for a particular condition, such as severe TBI. They organize the totality of care at a higher level than even a set of protocols. Pathways (as used here) represent the integration and coordination that has been worked out by a multidisciplinary team—not in the heat of a crisis or depending on who is on call, but through extensive dialogue among all the parties when there is no patient on their doorstep. At its best, the process of developing pathways generates a shared understanding of the reasons *why* participants have coalesced around their choices, defines *who* is responsible for doing what, and puts their pieces together in a coherent, non-conflicting way. Table 2 summarizes the relationship among these three tools.

Table 2. Relationship Among Guidelines, Protocols, and Pathways

Guidelines	Skeleton	What to do
Protocols	Flesh	How to do it
Pathways	Brain	Who is doing it, and why

These tools change both the level and the timing of a significant portion of clinical decision-making:

- Level: Instead of all decisions being made at the level of the individual patient, some can appropriately be made at the level of the patient population (e.g., severe TBI patients, asthma patients).
- Timing: Instead of many key decisions being made in the moment by the individual in charge at that time, they are made before the fact with representatives from all relevant disciplines present.

The result: rather than certain conflicts and problems coming up over and over, patient by patient, in crisis after crisis, a consensus is hammered around each point of decision and area of potential conflict. Pathways represent the end product of people working out differences in advance and building a road map that integrates their agreed-upon interventions and medications.

Goals of Care: The 3Cs

Let us come back to the question of what it is we are trying to achieve when we implement the Guidelines. Part III specified the objective as "change the behavior of physicians *and* get everyone on the same page *despite* the fragmented context of TBI care." We can complete this statement now by defining our goals: to achieve greater consistency, continuity, and coordination of patient care.

Interviewees' accounts vary considerably according to the particulars of their trauma centers and how they implemented the Guidelines. Yet, their various activities have common goals, and paramount among these are the "three Cs": consistency, continuity, and coordination of patient care. The trauma centers that have significantly improved outcomes through Guidelines implementation have done so not only because they are making better clinical choices, but also, and perhaps even primarily, because their realignment around the Guidelines has improved the three Cs of patient care.

Consistency of Care. Consistency of care means low variability in care from shift to shift, day to day, nurse to nurse, resident to resident, attending to attending, and patient to patient.

High variability among practitioners was one of the major problems in TBI care before the Guidelines came into play, and is a major problem throughout the health care system.

Evidence-based clinical pathways, guidelines, and protocols comprise a powerful set of tools for reducing variations in care, weeding out harmful practices, getting people to pay attention to the same critical variables, and preventing inappropriate redundancy. They are health care's equivalent of quality assurance processes in manufacturing. By keeping treatments within a narrower range of practice, the process becomes more efficient and the quality of the product—patient outcomes—improves.

Implementing guidelines and reducing variability mean that guidelines are not treated as an external force, but instead are the skeleton of an organic, unfolding process. Attending physicians ask questions on rounds that actively reinforce guideline use, nurses are empowered to challenge residents and attending physicians for noncompliance, and oversight committees (such as trauma committees) aggressively review exceptions and outliers and take appropriate action.

Continuity of Care. Continuity of care means that each shift hands off smoothly, so that the next set of caregivers is well informed about what has been observed and what will need particular attention under their watch. Medical charts are not up to the task. Handwriting is usually poor, notes are time-consuming to read, and caregivers pay attention to different things and observe and interpret the same thing in different ways. On the one hand, it is valuable and even essential that different eyes and ears pick up different things and form different hypotheses. On the other hand, that richness must be complemented by consistent tracking of salient issues and markers.

Protocolized guidelines have a role to play in this regard. They can direct every shift's attention to key, evidence-based, agreed-upon indicators that identify parameters that need to be achieved or maintained, describe how to intervene to achieve them, and say what to do if those interventions are not working. Other methods for attaining continuity of care include: preserving stability of the nursing staff who notice subtle and hard-to-quantify changes; having a trauma nurse meet patients arriving at the hospital and stay with them until they are admitted to the ICU; assigning case managers to follow patients from the first day of their hospital stay into rehabilitation; and controlling management of trauma patients while in the ICU.

Coordination. Coordination means working across disciplines to provide unified care for the patient. The downside of specialization and independent decision-making is inadequate attention to the interdependence of bodily systems and potential interactions among drugs and other interventions. Coordinated care means that physicians, nurses, and

allied professionals work together to clarify their responsibilities, objectives of care, and plans of treatment and to review drugs prescribed and potential interactions. They produce a single set of orders, or orders that have been coordinated with each other.

Clinical pathways and their protocols are one of the most powerful and efficient ways to coordinate care. Coordination is enhanced not only by having these tools in place and ensuring they are followed, but also by the processes of creating them. In an effective, well-facilitated, multidisciplinary development process, clinicians who may have had little or no communication sit down and listen to each other, become more aware of their interdependencies and disconnections, and examine evidence from many angles as the basis for mapping out their pathways and/or protocols.

The scope and depth of the need for coordination are in proportion to the degree of fragmentation of care and the complexity of the patient's situation. Coordination of patient care is so important and, in many cases (such as with TBI) must be achieved at so many points of potential breakdown, that multiple modes of coordination are needed. These might include the processes and outcomes of building pathways and protocols, oversight committees committed to achieving consistency and coordination of care, and specialized roles such as trauma program managers, advanced practice nurses, and intensivists.

Conclusions and Caveats

1. Coordination across disciplines and clinicians is needed to provide *unified* care (from a provider perspective) for patients. But, from the patient's perspective, care becomes *seamless* only when there is consistency and continuity of care as well as coordination.

2. The 3Cs model and the brain/skeleton/flesh metaphor are two ways of saying the same thing. One focuses on the goals of seamless care, and the other focuses on a set of tools for reaching them.

3. Well-implemented guidelines, protocols, and pathways redesign the default structure for care of a particular patient population. At their best, these three tools provide clear, well-considered default positions from which to deliver care.

4. They must, of course, be flexible and responsive to the patient and to accumulating bodies of experience and evidence. Excellence in health care requires finding a balance between default structures and individual patients.

5. Many kinds of decisions can appropriately be made for classes of patients, but all decisions must ultimately be tailored for individual patients, and some decisions must start with the patient and/or be made at that level.

GLOSSARY

Guidelines, protocols, and pathways are systematically developed tools for standardizing care. They usually reflect the consensus that has been reached or approximated by their (often multidisciplinary) developers, who are experts on the care of a particular patient population. As used in this study:

- *guidelines* are recommendations about what to do—e.g., "intubate the airway"
- *protocols* are detailed procedures for how to do it
- *pathways* are broader frameworks for organizing the care of a patient population, such as asthma patients or severe TBI patients

See Section IV for a way of thinking about these three interrelated tools.

A trauma center might decide to adopt any or all of the current 14 evidence-based commentaries currently covered by the Guidelines. The center needs to develop detailed protocols for how to execute those Guidelines in their hospital. Use of the term "protocols" in this study refers to Guidelines-based, hospital-specific protocols. [back to page 1]

Trauma refers to injuries sustained by force or impact due to accidents or assailants. Auto crashes are the source of 59 percent of traumatic injury, assaults 12 percent, falls 13 percent, and accidents 10 percent.[19] These national figures vary by locale; urban trauma centers are sometimes referred to as "knife and gun clubs" while rural centers have many farm accidents as well as car crashes. [back to page 4]

Neurotrauma is trauma that affects neurological systems such as the brain or spinal cord. [back to page 12]

Brain trauma, or traumatic brain injury (TBI) is injury to the brain due to accidents and force. By contrast, injury to the brain from a stroke has an internal cause. Like all trauma, brain trauma wounds can be open or closed and come from blunt or penetrating injury. TBI comes in three classes of severity: severe, moderate, and mild. Classification is made on the basis of neural assessments that translate into ratings such as those of the Glasgow Coma Scale. [back to page 1]

Secondary brain trauma occurs after the original insult from the effects of increased brain pressure and incidents of low blood pressure. [back to page 38]

Trauma centers. There are more than 1,200 trauma centers, of which at least 455 are Level I through Level III centers that treat severe TBI. They provide emergency care and specialized intensive care to critically ill and injured patients. The American College of Surgeons Committee on Trauma (ACS-COT) provides a detailed description of what is needed to set up a certain level of trauma care. State Departments of Health use the ACS-COT document as a template, but each sets its own standards for certification as a trauma center. In some situations (e.g., no state certification process), hospitals can self-designate as a trauma center. Trauma centers must meet many clinical and regulatory requirements. The associated administrative work takes up much of the time of trauma nurse coordinators and trauma registrars.[20] [back to page 1]

Classification system. The current classification of trauma centers has four levels, each of which requires more of the trauma center. Level I requires in-house surgery and anesthesia presence 24 hours a day, seven days a week; an operating room open and on standby for trauma patients; 24-hour CT scanner capability; and a neurosurgeon immediately available. Level II centers are also expected to provide comprehensive trauma care, but have a less stringent level of resources and are not required to have teaching and research programs. They are required to have in-house surgery and anesthesia presence within 10 to 20 minutes, an OR available, and a neurosurgeon on call. Level III must have written transfer agreements with centers that have neurosurgical availability. Trauma medical directors, program managers, and registrars can be part time. Level IV triages, treats minor injuries, and stabilizes patients with more severe injuries prior to transport to a higher-level trauma center.

A Level I or II trauma center has to find a way to treat and take care of incoming trauma patients on a 24/7 basis. University and teaching hospitals have residents on site; their attending physicians, as in non-teaching hospitals, usually take turns being "on call" for incoming trauma patients, deteriorating conditions, and other crises. Research has demonstrated that severely injured trauma patients have better outcomes if transported directly to a trauma center rather than being transferred from another hospital. [back to page 5]

Trauma surgeons are general surgeons with two years of specialized training following five years of general surgery residency. If there is a trauma service, they belong to that service, which is usually part of the general surgery department. [back to page 5]

Trauma nurses usually receive critical care training through specialized advanced curricula, on the job experience, and in-service training. [back to page 15]

Trauma networks is a term used here to designate the networks of specialists and services that take trauma call or perform services on and for trauma patients. [back to page 9]

Trauma team refers to a subset of the network that is working together at any given time on a patient. [back to page 9]

Neurosurgeons spend seven years as residents, learning to intervene in and operate on neurological systems, primarily the brain and spinal cord. When neurosurgeons are part of a university hospital, they may have an appointment in the neuroscience department. [back to page 5]

Intensivists are usually jacks-of-all-trades, who are on site most of the time and actively manage the ICU and coordinate the care of all of its patients, whatever service the patient is on. An intensivist's home discipline is most likely to be surgery, internal medicine, pulmonology, or anesthesiology, in addition to further training and qualification in critical care management. Many trauma surgeons do not practice critical care management, but of those surgeons who do critical care and practice as intensivists, most are trauma surgeons. [back to page 15]

Critical care or intensive care units (ICUs) are units within hospitals where patients are watched more closely and can be treated more aggressively than in a floor unit. Small and midsize hospitals might have only one ICU, but larger hospitals have several—e.g., surgical, neuro, pediatrics. The surgical ICU (SICU) might house trauma patients, post-surgical patients, and other seriously ill patients. [back to page 5]

TBI Guidelines. The current *Guidelines for the Management of Severe Traumatic Brain Injury* are put forward as 14 elements of care, around which a chapter of evidence and commentary is organized. Depending on the level of certitude and support in the literature, each is put forward as a **standard, guideline, or option.** Class I evidence is derived from prospective randomized controlled trials. Some, however, might be poorly designed, lack sufficient patient numbers, or suffer from other methodological inadequacies. Class II evidence is derived from clinical studies in which data were collected prospectively, and retrospective analyses were based on clearly reliable data. Types of studies include observational, cohort, prevalence, and case control. Class III evidence is usually derived from retrospectively collected data. Evidence used in this class indicates clinical series, databases or registries, case reviews, case reports, and expert opinion.

Standards are generally based on class I evidence. However, strong class II evidence might form the basis of a standard, especially if the issue does not lend itself to testing in a

randomized format. Conversely, weak or contradictory class I evidence might not be able to support a standard. **Guidelines** are usually based on class II evidence or a preponderance of class III evidence. **Options** are usually based on class III evidence.

The in-hospital Guidelines are directed at managing and reducing the secondary brain trauma that may develop after the primary insult. The Guidelines provide information to identify patients at risk for secondary trauma and its complications, and suggest interventions to maintain cerebral perfusion pressure (CPP) and reduce intracranial pressure (ICP) so as to improve oxygen delivery to the tissues. This requires dedicated, patient, and attentive monitoring, and proactive interventions when indicators are going in the wrong direction. ICP monitoring is considered by Guidelines authors and adopters as the cornerstone of TBI care.

The Guidelines have been endorsed by the American Association of Neurologic Surgeons, the World Health Organization neurotrauma committee, the New York State Department of Health, and other organizations.

The Brain Trauma Foundation has also developed and published the following Guidelines: *Guidelines for the Prehospital Management of Severe Traumatic Brain Injury, Early Indicators of Prognosis in Severe Traumatic Brain Injury,* and *Surgical Management of Traumatic Brain Injury*. [back to page 1]

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