

## American Burn Association Consensus Statements

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## The ABA's Pursuit of Excellence: A Long and Winding Road...to Your Door

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Quality is generally recognized to have three components: structure, process, and outcomes. The American Burn Association (ABA) has a long history of trying to improve quality of care for patients with burn injuries. Since its establishment by Dr. Irving Feller in the 1970s,<sup>1</sup> the National Burn Information Exchange, a nascent database relying on punch cards submitted by participating burn centers, has worked to drive quality improvement, regional healthcare planning, resource allocation, and research and

prevention. Over time, this project evolved into the voluntary ABA project, the National Burn Repository (NBR), which now reports on incidence, etiology, and acute outcomes. The 2011 NBR Summary Report included more than 160,000 submissions from burn centers in the United States and Canada (and in 2010, Sweden). Like all data repositories, it has imperfections including missing data fields, but the ABA has initiated measures to incorporate a validator to minimize inconsistent data.

A second ABA initiative was the Committee on Organization and Delivery of Burn Care project to establish quality indicators for burn outcomes. This culminated in a *Journal of Burn Care and Rehabilitation* publication<sup>2</sup> that acknowledged two types of standards: process (organizational) and practice (clinical goals). The authors also identified indicators, measures by which to evaluate progress.

In 2001, Dr. Jeffrey Saffle and colleagues published a series of Practice Guidelines for Burn Care in a supplement to the *Journal of Burn Care and Rehabilitation* ([http://www.ameriburn.org/resources\\_publications](http://www.ameriburn.org/resources_publications)). Because it was never listed in PubMed, it had limited circulation and access was restricted. Therefore, the Committee on Organization and Delivery of Burn Care revised a series of guidelines after 2006<sup>3</sup> and published them in the *Journal of Burn Care and Research*.

The culmination of the ABA's efforts to improve outcomes for patients with burn injuries has been the verification process, as outlined in the Guidelines for the Operation of Burn Centers, a chapter in the American College of Surgeons (ACS) Resources for Optimal Care of the Injured Patient ([http://www.facs.org/trauma/faq\\_answers.html](http://www.facs.org/trauma/faq_answers.html)). The verification process assesses process and emphasizes organizational infrastructure, including personnel qualifications, facility resources, and medical care services. This emphasis has been a great first step; but the verification stops short of assessing outcomes. In fact, examination of national repositories, including the University HealthSystem Consortium, the Centers for Medicare and Medicaid Services Hospital Compare Program (<http://hospitalcompare.hhs.gov/>), and the CDC National Health Safety Network (<http://www.cdc.gov/nhsn/dataStat.html>), has never demonstrated that verified burn centers have better outcomes. Furthermore, the Centers for Disease Control National Health Safety Network data suggest that compared with other intensive care units (ICUs), burn ICUs have significantly higher rates of catheter-associated blood stream infections, catheter-associated urinary tract infections, and ventilator-associated pneumonias in spite of many fewer catheters per 1000 hospital days and days of intubation.

Burn centers are valuable resources at significant risk because of increasing financial pressures. As healthcare dollars dwindle, burn centers will compete for increasingly limited healthcare funding. Other surgical specialties such as bariatrics have successfully linked specialty center accreditation with enhanced payment by benchmarking outcomes and demonstrating superior results. However, in spite of multiple attempts the burn community has never been able to link ABA verification with enhanced reimbursement. It is clear that to accomplish this goal, we must be able to link verification with improved outcomes, decreased mortality, shorter hospital stay, reduced hospital-acquired complications, improved functional recovery, return to work/school, cost containment, and resource optimization. Because the ACS National Surgery Quality Improvement Process metrics focus on elective surgical procedures and do not reflect injury severity or outcomes for patients with burns, inhalation injury, or large wounds, the burn community must develop criteria for quality of care in each of the domains that significantly impact our patients.

The National Quality Forum (<http://www.qualityforum.org>) identifies three main benefits to measuring outcomes:

1. Measures drive improvement, as evidenced by the fact that healthcare providers who review performance measures can adjust care, share successes, and probe for causes.
2. Measures inform consumers, as evidenced by the fact that consumers consult national resources such as HospitalCompare.hhs.gov to assess quality of care, make choices, ask questions, and advocate for good health care.
3. Measures influence payment, as evidenced by the fact that payers use measures as preconditions for payment and targets for bonuses, whether it is paying providers for performance or instituting nonpayment for hospital-acquired complications.

With the increasing national focus on quality metrics, the burn community must tackle how to move forward by establishing new burn-specific metrics beyond our traditional outcomes measures of survival and length of hospital stay. Just as the trauma community has created the Trauma Quality Improvement Program it may be time for the burn community to create Burn Quality Improvement Program (BQIP). Because hospitals focus on metrics to improve standings, the burn community needs burn-specific patient-safety data. The NBR, which currently reports incidence, etiology, and acute outcomes, could easily be adapted to include quality data. A revised NBR could include hospital-acquired conditions that

hospitals already upload to national administrative repositories. A next step could be to include long-term measures of recovery including functional, psychological, and vocational status. Eventually, it may be appropriate to record patients' experiences, just as reported in publically accessible CMS databases such as <http://hospitalcompare.hhs.gov>. Like all data repositories, the NBR has imperfections including missing data fields. However, measures by the ABA Burn Registry and NBR Advisory committees to work with Digital Innovation, Inc. (Forest Hill, MD) to incorporate a validator should minimize inconsistent data.

To initiate this project, the ABA convened a consensus symposium in February 2012 to define burn-specific outcomes in five areas: functional outcomes, nutrition, psychological outcomes, resuscitation, and wound repair. After reviewing the literature, debating the issues at the consensus conference and providing opportunities for feedback from the burn community at an open forum at the 2012 annual meeting of the ABA and on an ABA-sponsored Web site, the consensus panels devised recommended metrics that could be tracked locally or as part of the NBR. These have been written as white papers and are published here in the *Journal of Burn Care and Research*.

Our plan will be to incorporate these quality outcomes indicators into a revised Web-based NBR. The distinction between this new platform and the existing national databases will be the ability to stratify data

according to burn patient injury severity, with a focus on burn-specific injury characteristics including burn size, site, and inhalation injury. Once this platform has been built, a pilot study with 15 to 20 verified burn centers for adult and pediatric patients will beta test the data collection and reporting system to determine relevance of the metrics. The ABA will then introduce this as a new BQIP to augment our current TRACS system. The expectation will be for burn directors to perform quarterly analysis of their benchmarks to assess their performance compared with a national average to drive improvement in clinical care and to identify gaps in knowledge. Eventually, demonstration of such process improvement initiatives using the ABA BQIP data repository will be necessary for ABA/ACS verification.

Establishing benchmarks for important quality outcomes relevant to burn patients may finally allow us to follow the ACS program in bariatric surgery and link quality-based purchasing with verification. For this collaborative project to succeed, the burn community will need to understand the need and embrace the effort.

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## Psychological Outcomes

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The purpose of the Psychological Outcomes Consensus Committee was to establish quality metrics for psychological outcomes after burn injuries. We were charged with reviewing the literature and critically evaluating evidence for the use of screening measures and standardized assessment tools, with the goal of establishing evidence-based practice guidelines for adults and children across the recovery continuum for both clinical and research purposes. We focused on metrics for depressive symptoms and symptoms of

both acute stress disorder (ASD) and posttraumatic stress disorder (PTSD). The committee chose to focus on these three disorders, based on prevalence and the impact that symptoms have on other aspects of burn care and quality of life. Our multidisciplinary committee was sensitive to the fact that many burn centers do not have a dedicated mental health professional on the team who routinely screens for these disorders and that screening will likely be done by a bedside nurse, a clinic nurse, or possibly a social worker. Although the committee expects burn centers to make appropriate referrals to mental health professionals for treatment if indicated, our charge did not include specific treatment guidelines. The taskforce determined that there are insufficient data on both screening and assessment tools in the burn population to advocate for the use of specific measures; because standard tables of evidence could not be created, we listed commonly used measures with their characteristics to guide burn team choice of measures. It is likely that screening for psychological disorders will eventually affect reimbursement, and proactively setting the standards for appropriate screening for patients with burn injuries is essential.

## DEPRESSION

### Definition

Major depressive disorder (MDD) is a clinical diagnosis based primarily on subjective, self-reported symptoms, evaluated with respect to intensity, duration, and impact on daily functioning. The Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV)<sup>1</sup> defines disorders including MDD based on the presence of a minimum number of symptoms or features.<sup>2</sup> The diagnosis of MDD requires the presence of five of nine psychological and somatic symptoms and must include at least one of the two essential criteria, depressed mood or loss of interest or pleasure (anhedonia). The symptoms must be consistently present for at least 2 weeks and cause clinically significant impairment in daily functioning. See the DSM-IV<sup>1</sup> for criteria for MDD. It is important to note that even if a person does not meet criteria for a diagnosis of MDD, depressive symptoms can be debilitating, interfere with care, and therefore warrant treatment.

### How It Meets Clinical Care Quality Outcomes

Depressive symptoms are one of the most commonly reported psychological problems after a burn injury. Frequency rates of depressive symptoms within the first year after injury vary widely depending upon the measure used and the definition of depressive

symptomatology vs a DSM-IV diagnosis of depression. Rates range from about 4% at discharge to 10 to 23% 1 year postinjury,<sup>3-5</sup> with increasing prevalence after discharge through the first year. Whereas no current measures specifically address depression in patients with burn injuries, it is unclear whether burn-specific measures are actually needed. In fact, the taskforce cautions against the development of new depression measures for this population until the inadequacy of existing measures is well established; instead, we encourage efforts to validate existing measures that have been shown to be valid and reliable across other medical and general populations. Validation of the existing general measures of depression for the population of burn survivors may provide greater understanding of depression after burn injury and allow comparison across other patient populations. Individual symptoms of depression can be debilitating and interfere with treatment, and one of the first signs of depression in a medical setting (inpatient or outpatient) is refusal to participate in prescribed therapies. Therefore, if symptoms of depression interfere with patient ability to get better (eg, adherence to therapies, withdrawal), then the symptoms should be treated, even without a formal diagnosis.

### Proposed Metrics for the TRACS Database

Review of evidence-based literature supports the use of three measures for depression (Table 1).

1. Beck Depression Inventory-II<sup>6</sup>
2. Hospital Anxiety Depression Scale<sup>7</sup>
3. Brief Symptom Inventory<sup>8</sup>

However, these lengthy instruments must be purchased and should be administered by a trained mental health professional, which creates potential barriers for most burn units.

The committee was encouraged by the widespread use of the Patient Health Questionnaire (PHQ)-9 item<sup>9</sup> and especially the PHQ-2 item (first two items of the PHQ-9) in other hospital-based populations. This measure is also gaining popularity for researchers. Therefore, we recommend the use of this measure for inpatient and outpatient screening. Given the sensitivity of the PHQ-2, the administration of these two simple questions by a bedside intensive care unit (ICU), acute care or clinic nurse may provide the most practical screening option for all three settings. Positive indicators of depressive symptoms on the screening tools warrant referral to a mental health professional to thoroughly diagnose MDD and to make treatment recommendations. The mental health professional might then consider use of one of the measures that have been validated in the



**Table 1.** Summary of recommended depression measures

Measure	Reference	Items	Time, min	Cost	Setting	Age
PHQ-2 or 9	Spitzer et al (1999) <sup>9</sup>	9	3	Free	Inpatient or outpatient Research or clinical	Adult
Beck Depression Inventory-II	Beck et al (1996) <sup>6</sup>	21	5	Fee	Outpatient Research or clinical diagnostic by a mental health professional	Adult
Hospital Anxiety and Depression Scale	Zigmond and Snaith (1983) <sup>7</sup>	14	2–5	Fee	Outpatient Research or clinical diagnostic by a mental health professional	Adult
Brief Symptom Inventory	Derogatis (1975) <sup>8</sup>	53	8–12	Fee	Outpatient research or clinical screen	Adult
Child Depression Inventory (short form)	Kovacs (1992) <sup>11</sup>	10	5	Fee	Inpatient or outpatient Research or clinical diagnostic by a mental health professional	Children and adolescents
Achenbach Child Behavior Checklist	Achenbach and Rescorla (2001) <sup>10</sup>	118	15	Fee	Outpatient Research or clinical diagnostic by a mental health professional	Children and adolescents

PHQ, Patient Health Questionnaire.

burn population to complete their assessment. The committee recommends three questions to screen for depressive symptoms: The first question is posed to the treatment team and is an important behavioral observation: “Is the patient refusing treatment regularly?” The next two questions are asked of the patient: “Do you feel sad or tearful for most of the day, every day?” and “Do you have little interest or pleasure in doing things?”

The committee found no validated screening tools for depression in children with burn injuries. The Achenbach Child Behavior Checklist<sup>10</sup> is widely used for research and in outpatient settings for young burn survivors, but its use as an inpatient screening tool is not practical. In the ICU and acute care settings, behavioral indicators may be the most accurate and practical assessment of mood in children. Therefore, we recommend the following screening be assessed by a member of the medical team: 1) frequent tearfulness; 2) withdrawal or refusal to participate in therapies; 3) agitation. The presence of these behaviors warrants a referral to a mental health professional. In the acute and outpatient setting, the Child Depression Inventory<sup>11</sup> seems to be the best option; a downside is that it does need to be purchased and administered by a mental health practitioner.

The committee recommends that all inpatients be screened for depressive symptoms within 48 hours of accessibility (eg, mental status clears) and at least one time before discharge. All outpatients should be screened at their first clinic visit after discharge and as indicated thereafter.

By including psychological metrics in the National Trauma Registry of the American College of Surgeons

(TRACS) database, the committee anticipates a better understanding of the overall prevalence of depression among patients with burn injuries. The proposed variables to be entered into TRACS for both adult and children include:

1. Was the patient screened for depression? (yes/no)
2. Was the screen positive? (yes/no)
3. Was a referral to a mental health provider made? (yes/no)
4. Was there a diagnosis of MDD? (yes/no)

As with depression, the following variables should be added to the NTRACS database:

1. Was the patient screened for ASD/PTSD? (yes/no)
2. Was the screen positive? (yes/no)
3. Was a referral to a mental health provider made? (yes/no)
4. Was there a diagnosis of ASD/PTSD? (yes/no)

### Opportunities for Research

Our review identifies the need for standard guidelines to assess depression and validation of existing measures of depression for the burn population to more accurately determine rates of depression and evaluate treatment. Clearly, the burn community must rigorously evaluate the depression measures used in the small existing body of research on depression and burn injury. In order to accomplish this, researchers must report psychometric properties of measures in their studies to validate existing measures of depression for the burn population. The committee felt

that identification of a standard set of psychological outcome measures used across funding agencies would provide great potential benefit to understanding psychological responses after burn injuries. For example, groups participating in multicenter clinical trials, such as the National Institute on Disability and Rehabilitation Research (NIDRR)-funded Burn Model Systems and the Burn Science Advisory Panel could consider adopting the same evidence-based psychological outcome measures. Further, adoption of more widely used measures would allow comparison with patient populations with other disabilities.

### Recommended Depression Measures

	Inpatient	Outpatient	Research
Adults	PHQ-2 (Screening)	PHQ-2 (screening)	SCID (gold standard)
	BDI-II (diagnosis/severity)	PHQ-9 (diagnosis/severity)	PHQ-9
	HADS (diagnosis/severity)	BDI-II BSI	BDI-II HADS BSI
Children	Behavioral indicators (screening): frequent tearfulness, withdrawal, refusal to participate in therapies	Behavioral indicators (screening): frequent tearfulness, withdrawal, refusal to participate in therapies Child Depression Inventory (diagnosis/severity)	Diagnostic interview: Achenbach Child Behavior Checklist

*PHQ*, Patient Health Questionnaire; *SCID*, structured clinical interview; *BDI*, Beck Depression Inventory; *HADS*, Hospital Anxiety Depression Scale; *BSI*, Brief Symptom Inventory.

## ACUTE STRESS DISORDER/ POSTTRAUMATIC STRESS DISORDER

### Definition

One of the most distressing psychological problems associated with a burn injury is ASD and its subsequent form, PTSD. Both of these disorders are associated with poorer physical and social function and greater psychosocial distress.<sup>12</sup> The full diagnostic criteria for both disorders can be found in the DSM-IV Manual.<sup>1</sup> Briefly, a person must have been exposed to a traumatic event and have subsequent episodes of reexperiencing the event (nightmares or flashbacks), symptoms of avoidance, and symptoms of hypervigilance. He or she may also experience numbing or dissociation. Symptoms occurring in the first month after the traumatic event constitute ASD; thereafter it is PTSD. When ASD symptoms occur early in the

burn management they can result in agitation and disrupt normal medical care.

### How It Meets Clinical Care Quality Outcomes

The burn survivor has a great risk for ASD and PTSD because his or her trauma occurs both in the accident and in the ongoing daily treatment of the burn wound. The prevalence of ASD in the burn survivor ranges from 6 to 33% regardless of the type of trauma.<sup>13</sup> PTSD is even more common, with rates of 24 to 40% at 6 months postinjury to 15 to 45% at 12 months postinjury. Studies of children suggest lower rates of 2 to 19% for current PTSD and 30% some time during the lifetime. The variability in reported rates reinforces the problem with use of different measurement tools and nonstandard sampling characteristics. ASD does not always lead to PTSD, but its presence is one of the strongest predictors of PTSD. The presence of ASD or PTSD symptoms can cause a disruption in clinical care, by interfering with a patient's ability to participate in therapies, prolonging delirium, and increasing the need for physical and chemical restraints. ASD is often misdiagnosed as agitation or psychosis and can lead to the overuse of sedation and pain medications. In the outpatient setting, PTSD can interfere with both physical therapies and patient ability to return to work/school. PTSD has also been found to lead to depression and sometimes suicide. As with depression, even if a person does not meet full criteria for a formal diagnosis, ASD/PTSD symptoms can be debilitating and should be treated. The committee recommends screening for ASD/PTSD in both the inpatient and outpatient settings and a referral to a mental health professional for a positive screen.

ASD/PTSD screening tools (Table 2) have been developed for use in large populations in a busy setting where long interviews are not practical. One screening tool, developed for ASD after burn injuries<sup>14</sup> provides a checklist based on DSM-IV criteria and is easy to use in the ICU setting. The Department of Veterans Affairs National Center for PTSD Web site (<http://www.ptsd.va.gov/professional/pages/assessments/child-trauma-ptsd.asp>) provides a broad overview of all the possible ASD/PTSD tools.

### Recommended ASD/PTSD Measures

In forming a recommendation, the consensus committee considered ease of administration, cost, and widespread use among other disability populations. The PTSD Symptom Checklist-Civilian version has garnered popularity for its psychometric properties, ease of use, and free availability in the public domain. Other disability groups, such as the NIDRR-funded

	Inpatient	Outpatient	Research
Adults	ASD screen, <sup>14</sup> as well as behavioral indicators such as sleep problems and agitation	PCL-C SPAN	PCL-C Davidson Trauma Scale
Children	ASD screen, <sup>14</sup> as well as behavioral indicators such as sleep problems and agitation	UCLA PTSD Index	UCLA PTSD Index Diagnostic Interview for Children

ASD, acute stress disorder; PCL-C, PTSD Symptom Checklist-Civilian version; SPAN, Startle, physiological Arousal, Anger, Numbness; PTSD, posttraumatic stress disorder.

Traumatic Brain Injury Model Systems and the Spinal Cord Injury Model Systems, have also adopted this tool to assess those patient populations.

### Opportunities for Research

Again, the gold standard for assessing PTSD in clinical research is the diagnostic interview (eg, SCID). If this is not feasible, there is good evidence for the PTSD Symptom Checklist-Civilian version, the Davidson Trauma Scale, and the UCLA PTSD Index. As with depression, the consensus committee cautions against developing new measures of ASD or PTSD specifically for the burn population and endorses validating existing measures for this population, which will require researchers to report psychometric properties of the measures used for their studies. Collaboration among researchers in large multicenter clinical trials and model systems would allow for larger sample sizes and comparisons across disability groups. Finally, the committee felt that research aimed at preventing the onset of PTSD with the inhibition of encoding traumatic memories by

administering certain medications (eg, propranolol, morphine, sertraline)<sup>13,15,16</sup> should be a research priority. Improved pain management has also been suggested as a mechanism to prevent the onset of ASD/PTSD symptoms, and warrants a multicenter trial.

### What Are the Potential Effects on Reimbursement or Hospital Costs?

In order to demonstrate that the multidisciplinary burn community addresses long-term needs of burn patients, burn centers should demonstrate that they screen for the two most common posttraumatic psychological disturbances, depression, and ASD/PTSD, and that they have a mechanism for referring patients for treatment who screen positive on the screening measure. Recently, the Medicare Provider Quality Reporting System has suggested that medical providers must screen for a minimum of three disorders in order to receive full reimbursement. They have provided a list of several potential disorders to screen for during inpatient and outpatient care. Disorders most relevant to psychological outcomes include depression, pain, alcohol abuse, and tobacco use. At this point, Provider Quality Reporting System is offering a 1% incentive when providers screen for a minimum of three disorders. Eventually, providers will be penalized if they do not screen for a minimum number of disorders.

### SUMMARY AND RECOMMENDATIONS

1. All inpatients should be screened for depressive and ASD symptoms within 48 hours of accessibility (eg, delirium cleared) at least once before discharge
2. All outpatients should be screened for depressive and ASD/PTSD symptoms at their first clinic visit after discharge and as indicated thereafter
3. Verified burn centers should demonstrate that they have a referral process in place for an appropriate intervention by a licensed mental health

**Table 2.** Summary of recommended ASD/PTSD measures

Measure	Reference	Items	Time, min	Cost	Setting	Age
PCL	Weathers et al (1993) <sup>17</sup>	17	5–10	Free	Inpatient or outpatient Clinical or research	Adult
SPAN	Meltzer-Brody et al (1999) <sup>18</sup>	4	2		Outpatient Clinical	Adult
SCID	First et al (1996) <sup>19</sup>	21	30		Research	Adult
Davidson Trauma Scale	Davidson et al (1997) <sup>20</sup>	17	12		Research	Adult
UCLA PTSD Index	Pynoos et al (1998) <sup>21</sup>	48	20	Free	Outpatient Clinical or research	Child

ASD, acute stress disorder; PCL, PTSD checklist; PTSD, posttraumatic stress disorder; SCID, structured clinical interview.

practitioner should the patient screen positive for depressive, ASD, or PTSD symptoms

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## Burn Resuscitation

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Fluid resuscitation remains the foundation of the early management of the burn-injured patient. Over the last 70 years more than a dozen widely used formulas have been advocated to treat the altered pathophysiology of burn shock, which includes both hypovolemic and cellular shock with hemodynamic challenges, decreased cardiac output, increased extracellular fluid, decreased plasma volume, and oliguria. The primary goal of resuscitation remains restoration and preservation of tissue perfusion in order to avoid ischemia and worsening of tissue injury. Burn wound edema, transvascular fluid shifts, and an increase in total body capillary permeability is exemplified by burn injury. Changes in the microvasculature caused by direct thermal injury and to inflammatory responses disrupt the normal capillary barrier that separates intravascular and interstitial compartments, and leads to rapid equilibration between compartments. This results in severe plasma volume depletion, increased extracellular fluid, and intravascular hypovolemia.

The Parkland formula (4 ml/kg/%TBSA) and modified Brooke formula (2 ml/kg/%TBSA) are the two most widely used resuscitation formulas.<sup>1</sup> Both formulas originally prescribed colloid administration over the second 24 hours, though many centers have abandoned this practice. In many cases these formulas have served merely as guidelines, as many authors have reported that they significantly underestimate actual fluid requirements. There is general agreement that there is an increasing tendency to over-resuscitate during burn shock.<sup>2-4</sup> To date, one of the unanswered questions in burn resuscitation is: what is the optimal use of colloids,<sup>5,6</sup> hypertonic saline,<sup>7</sup> and antioxidants?<sup>8</sup> Additionally, appropriate timing and use of treatments such as vasoactive agents,<sup>9</sup> renal replacement therapy (including high-volume hemofiltration),<sup>9,10</sup> and plasma exchange<sup>11</sup> require further study. Questions remain about what constitutes optimal monitoring of resuscitation, optimal resuscitation endpoints, and use and implementation of nursing<sup>12</sup> or computer-driven resuscitation protocols<sup>13</sup> to improve precision in resuscitation. In this environment, the Resuscitation Consensus Panel of the American Burn Association Quality Consensus Conference has been charged with identifying quality indicators for burn resuscitation.

This review led to the conclusion that there is insufficient evidence to support a resuscitation treatment standard at this time, and there is no common or nationally recognized benchmark at this time. Exploring processes across centers will help identify best practices and provide feedback regarding how high-performing centers separate themselves with respect to burn resuscitation.

The Consensus Panel reached the consensus that successful fluid resuscitation of a burn patient should occur within a 72-hour period after burn injury and use of the 72-hour marker will offer an outcome parameter that can be qualitatively assessed. Additionally, the group also agreed that there is a need to collect multicenter data to evaluate whether the attainment of a successful resuscitation could be reached at 24, 48, or 72 hours among patients with a burn size  $\geq 20\%$  TBSA. Analysis of the collected data may allow establishment of more comprehensive outcome parameters, providing the means for developing distinct quality indicators that could be used to differentiate successful fluid resuscitation from unsuccessful resuscitation. Recognizing that some patients with burns less than 20% TBSA may require or receive resuscitation, the Consensus Panel chose to recommend initial data collection to those patients with  $\geq 20\%$  TBSA burn to provide cleaner data for analysis. Additionally, differences between adult and pediatric patients could be further analyzed in subgroup analysis. Recommendations have been proposed under three categories:

1. Specialized care to burn patients
2. Preservation of vital organs
3. Preservation of life and quality of life

## SPECIALIZED CARE TO BURN PATIENTS

### How It Meets Clinical Care Quality Outcomes

Provision of specialized care to a burn patient that sustains, protects, and rehabilitates within the acute phase of injury represents a burn unit priority. Specialized care in the context of an environment (verified or self-defined burn center) should provide real-time monitoring of vital parameters as well as rapid intervention when necessary. Morbidity or consequences that lead to further deterioration, such as development of compartment syndromes, acute kidney injury, pulmonary edema, pneumothorax, and the acute respiratory distress syndrome, serve as markers for negative outcome. These morbidities arise from three potential system failures that serve as areas for quality improvement strategies: chance, fault within the system, or human error. Examples of system failures include overuse, underuse, or inappropriate use of resources (eg, too much fluid, too little fluid, or wrong fluid).

### Proposed Metrics To Be Added to the TRACS Database

Because of the fact that provision of specialized care of a burn patient that will sustain, protect, and

rehabilitate in the acute phase of injury is a priority in the burn unit, processes to provide this care should be monitored. The proposed outcome measures are:

1. Whether resuscitation was facilitated by use of a protocol or computer decision support.
2. Whether burned surface area was calculated by use of a Lund–Browder diagram or electronic program.
3. What formula or method was used to determine starting fluid rate and what urine output was targeted.

### Opportunities for Research Because of Lack of Level 1 Evidence

The Consensus Panel has identified opportunities for research in of processes and delivery of care and the perceived or potential benefit to protocols, establishing goals of care, and targeting endpoints of resuscitation.

## PRESERVATION OF VITAL ORGANS

### How It Meets Clinical Care Quality Outcomes

Preservation of vital organ function at the least physiologic cost and the least number of complications is the simplified goal of fluid resuscitation. The amount of fluid administered should be enough to maintain vital organ function without producing iatrogenic pathologic changes. Markers of a negative outcome, which could be used in this domain, may be those values that determine whether successful perfusion to tissue has been maintained, such as base deficit and lactate, as well as markers of organ dysfunction, such as acute kidney injury with increase in creatinine or acute lung injury with alteration in PaO<sub>2</sub>:FiO<sub>2</sub> ratio.

### Proposed Metrics To Be Added to the TRACS Database

In order to monitor preservation of vital organ function at the least physiologic cost, with the least number of complications, we propose collection of the following clinical parameters:

1. *Patient demographics:* Age, sex, admission weight, presence of comorbidities.
2. *Injury characteristics:* %TBSA burn, %full-thickness or %grafted, time of injury, time of admission, presence of inhalation injury or need for intubation, concomitant trauma.
3. *Resuscitation characteristics:* Lab values (base deficit, lactate, hemoglobin/hematocrit, blood urea nitrogen, and creatinine), intake and output values (prehospital and total fluid volumes, use of

adjunct fluids and volume—including high-dose vitamin C, hypertonic saline, fresh frozen plasma and albumin, urine output, input/output ratio, and bladder pressures), and treatments (use of vasopressors, initiation of tube feeds, use of renal replacement therapy or plasma exchange, need for decompressive procedure—escharotomy, fasciotomy, canthotomy, or laparotomy, and time to first operation).

4. *Timing and frequency of variable collection:* Intervals for the collection of clinical data will be every 6 hours for the first 24 hours of resuscitation postinjury (6, 12, 18, and 24 hours), then every 12 hours up to the 72-hour mark (36, 48, 60, and 72 hours).

### Opportunities for Research Because of Lack of Level 1 Evidence

1. Optimal timing, use, and efficacy of adjuncts to resuscitation: high-dose vitamin C, hypertonic saline, fresh frozen plasma, and albumin.
2. Role for high-volume hemofiltration, plasma exchange, and renal replacement therapy in the patient with acute kidney injury.
3. Effect of inhalation injury, intubation and mechanical ventilation, opioids and sedation, and obesity on fluid requirements and contribution to “fluid creep.”

## PRESERVATION OF LIFE AND QUALITY OF LIFE

### How It Meets Clinical Care Quality Outcomes

Compassionate care is a priority in burn centers and preservation of “meaningful life” as valued by the patient and family, could be considered as that which is an acceptable “quality of life.” The easiest marker of outcome in this domain is mortality, which can be measured by using crude mortality rates or a standard observed/expected ratio. Crude mortality has been reported for years, but lacks an ability to adjust for differences in severity of illness and coexisting medical or psychosocial comorbidities. A standardized mortality ratio, defined as the ratio of observed mortality rate to expected mortality rate, allows for risk adjustments that are performance-based comparisons by adjusting for disease category and severity of derangement. Stratification of the data can then be used to develop an applicable scoring system. The scoring system would then be used to determine whether the outcome of mortality is within an expected rate or whether there is an opportunity for improvement.

## Proposed Metrics To Be Added to the TRACS Database

Generation of and contribution to a well-populated and accurate National Burn Repository (NBR) will help in stratification of data to develop an applicable scoring system and determine how individual mortalities or burn centers compare with an expected rate. The outcome measures are:

1. Mortality (yes or no)
2. Withdrawal of support (yes or no)
3. Discharge location

## Opportunities for Research Because of Lack of Level 1 Evidence

1. Determination of an accurate expected mortality prediction for an individual patient, or validation of the existing revised Baux score through use of the NBR, to allow for creation of standardized mortality ratios.
2. Survey of major burn survivors regarding qualities that are perceived to be important for “meaningful quality of life.”

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# Nutrition Outcomes

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The response to injury after a burn increases normal metabolism to such a profound degree that without caloric intervention severely injured burn patients would universally succumb to their injuries from protein-calorie malnutrition.<sup>1-5</sup> Postburn hypermetabolism is associated with profound proteolysis resulting in lean body mass loss and muscle wasting. Appropriate monitoring for nutritional needs and deficiencies and provision of adequate calories, nitrogen, micronutrients, and supplements is critical to the success of burn care. Modulation of the stress response has been attempted both with nonpharmacologic and pharmacologic means.<sup>6-12</sup> Nonpharmacologic means include: early operative intervention, thermoregulation of environment, and enteral nutrition. Pharmacologic interventions have included intensive insulin control,  $\beta$ -blockade (BB), and anabolic agents. The goal of the Quality Consensus Conference was to develop metrics that may be added to the American Burn Association (TRACS) Burn Registry database for the purpose of tracking burn outcome measures. The following summary outlines metrics proposed by the Nutrition Consensus Work Group:

1. Total calorie and protein intake during the first week of admission
2. Weight loss throughout the acute phase of injury (admit weight [or dry weight] - discharge weight)
3. Use of glutamine (yes or no)
4. Weekly average blood glucose levels
5. Average weekly heart rate
6. Use of oxandrolone (yes or no). These metrics are based on available evidence, although numerous gaps were identified in the evidence. Therefore, areas of research needs are also presented in this report.

## PROVISION OF ENERGY AND PROTEIN

### How It Meets Clinical Care Quality Outcomes

The delivery of adequate calories and protein is a priority in the burn unit, as it reduces morbidity and mortality associated with critical illness. Cumulative energy deficits during the first week of admission correlate with numerous complications including infection, sepsis, and pressure sores.<sup>13-15</sup> Correspondingly, substantial loss of lean body mass impairs wound healing.<sup>16</sup> Therefore, monitoring calorie and protein intake is essential.

Available tools for monitoring nutritional status after a burn injury are not consistently used among

the burn community. Trending visceral protein measurements with acute-phase reactants is a common practice among burn units; however, supporting evidence is lacking. Two studies, including 121 burn patients<sup>17,18</sup> suggest that C-reactive protein/prealbumin (transferrin) predicts morbidity and mortality. In contrast, two smaller studies<sup>19,20</sup> suggest that these biomarkers are unreliable. Because of the lack of evidence and consensus, no recommendation on tracking visceral proteins can be made at this time.

### Proposed Metrics To Be Added to the TRACS Database

Because of the fact that adequate provision of nutrition is essential for positive outcomes, energy and protein intake should be monitored closely.

The proposed measureable outcomes are:

1. Total calorie and protein intake during the first week of admission
2. Weight loss throughout the acute phase of injury (admit weight [dry weight] and discharge weight)

### Opportunities for Research Because of Lack of Level 1 Evidence

1. Multicenter trials to develop equations that accurately estimate energy needs for all populations of burn patients (adult, pediatric, and obese patients)
2. Contemporary studies to assess the protein needs of pediatric and adult burn patients
3. Multicenter studies to assess the reliability of visceral proteins for assessing nutritional status and predicting outcomes

## NUTRITIONAL ADJUNCTS

### How It Meets Clinical Care Quality Outcomes

Specific nutrient supplementation, in addition to standard nutrition support, is often administered to burn patients. Studies report several advantages to glutamine; however, information on the benefits of other nutrients is lacking. Glutamine has several valuable functions that may be beneficial to burn patients. Evidence among adult burn patients shows that enteral glutamine supplementation decreases infection rates,<sup>21,22</sup> mortality,<sup>21</sup> length of stay (LOS),<sup>22,23</sup> and preserves gut integrity.<sup>22,23</sup> Of note, these studies include small sample sizes ( $n = 40-48$ ) and diverse dosing methods. Nevertheless, it is reasonable to conclude from this data that adult burn



patients benefit from glutamine. However, supporting evidence among pediatric burn patients is scarce. The only study addressing this population, published in 2004 by Sheridan et al,<sup>24</sup> found no benefits to glutamine supplementation. Although other single nutrients or nutrient combinations are commonly supplemented in burn patients, no concrete evidence is available to support this practice. Studies do report depressed levels of vitamin C,<sup>24</sup> vitamin D,<sup>25</sup> selenium,<sup>26,27</sup> vitamin E,<sup>24,28</sup> zinc, and copper<sup>26,29-32</sup> among burn patients. However, supplementation studies are scarce and do not provide definitive guidance for appropriate micronutrient provision. Because of lack of research, no recommendation on micronutrient supplementation or tracking micronutrient status can be made at this time.

### Proposed Metrics To Be Added to the TRACS Database

Data indicate that glutamine is beneficial to adult burn patients. Glutamine's use should be monitored closely.

The proposed outcome measure is:

Use of glutamine (yes or no)

### Opportunities for Research Because of Lack of Level 1 Evidence

Multicenter trials are needed to assess the benefits of glutamine for pediatric burn patients and to determine specific micronutrient benefits for pediatric and adult burn patients.

## CONTROL OF STRESS-INDUCED HYPERGLYCEMIA

### How It Meets Clinical Care Quality Outcomes

Hyperglycemia has been associated with several adverse effects in burn patient populations. These include: stimulation of a persistent inflammatory state; poor wound healing, protein catabolism, infection, and death.<sup>33-43</sup> Correction of hyperglycemia may ameliorate these adverse effects, affecting patient LOS, discharge disposition (home vs nursing home or rehabilitation center) and reintegration into society.

### Proposed Metrics To Be Added to the TRACS Database

Data indicate that hyperglycemia control is beneficial for pediatric and adult burn patients.

The proposed outcome measure is:

Weekly average blood glucose levels

### Opportunities for Research Because of Lack of Level 1 Evidence

1. Multicenter trials to address the impact of the treatment of stress-induced hyperglycemia on the standard clinical outcomes of LOS, wound healing, infection, and mortality.
2. Multicenter trials should specify the use of multichannel glucometers, as single-channel glucometers are prone to significant error in anemic patients.<sup>44</sup>

## BETA-BLOCKADE

### How It Meets Clinical Care Quality Outcomes

Catecholamines are the main drivers of the hypermetabolic response to burn injury,<sup>45</sup> with levels rising nearly 10-fold after injury.<sup>45,46</sup> Catecholamines increase cardiac work, drive lipolysis, enhance glycogenolysis, and impair glucose disposal by altering insulin signaling.<sup>47</sup> Blocking the catecholamine surge could potentially improve multiple aspects of the postburn hypermetabolism. Known benefits of  $\beta$  blockers include suppression of lipolysis, decreased resting energy expenditure, preservation of lean body mass, and decreased LOS.<sup>48-53</sup>

### Proposed Metrics To Be Added to the TRACS Database

Data indicate that BB is beneficial to pediatric and adult burn patients. BB use should be monitored closely.

The proposed outcome measures are:

1. Average weekly heart rate
2. Weight loss (admit weight [dry weight] and discharge weight)

### Opportunities for Research Because of Lack of Level 1 Evidence

A multicenter prospective, randomized, double-blind, controlled study should address the pediatric and adult populations that benefit from BB tracking clinical outcomes and the safety of  $\beta$ -blocker use.

## OXANDROLONE

### How It Meets Clinical Care Quality Outcomes

Hypermetabolism leads to protein-calorie malnutrition, muscle wasting, deconditioning, and delayed wound healing. These factors can prolong LOS and hospital costs. Modulation of the postburn hypermetabolism with oxandrolone supplementation can potentially ameliorate these consequences.<sup>53-61</sup>

## Proposed Metrics To Be Added to the TRACS Database

Data indicate that oxandrolone is beneficial to pediatric and adult burn patients. Oxandrolone use should be monitored closely.

The proposed outcome measures are:

1. Use of oxandrolone (yes or no)
2. Weight loss (admit weight [dry weight] and discharge weight)

## Opportunities for Research Because of Lack of Level 1 Evidence

A multicenter prospective, randomized, double-blind controlled study of pediatric and adult burn patients with burn sizes >20% should address which patients benefit from oxandrolone, the safety of its use, and appropriate clinical outcome measures (LOS and maintenance of body weight).

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## Functional Outcomes

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Almost all burn survivors who require admission to a verified burn center will have functional deficits, at least temporarily. Although the overall incidence of major burn injuries has declined, patients who do sustain severe burn injuries are more likely to survive<sup>1,2</sup> because of advancements in critical care and surgical management. Thus,<sup>3</sup> patients who survive are likely to have complex and burn-specific rehabilitation needs to reduce the risk of chronic disability. The evaluation of the functional outcomes of burn survivors is an equally complex challenge. The World Health Organization developed the International Classification of Functioning, Disability and Health,<sup>4</sup> which divides the assessment of health outcomes into body functions and structure, activity, and participation. The deficits identified during the assessment process are subsequently referred to as impairments (body functions and structure limitations), activity limitations, and participation restrictions. This classification is useful for the conceptualization and organization of the outcome measures and findings that are commonly associated with burn injuries. One of the most obvious body structures affected by a burn injury is

skin. After wound healing, skin-associated impairments that have been identified include the formation of hypertrophic scar,<sup>5-7</sup> pruritus,<sup>7-16</sup> impaired sensation,<sup>7,13,17-22</sup> edema,<sup>23,24</sup> thermoregulation,<sup>25</sup> and pain.<sup>7,13,26,27</sup> Additional body functions and structure-level impairments include decreased joint range of motion,<sup>28-31</sup> decreased muscle strength,<sup>32-39</sup> impaired balance,<sup>31</sup> and reduced cardiovascular endurance<sup>33-38,40</sup> as well as cognitive deficits, particularly related to electrical injuries.<sup>41-45</sup> Activity limitations that have been described in burn survivors include a broad spectrum of activities including hand function,<sup>31,46-51</sup> mobility,<sup>39,52,53</sup> activities of daily living,<sup>39,52,54,55</sup> and sexuality.<sup>56,57</sup> Participation restrictions have been examined as they apply to return to work (RTW)<sup>58</sup> or school<sup>59-62</sup> and community reintegration.<sup>55,63</sup> Evaluation of overall quality of life is a complex construct that includes variables representing all three domains of the International Classification of Functioning, Disability and Health including impairments, activity limitations, and participation restrictions. Quality of life in burn survivors has been evaluated using a number of different quality-of-life measures, which evaluated the predictive impact of a number of potentially related variables.<sup>39,51,53,54,64-82</sup> Perusal of the literature demonstrates that the list of measures used to capture functional outcomes in the burn survivor population is extensive and diverse. Each measure was reviewed as a potential metric for prospective and ongoing inclusion in the American Burn Association TRACS/National Burn Registry. The following summary outlines the metrics proposed by the Functional Outcomes working group:

1. Documentation of injury using photography
2. Patient assessment by occupational or physical therapy
3. Self-report of health-related quality of life
4. Employment and/or school status postburn

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## PHOTOGRAPHIC DOCUMENTATION OF INJURY

### How It Meets Clinical Care Quality Outcomes

Documentation of injury using photography is a process indicator that is believed to be a necessary standard, indicative of quality healthcare.

### Proposed Metrics for the TRACS Database

1. Were photographs taken at admission and stored in the medical record? (yes/no)
2. Were photographs taken at wound closure or discharge from acute care and stored in the medical record? (yes/no)
3. Were photographs taken at 1 month, 6 months, and 12 months after burn injury and stored in the medical record? (yes/no for each time point)

## OCCUPATIONAL AND/OR PHYSICAL THERAPY ASSESSMENT

### How It Meets Clinical Care Quality Outcomes

Despite a lack of research identifying best practices in burn rehabilitation, the Functional Outcomes working group supports the clinical competencies recently published for burn rehabilitation therapists.<sup>83</sup> Specifically, the panel believes that a key indicator of quality patient care after an acute burn injury requiring hospitalization is a comprehensive rehabilitation evaluation (competency 1.1.4)<sup>83</sup> within 48 hours of admission to a burn center.

### Proposed Metrics for the TRACS Database

Did an occupational or physical therapist assess the patient within 48 hours of admission? (yes/no)

## HEALTH-RELATED QUALITY-OF-LIFE ASSESSMENT

### How It Meets Clinical Care Quality Outcomes

The ideal goal after treatment for a burn injury, as stated by the British Burns Association, is “to recover the individual to the preinjury state and for them to return to their place in society with unaltered potential” (<sup>84</sup> p. 16). The Consensus Panel agreed that our ultimate clinical goal is to achieve functional outcomes that patients are satisfied with, whether or not a residual impairment persists. They also agreed that the following guiding principles would be used for metric selection: 1) limit proposed data collection to a realistic target, 2) ensure that the measure can be administered

in a consistent, standard manner across time and different locations, 3) ensure that the burn survivor can be followed up after discharge from the acute care burn center and that the measure can be administered by telephone, and 4) ensure that the measurement has specifically been developed to evaluate burn survivors so that important injury-specific information is captured. We concluded that because self-reported quality of life is the ultimate goal of rehabilitation programs, health-related quality-of-life (HRQoL) measures should be prioritized in the development of functional outcome metrics within TRACS. This conclusion does not reduce the need to better understand the relationship between HRQoL and burn-related impairments and activity limitations, but these relationships could more accurately and feasibly be examined on a smaller scale by centers that are appropriately funded and resourced to do so.

### Proposed Metrics for the TRACS Database

One of the following questionnaires should be completed at hospital discharge, 1 month, 6 months, and 12 months postburn, depending on the age of the patient/burn survivor at the time of the assessment:

- a. Burn Specific Health Scale-Brief (BSHS-B) (adults)
- b. Health Outcomes Burn Questionnaires (children aged 0 to 5 years and children aged 6 to 17 years)

The BSHS-B for individuals aged 18 years and older, contains 40 self-report statements; burn survivors provide their perceived difficulties on a 0 to 4 scale where 0 indicates “extreme” difficulty and 4 is defined as “not at all” difficult. Each item is divided into nine subscales: heat sensitivity, affect, hand function, treatment regimens, work, sexuality, interpersonal relationships, simple abilities, and body image.<sup>85</sup> The BSHS-B has been shown to have adequate reliability and validity by establishing its association with injury severity, long-term use of care facilities, sociodemographic variables, personality traits, coping strategies, dysfunctional beliefs, and HRQoL.<sup>86</sup>

For the pediatric population, two questionnaires exist. For children aged 0 to 5 years, the Children Burn Outcomes Questionnaire for infants and children is recommended.<sup>87</sup> The parent or guardian should complete this questionnaire. The measure consists of 55 items and 10 domains (play, language, fine motor, gross motor behavior, family, pain/itching, appearance, satisfaction, concern/worry) that are evaluated on a 0 to 4 scale.

For children aged 6 to 17 years, the Children Burn Outcomes Questionnaire is recommended.<sup>88</sup> Parents or guardians complete the questionnaire for children younger than 11 years, and children aged 11 to 17 years old complete the questionnaire as a self-report measure. This questionnaire consists of 52 items and 12 domains (upper extremity function, physical function and sports, transfers and mobility, pain, itch, appearance, compliance, satisfaction with current state, emotional health, family disruption, parental concern, and school reentry). Using these outcome measures, extensive data has been collected and analyzed as part of the Multi-Center Benchmarking Study.<sup>89</sup> As a result, recovery curves have been developed to allow comparisons with the questionnaires outcome domains.

## EMPLOYMENT AND SCHOOL REENTRY

### How It Meets Clinical Care Quality Outcomes

A single outcome variable indicative of successful reintegration, functional abilities, and social rehabilitation after injury is RTW<sup>58,90</sup> and school.<sup>59-61</sup> In the adult population, despite both physical and psychosocial barriers to RTW, many burn survivors do RTW within several months of injury,<sup>91</sup> yet as many as 28% never return to any form of employment.<sup>58</sup> In the pediatric population, return to school is relatively short.<sup>59-61</sup> Consequently, documentation of this variable is an important tool to assist with monitoring the efficacy of burn care.

### Proposed Metrics for the TRACS Database

1. Date that the patient returned to work or school (days to RTW /school can then be calculated from date of injury)
2. How many hours per week does the patient go to work for pay or to school? \_\_\_\_\_
- 3) Compared with before the burn injury is the patient currently with:
  - i. same job, same employer
  - ii. different job, same employer
  - iii. same job, different employer
  - iv. different job, different employer, or
  - v. was not working before burn injury?

## GAPS IN KNOWLEDGE AND OPPORTUNITIES FOR RESEARCH

One of the most important measurement challenges in understanding functional outcomes after burn injury is targeting appropriate constructs of interest

without creating excessive respondent burden or a data set that becomes unwieldy and nonfeasible over the long term or across multiple centers. There are also inherent challenges to measuring functional outcomes across the life span, of diverse populations, with hugely variant premorbid health and individual functional outcome expectations, which are based on their preinjury work, leisure, domestic activities, and demands. Further research is required to better understand the relationship between HRQoL and burn-related impairments and activity limitations and to develop measures for outcomes of particular interest in burn rehabilitation.

Establishing outcome measures that can be compared across centers will help with research on comparative outcomes, and over time some standards could perhaps be used as a quality-assessment tool to facilitate additional reimbursement or as a component of the burn-verification process. The challenge of this approach is that the biggest predictor of these types of outcomes after a burn injury are premorbid psychosocial factors, which may make comparison very difficult, thus, efforts will need to be made to control for these factors where possible. These recommendations by the Functional Outcomes work group are considered a starting point in what should be an ongoing development process to gradually refine and enhance the data collection associated with this metric.

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# Burn Wound Healing Outcomes

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Development of metrics for burn care, including healing of skin wounds during the acute phase of treatment, is essential in an environment of decreasing resources and increasing interest in quality and accuracy of medical information. Advantages of consensus metrics include: tracking of trends in care; consistency of care; and correlation of treatment with medical outcomes. For cutaneous burn wounds, these advantages are confounded by factors that contribute to the heterogeneity of burn wounds, including but not limited to: TBSA of injury, depth of injury (partial or full thickness), cause, patient-dependent factors such as age, sex, and comorbidities, anatomic site, and time between injury and treatment. Similar factors contribute to complex injuries from trauma, and allow for risk adjustment of individuals in the population, who otherwise may be outliers to the statistical mean of the entire population.<sup>1-3</sup> Despite these confounding factors, certain common definitive events are necessary to accomplish healing of a burn wound, including: accurate diagnosis of burn

depth, debridement or excision of devitalized tissue, dressing or grafting of the prepared wound bed, and assessment to determine wound closure. In the absence of confounding factors or comorbidities, wound closure is one of the key criteria for discharge from acute care whether in hospital, or ambulatory care. Not surprisingly, these metrics for wound healing have been used repeatedly in the assessment of developing therapies for wound care. In response, review by the FDA of novel therapies has led to Guidance for Industry: chronic cutaneous ulcer and burn wounds—developing products for treatment.<sup>1</sup> With reference to cutaneous burns, this Guidance considers hemodynamic resuscitation, management of comorbidities, timely burn debridement and excision, wound closure, management of wound infection, pain control, nutritional support, measures to inhibit excessive scar formation, and rehabilitation, including passive range of motion when burns overlie joints. Other burn societies, most recently the Australia–New Zealand Burn Association, have also recognized the need for metrics of quality in burn care,<sup>4,7</sup> the need to accumulate data from the practicing community, definition of clinical criteria for data collection, risk adjustment to compensate for variability in clinical populations, and data validation for use. In this context, the participants in the Wound Healing Breakout Session of the Burn Quality Consensus Conference discussed metrics for evaluation of quality in healing of burn wounds. Particular focus was given to diagnosis of burn depth, debridement or excision of devitalized tissue, wound infection, and wound closure. Each of these aspects of burn wound healing will be reviewed as a potential metric for prospective capture and trending in the American Burn Association TRACS/National Burn Registry to allow tracking of quality of burn care. Whereas burn wound healing involves a prolonged process that starts immediately after injury and may continue for many months or years, this consensus statement will focus on the early phase of burn wound healing

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during the first few weeks up to a month. Because of the obvious importance of wound closure in the healing process, wound closure should be considered definitive to any burn care program. Burn wound infection is also of utmost importance because it can lead to burn injury progression or conversion of a superficial burn to a deeper wound. Microbial contamination in burn wounds may also result in systemic infection or sepsis, leading to increased morbidity and mortality. Another important element that measures the quality of care related to the early phase of burn wound healing is the success of autografting after excision of deep burns. Thus, the need for additional grafting or regrafting after a failed first attempt should be measured. The following summary outlines the metrics developed by the Wound Healing Breakout Session Group:

1. Time to burn eschar removal,
2. microbial bioburden or presence of infection in burn wounds,
3. time to wound closure, and
4. failure of, and need for additional autografting of prepared wounds.

## DEBRIDEMENT OR EXCISION OF THE BURN ESCHAR

### How It Meets Clinical Care Quality Outcomes

Among the most direct and effective interventions for reduction of risks from cutaneous burns is removal of the burn eschar.<sup>8-11</sup> Devitalized skin is a rich medium for microbial growth, and also is known to promote inflammation by release of cytokines and growth factors from injured or lysed skin cells.<sup>12-14</sup> Consequently, practices for care of burn wounds have favored early and complete removal of the burn eschar, but variability in the burn community is recognized, and data are not available.

### Proposed Metric for the TRACS Database

Because of the impact of timely removal of the burn eschar on wound closure and scarring, the proposed outcome measure regarding excision of the burn eschar is: Time (in days) from occurrence of the burn injury to complete (>95%) removal of the burn eschar.

## BURN WOUND INFECTION

### How It Meets Clinical Care Quality Outcomes

The ability of the burn wound to heal is inextricably linked to the presence or absence of infection in the wound bed. All burn wounds have microorganism

colonization, which may include bacteria, fungi, or viruses. However, the presence of these microorganisms does not indicate a wound infection. Wounds require constant surveillance to determine whether there are any changes that indicate the evolving development of infection.<sup>15,16</sup> In the preexcisional era of burn care, wound infection was diagnosed as *invasive* when bacteria or fungi caused early separation of the eschar layer and subsequent systemic sepsis. This type of wound infection is not often seen in the excisional era of burn wound care as most burn surgeons excise the deep burn followed by skin grafting before bacterial invasion occurs.

## Definitions and Measurement of Wound Infection

Definitions of wound infection have received extensive consideration as standards in care have advanced. Definitions for surveillance of burn wound infections were proposed in an American Burn Association Consensus Panel Publication on infections and sepsis after burn injuries<sup>15</sup>; the authors emphasized the importance of microbial surveillance. The recommendations of that conference included definitions of wound colonization, wound infection, invasive infection, cellulitis, and necrotizing infection including fasciitis. General definitions for burn wounds were also described in a report of the Centers for Disease Control and National Healthcare Safety Network.<sup>16</sup> Each of these reports provided definitions that have been harmonized in this article to characterize and differentiate invasive and noninvasive infections of burn wounds.

Presence of *invasive* burn wound infection may be defined as:

Infection occurring in a deep partial-thickness or full-thickness burn wound, associated with a change in burn wound appearance or character, such as rapid eschar separation or dark brown, black, or violaceous discoloration of the eschar; requires surgical excision of the burn and treatment with systemic antimicrobials; and may be associated with any of the following:

- a. Inflammation (such as edema, erythema, warmth, or tenderness) of surrounding uninjured skin;
- b. Histopathologic examination of the burn biopsy specimen showing an invasion of the infectious organism in adjacent viable tissue;
- c. Isolation of the organism from a blood culture in the absence of other identifiable infection;
- d. Systemic signs of infection such as hyperthermia, hypothermia, leukocytosis, tachypnea, hypotension, oliguria, hyperglycemia

at a previously tolerated level of dietary carbohydrate, or mental confusion.

What is more commonly seen is a *local or noninvasive* wound infection in a healing partial-thickness or grafted full-thickness injury, which can cause delayed healing or failure of the skin graft. Presence of noninvasive (local) burn wound infection may be defined as:

Burn wounds that have a purulent exudate that is culture positive (if performed), requires a change in treatment (which may include a change or addition to antimicrobial therapy, the removal of wound covering, or an increase in the frequency of dressing changes); and at least one of the following:

- a. Loss of synthetic or biologic covering of the wound;
- b. Changes in wound appearance, such as hyperemia;
- c. Erythema in the uninjured skin surrounding the wound;
- d. Systemic signs, such as hyperthermia or leukocytosis.

Microorganisms responsible for these infections include bacteria, fungi, or viruses. Bacteria include gram-positive organisms such as *Staphylococcus aureus*,  $\beta$ -hemolytic *Streptococcus group A*, or *Enterococcus* species (including vancomycin-resistant enterococci). Gram-negative organisms include non-enteric organisms such as *Pseudomonas aeruginosa* and *Acinetobacter baumannii* or enteric organisms such as *Klebsiella* species, *Escherichia coli*, or *Enterobacter* species. Yeasts include the *Candida* species and are generally part of the body's normal flora. Environmental fungi, of which the most common are the *Aspergillus* species, can cause life-threatening, invasive infection and extensive tissue loss. Viral infection, most commonly *Herpes simplex* virus, is less frequent.

Of increasing importance are the antimicrobial resistance patterns identified in many of the bacterial organisms, which may affect the effectiveness of prevention and treatment efforts. Specific organisms of concern include methicillin-resistant *S. aureus*, vancomycin-resistant *Enterococcus*, and multiple-drug-resistant *A. baumannii* and *P. aeruginosa*. In recent years, the frequency of identifying these organisms has increased and several strains of *Acinetobacter* and *Pseudomonas* have been found to be resistant to all tested antimicrobials except colistin.

### Proposed Metric for the TRACS Database

Because of the impact of burn wound infection on wound closure and scarring, the proposed outcome measure are:

1. Occurrence of invasive burn wound infection.
2. Occurrence of noninvasive burn wound infection.

## WOUND CLOSURE

### How It Meets Clinical Care Quality Outcomes

Wound healing is a complex yet highly regulated process that comprises several overlapping phases including inflammation, new tissue formation, and remodeling.<sup>17</sup> One of the earliest and most important phases of wound healing is wound closure, which is generally defined as complete wound reepithelialization or reestablishment of the outermost epidermal layer, the stratum corneum. Wound closure reestablishes a microbial barrier, reducing the risk of infection and limiting evaporative fluid losses. Early wound closure may also affect the ultimate healing of burns, their function, and appearance. Multiple studies have shown that burns that reepithelialize earlier are less likely to scar, possibly because of a reduction in inflammation and granulation tissue formation.<sup>18</sup> A wide body of evidence has demonstrated that superficial burns that heal or close within 2 to 3 weeks usually resolve without hypertrophic scarring or functional impairment.<sup>19</sup> In contrast, deep burns that fail to heal within 3 weeks frequently lead to hypertrophic scarring and functional impairment.<sup>20</sup>

### Definition and Measurement of Wound Closure

Despite the importance of wound closure, there is no standard, validated method used to measure wound closure. Anatomically, wound closure is defined by reestablishment of a neoepidermis that completely covers the wound. From a physiologic standpoint, wound closure is characterized by reestablishment of the barrier function as defined by a reduction in water vapor transmission, and/or a decrease in the surface hydration of the skin.<sup>21,22</sup> Although the anatomy and physiology of the skin are interrelated, anatomic restoration of the epidermis generally precedes physiologic restoration of the barrier by days to weeks.<sup>23</sup>

The prevailing standard for complete wound reepithelialization is histologic analysis of tissue specimens.<sup>24,25</sup> A major limitation of this method is that it is invasive, exposing the patient to pain and the risk of infection and scarring from the biopsy itself. Histologic analysis may also be subject to sampling bias, because it only represents the wound site biopsied, and it may not be representative of the entire wound. Additionally, sample preparation can sometimes inadvertently remove the fragile neoepidermis.

Thus wound closure is generally determined by non-invasive assessments of the skin surface, which examine the entire wound area.<sup>26</sup>

There is no standard clinical definition of wound reepithelialization, and it is often presumed that experienced clinicians have good interobserver agreement. The Wound Healing Consensus Work Group suggests that a wound is closed when it no longer readily transmits water, no longer needs dressings or bandages, is dry to the touch, and more pink or opalescent than red or transparent. One simple way to determine whether the wound surface is dry is to blot it with a tissue paper and see if the paper absorbs moisture. A recent study in a porcine burn model found high interobserver agreement of clinicians in determining clinical wound reepithelialization based on photos, but there was poor agreement between the clinical assessment and the histologic assessment questioning the validity of clinical assessment in the porcine model.<sup>27</sup> No similar study in humans was found, and it is unclear whether results in swine correlate with those in humans.

Several noninvasive methods have been used to assess the anatomical and functional integrity of the wound. Anatomical integrity can be assessed using either high-frequency ultrasound or optical coherence tomography.<sup>28-30</sup> However, both these methods are still experimental and have not been validated on a large scale. Furthermore, they are unlikely to be widely available to clinicians, limiting their broad applicability. Barrier properties of the skin can be measured noninvasively by one of two methods: electrical resistance and water vapor transmission. These properties are assessed in dermatologic practice with instruments that are validated and calibrated for human skin.<sup>31</sup> These instruments may be considered for measurements of healing in burn wounds, but impose a cost and requirements for training.

### Proposed Metric for the TRACS Database

Wound closure can be summarized more simply by one of two methods. With daily wound assessment, the approximate time to complete closure can be determined. If wounds cannot be assessed frequently, the percentage of the burns that are reepithelialized or closed at specific time points (3 or 4 weeks) may be determined. In order to limit the number of burn metrics, the panel proposed using the *time to complete wound closure in days* as the ideal quality metric for wound closure. Because some patients will be discharged before complete wound closure, we propose measuring the size (TBSA) of open wounds at hospital discharge as an alternative metric of wound

closure. Although no recommendations for benchmarking are proposed here, data collection might allow eventual optimal quality standards. The proposed outcome measures for wound closure are:

1. Time (in days) to complete (>95%) wound closure
2. Size (TBSA) of open wounds at the time of hospital discharge.

## AUTOGRAFTING OF DEEP BURNS

### How It Meets Clinical Care Quality Outcomes

With regard to large deep burns (ie, >20% TBSA), the Consensus Work Group recognized that comorbidities and limited availability of donor skin might complicate and protract wound closure. Therefore, metrics for large superficial and small deep burns may not be reliable for larger deep burns. Rather, as a metric for whether or not the treatment of large, excised burns is effective, the panel believed that failure of autograft procedures that require regrafting provides a valid measure of quality. This metric would be applied to grafting of burn wounds, regardless of whether the graft was with donor skin, engineered skin, or cell therapies. The metric would not be applied to healing of donor sites for skin autograft because they are surgical wounds, not burns. The committee also recognizes that the ability of a graft to take is dependent on multiple patient, environmental, and practitioner factors that need to be taken into account when considering why a particular graft failed to take.

### Proposed Metric for the TRACS Database

Because of the fact that failure of autografting delays healing and negatively affects patient outcome the proposed outcome measure regarding closure of deep excised burn wounds is: occurrence of regrafting of any autografted site.

## GAPS IN KNOWLEDGE AND OPPORTUNITIES FOR RESEARCH

After specification of the metrics for wound healing, gaps in knowledge that provide opportunities for prospective research were addressed. The Consensus Work Group identified four topics:

- A. To develop and test metrics for burn wound healing.
- B. To include wound treatment of outpatients as part of the data collection, because data in the National Burn Repository includes only inpatients.



- C. To evaluate whether best practices and outcome metrics correlate with less scar, or less grafting.
- D. To determine whether or not risk adjustments for mortality<sup>3</sup> are applicable to wound closure.

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