Prevention and Treatment of Pressure Ulcers in 2014

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PRESSURE ULCER STATISTICS- BASIC FACTS

- Pressure Ulcer- associated with increased morbidity, length of stay, sepsis and mortality.
- Estimated 660 patients die each year with hospital acquired pressure ulcers.
- Estimated cost of a single full-thickness pressure ulcer - $70,000.00 USD.
- Estimated US pressure ulcer treatment cost is $11 billion USD per year.

<table>
<thead>
<tr>
<th>Care Setting</th>
<th>Prevalence</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Care</td>
<td>10% - 16%</td>
<td></td>
</tr>
<tr>
<td>Long Term Care</td>
<td>2.3% - 26%</td>
<td></td>
</tr>
<tr>
<td>Home Care</td>
<td>0% - 23%</td>
<td>0% - 17%</td>
</tr>
<tr>
<td>Hospice</td>
<td>0% - 28%</td>
<td></td>
</tr>
<tr>
<td>Nursing Homes</td>
<td>2.3% - 23.9%</td>
<td></td>
</tr>
<tr>
<td>Rehabilitative Care</td>
<td>0% - 6%</td>
<td></td>
</tr>
</tbody>
</table>

PRESSURE ULCER STATISTICS MANDATED CHANGE
CMS Motivation:
Pressure ulcers are both a high cost and high volume adverse event.
- CMS payments in 2006:
  - 352,946 Medicare pts with PU as 2nd diagnosis
  - Charged $40,381 USD per case (average)
  - Annual cost of $13 billion
- 2003 JAMA article foresight:
  - $10,845 per healthcare-acquired PU
  - Total $3.5 billion annually

CMS Rationale:
- Incentivize healthcare providers to perform careful skin examinations on admission
- Improve identification of “decubitus ulcers”
- If the condition is present on admission, the provision will not apply

CMS 2008 Final Rule
The “Final Rule” for changes to the Medicare program’s hospital inpatient prospective payment system (IPPS), effective Oct. 1, 2008 mandates: Hospitals will not receive payments for healthcare-acquired pressure ulcers (PU).

PRESSURE ULCER CARE QUICK FACTS

- Inpatient Acute Care Major Source: Pressure ulcers are often blamed on poor nursing care in long-term care facilities, but the incidence is actually higher in acute care hospitals.
- Nutrition is Key: The most important reversible host factor contributing to wound healing is nutritional status. Several studies suggest that dietary protein, in particular, is important in healing pressure ulcers.
- Surgical Closure: results in more rapid resolution of the wound. The chief problems are frequent recurrence and inability of frail patients to tolerate the procedure.
- Dehydration is a Route Cause: Any therapy that dehydrates the wound, such as dry gauze, heat lamps, air exposure, or liquid antacids, is detrimental to chronic wound healing.

Complications:
Most common complications are increased mortality, osteomyelitis, and sepsis. 20% Mortality Rate Hospitalized.

INSTITUTE FOR CLINICAL SYSTEM IMPROVEMENT (ICSI)
2010 GUIDELINES (UPDATED 2012, REVIEWED W/O REVISION MAR 2014)

- Continuity of Care across care settings: inpatient and outpatient with focus on patient-centered home
- All Encompassing Involvement: patient, family members, caregivers, medical team
- Multi-disciplinary Team: physicians, nurses, surgeons, case managers, social workers, home health, nutrition, financial specialists, rehab specialists, physical and occupational specialist

https://www.icsi.org/_asset/6t7kxy/PressureUlcer.pdf
SET A GOAL: ELIMINATE PRESSURE ULCER DEVELOPMENT
Eliminate The Development Of Pressure Ulcer Development and Progression In Your Medical System Of Care

- Develop, Implement, Execute Plans of Care to Prevent, Identify and Treat Pressure Ulcers
- Identify At-Risk Patients
- Identify Pressure Ulcers On Admission to the Care Setting
- Track all Identified Pressure Ulcers- Develop, Progress, Resolve, Recurrence
- Institute Treatment Algorithms and Implement Quality Tracking Process
- Educate Medical Staff, Patients, Family, Caregivers, (Administrators, Community, Legislators)
- Coordinate, Communicate, Reports- Transfer/Discharge

OUTPATIENT PRESSURE ULCER ASSESSMENT OF AT-RISK PATIENTS

Pressure Ulcer Prevention Plan Documentation and Education of Patient and Caregivers

- Minimize/eliminate friction and shear
- Support surfaces
- Minimize pressure
- Manage moisture
- Maintain adequate nutrition/hydration
- Educate patient/caregivers

OUTPATIENT PRESSURE ULCER ASSESSMENT OF AT-RISK PATIENTS

Risk Assessment and Documentation (Outpatient and Inpatient)

- Assess All Patients for Risk of Pressure Ulcer Development
- Use a Validated Assessment Tool
- Perform Routine Scheduled and Event Specific Reevaluations

At time of Admission and Transfers:
- Outpatient/Inpatient
- 24 hr Stay
- Same day Surgery
- Emergency Room
- Cath Lab

Test Specific to Care Setting:
- Outpatient (yes/no)
- Inpatient- Braden Q

Reevaluation:
- Daily (q8-24hrs)
- Change in Care Level
- Change in Condition
- Devices- around and under as needed
EPIDEMIOLOGY OF PRESSURE ULCERS PATIENT RISK FACTORS

Margolis (Aging): studied 75,168 older individuals
- Pressure ulcers occurred in 1,211 individuals
- Conditions significantly associated with PU development:
  - Alzheimer’s disease
  - Congestive heart failure (CHF)
  - Chronic obstructive pulmonary disease (COPD)
  - Cerebral vascular accident (CVA)
  - Diabetes mellitus (DM)
  - Deep venous thrombosis (DVT)
  - Hip fracture
  - Hip surgery
  - Limb paralysis
  - Lower limb edema
  - Malignancy
  - Malnutrition
  - Osteoporosis
  - Parkinson’s disease
  - Rheumatoid arthritis
  - Urinary tract infections

MODELS OF PRESSURE ULCER DEVELOPMENT IN SPINAL CORD PATIENTS- REVEALS BOTH INTRINSIC AND EXTRINSIC FACTORS PLAY A ROLE

AT-RISK ASSESSMENT FOR OUT-PATIENTS YES/NO QUESTIONNAIRE
OUTPATIENT RISK ASSESSMENT TOOL
EXAMPLE QUESTIONNAIRE - (YES/NO) FORMAT

Outpatient Risk Assessment
Prevents skin movement and initiate a pressure ulcer prevention plan if any of the following questions are "yes"?

- Is the patient bed- or wheelchair bound or does he/she require assistance to transfer? ☐ ☐
- Will the patient be immobile or sedentary for more than two hours? ☐ ☐
- Is the patient immobilization of arms and/or legs? ☐ ☐
- Does the patient have existing pressure ulcers, history of pressure ulcers or breakdown? ☐ ☐
- Does the patient appear frail or malnourished? ☐ ☐
- Additional question for young children
- Is the child demonstrating inadequate tissue perfusion with evidence of skin breakdown? ☐ ☐

AT-RISK ASSESSMENT FOR INPATIENTS
BRADEN Q SCALE

BRADEN Q SCALE: RISK ASSESSMENT
### BRADEN Q SCALE RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Component</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>0-16</td>
</tr>
<tr>
<td>Sensation</td>
<td>1-2</td>
</tr>
<tr>
<td>Activity</td>
<td>0-8</td>
</tr>
<tr>
<td>Continence</td>
<td>0-6</td>
</tr>
<tr>
<td>Feelings</td>
<td>0-2</td>
</tr>
<tr>
<td>Depression</td>
<td>0-2</td>
</tr>
</tbody>
</table>

**Tolerance of The Skin and Impairing Reaction**
- crumbs: 0-2
- slight blanching: 3-4
- blanching: 5-6
- severe blanching: 7-8
- swelling: 9-10
- gangrene: 11-12
- tissue necrosis: 13-16

### COMPONENTS OF "COMPLETE" DOCUMENTATION

**PRESSURE ULCER RISK FACTOR CHART**

- Specific Risk Care Plan
- Appropriate Support Surface
- Appropriate Lower Extremity Device

**Individualized Care Plan Components**
- Specific Risk Care Plan
- Appropriate Support Surface
- Appropriate Lower Extremity Device

**MONITORING HEALING IN PRESSURE ULCER CARE**

**PRESSURE ULCER SCALE FOR HEALING (PUSH-TOOL)**

<table>
<thead>
<tr>
<th>Length (cm)</th>
<th>Width (cm)</th>
<th>Area (sq cm)</th>
<th>Exudate</th>
<th>Tissue Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>0.3-0.6</td>
<td>0.3-0.36</td>
<td>None</td>
<td>0</td>
</tr>
<tr>
<td>6-9</td>
<td>0.7-1.0</td>
<td>0.6-0.9</td>
<td>Light</td>
<td>1</td>
</tr>
<tr>
<td>9-12</td>
<td>1.1-3.0</td>
<td>0.9-2.7</td>
<td>Moderate</td>
<td>2</td>
</tr>
<tr>
<td>12-24</td>
<td>3.1-4.0</td>
<td>2.7-12.7</td>
<td>Heavy</td>
<td>3</td>
</tr>
<tr>
<td>&gt;24</td>
<td>&gt;4.0</td>
<td>&gt;12.7</td>
<td>Necrotic</td>
<td>4</td>
</tr>
</tbody>
</table>

*The PUSH-tool (research-validated tool captures the key assessments used to track pressure ulcer progression)*
RISK ASSESSMENT TOOLS IN PRESSURE ULCE R CARE
SPINAL CORD INJURY PRESSURE ULCER SCALE- ACUTE (SCIPUS-A)

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Coded Value</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Extent of Paralysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Level of Activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Mobility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Urine Incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Mobility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Pulmonary Disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Serum Creatinine &gt; 1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Albumin &lt; 3.4 or decreased from admit &gt; 0.2 g/dl</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Score (0-25)


SCIPUS-A Risk Levels:
- Low               0-12
- Moderate      13-18
- High              19-20
- Very High     21-25

SCIPUS-A Additional Parameters
- Paralysis extent
- Pulmonary disease
- Serum creatinine
- Albumin levels

PRESSURE ULCER DIAGNOSIS AND EVALUATION

PRESSURE ULCER IDENTIFICATION, EVALUATION AND DOCUMENTATION

Wound Assessment- Identify, Evaluate and Document

Comprehensive Skin Evaluation:
- Head-to-toe
- Front-to-back
- Visualize and Palpate

Skin Condition:
- Moisture
- Texture
- Turgor
- Temperature
- Color
- Consistency

Alterations:
- Pressure Ulcer
- Diabetic Foot
- Arterial Insufficiency
- Rheumatologic
- Dermatologic

Comprehensive Evaluation:
- History/PU Risk Factors
- Wound Description
- Define PU staging
- Evaluate nutrition status
- Assess infection
- Psychosocial needs

Comprehensive Patient Assessment including Wound Evaluation and Documentation

Document Skin Alterations

Skin Condition and Inspection

Comprehensive Skin Evaluation

Wound Assessment- Identify, Evaluate and Document
## WOUND ASSESSMENT TOOL/PROTOCOL

### ASSESSMENT FACTOR CONSIDERATION

| A | Anatomic Location | Describe location using precise anatomical terms, as much as possible. Consider using a body diagram to clearly communicate location of the pressure ulcer. |
| S | Size, Shape | Disposable measuring guide—measure length, width, depth in cm, at the longest or widest portion of the pressure ulcer, clockwise from the direction of the circle. |
| S | Stage | NPUAP Staging System. No back stage, Eschar Covered is Unstageable. |
| E | Exudate | Amount: none, light/scant, mod, lrg; Character: serous, serosanguineous, bloody, purulent |
| S | Surrounding Skin | Periwound-Assess and describe color, texture, temperature, presence of induration, maceration, or integrity of |
| S | Sinus Tract, Tunneling | Measure length/depth using gloved finger or carefully placed cotton-tipped applicator. Describe location utilizing the face of a clock, as above |

### ASSESSMENT FACTOR CONSIDERATION

| M | Margins | Note presence of undermining (tissue destruction around the perimeter of the wound under the intact surface/skin) |
| E | Edges | Describe wound edges using terms such as indistinct, distinct attached, not attached, defined, undefined or rolled under |
| N | Nose (Odor) | Some dressings or topical solutions can affect the odor |
| T | Tissue | Note characteristics and percentage of tissue in wound base—epithelium, granulation, slough, or necrotic tissue. Necrotic tissue can be further described as white/grey, yellow, soft, black/brown, or hard black eschar. |
PRESSURE ULCER TREATMENT OPTIONS

Wound Treatment Overview

- Identify Treatment Goals
- Implement and Document Interventions
- Interdisciplinary and Interfacility Communication and Documentation

Goal Directs Plan:
- Healing
- Symptom control
- Pain/Pruritus
- Palliative

Advanced Notification:
- Wound Description
- Stage/Category
- Treatment Goals
- Prior Therapies
- Follow-up Care Plan

Standard Care:
- Clean/Debride/Dress
- Prevent/Protect
- Off-load
- Drains
- Nutritional stability
- Moisture control

Advanced Care:
- Bioburden Reduction
- Min Medical Honey
- Medical Honey
- Tissue/Biologics
- NPWT
- Surgery

NUTRITION
ADVANCED THERAPIES - REDUCE BIOBURDEN

- Mechanical Debridement
- Surgical Debridement
- Mist Therapy
- Medicinal Honey
- Chemical Debrider

CATEGORIES OF SKIN SUBSTITUTES

- Xenograft Collagen (Animal)
  - Porcine (pig)
  - Bovine (cow)
  - Equine (horse)
  - Ovine (sheep)
  - Piscine (fish)

- Allograft Tissue (Human)
  - Cadaveric Skin
  - Cultured Adult Cells
  - Cultured Fetal Cells
  - Placental Tissues

- Engineered Tissue (Other/Biologic)
  - Bioengineered human/xenograft
  - Bio-Synthetic (human/synthetic)
  - Synthetic

- Xenograft Cells (Animal)
  - Fetal Bovine (cow)

ENERGY THERAPIES TO SUPPORT TISSUE GROWTH

- Negative Pressure Wound Therapy
- Electrical Stimulation
- Mist Therapy
PAIN MANAGEMENT

- Pharmaceuticals
- Non-pharmaceutical Therapies
  - Electrical stimulation
  - Pulsed Electromagnetic Stimulation
  - Ultrasound
  - Psychosocial Interventions

ALLOGRAFT TISSUES USE IN WOUND CARE ARE HIGHLY VARIABLE

- Species source
- Tissue source
- Sterility level
- Additives
- Delivery formats
- Preparation requirements
- Procurement
- Production/Manufacturing
- Regulatory status

Product Categories/Regulatory Comparisons
PMA vs. HCT/P vs. 510(k)

<table>
<thead>
<tr>
<th>Premarket Approval (PMA)</th>
<th>HCT/P: Registration and Listing</th>
<th>510(k) Premarket Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA scientific and regulatory review to evaluate safety and effectiveness prior to marketing</td>
<td>Don't require Premarket Approval</td>
<td>Clearance by FDA based on substantial equivalence to a legally marketed predicate device</td>
</tr>
<tr>
<td>Donor screening</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Approved
21 C.F.R. Part 814

Registered
21 C.F.R. § 1271

Cleared
21 C.F.R. § 807.87
DOCUMENTATION IS THE BEST PREVENTION!

The palest ink is better than the best memory.
--Chinese Proverb

Documentation reflects the quality of medical care rendered and will be more closely tied to facility reimbursement.

SUMMARY: PRESSURE ULCER PREVENTION AND TREATMENT PROTOCOLS, PLANS AND PROGRAMS

Pressure Ulcer Quality Process

- Design
- Implement
- Monitor
- Execute
- Report

8 Required Pressure Ulcer Protocols, and Programs

- Pressure Ulcer Prevention Plan
- At-risk Identification Protocol
- Skin And Wound Assessment Protocol
- Comprehensive Patient Assessment and Wound Identification Protocol
- Pressure Ulcer Wound Identification, Re-Assessment & Progression Evaluation Protocol
- PU Treatment Plan and Algorithm Protocol
- Pressure Ulcer Education and Training Program
- PU Coordination and Communication Plan

QUESTIONS

Q&A