

NEED SPECIFICATION STATEMENT

Reducing Decubitus Ulcer Incidence



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NEED STATEMENT

There is a need to reduce decubitus ulcers at pressure points in long term patients over the age of 65 from 66% incidence to 25%.

PROBLEM

Patients in acute care units, over the age of 65, have a 66% incidence rate of contracting decubitus ulcers (DU) ^[1]. DUs are difficult to cope with by limiting mobility and causing severe pain without contact. Further risks include infections and mortality ^[2, 3].

Decubitus ulcers occur where skin and muscle tissues break down due to lack of oxygenation through proper blood circulation. Skin friction and shear, skin maceration, and prolonged body pressure promote this decomposition. Friction and shear promotes tissue fatigue which wears away already thin or aged skin. Maceration is where the skin is constantly wet and leads to break down. Atrial and venous vessel pressures are 32 mmHg and 8-12 mmHg, respectively ^[4]. External pressures which exceed these will cut off circulation. DUs caused by prolonged pressure contact are called pressure ulcers (PU).

Locations include pressure points and bony areas such as toes, ankles, knees, sacrum, spine, and shoulders ^[5]. These points are illustrated in Figure 1.

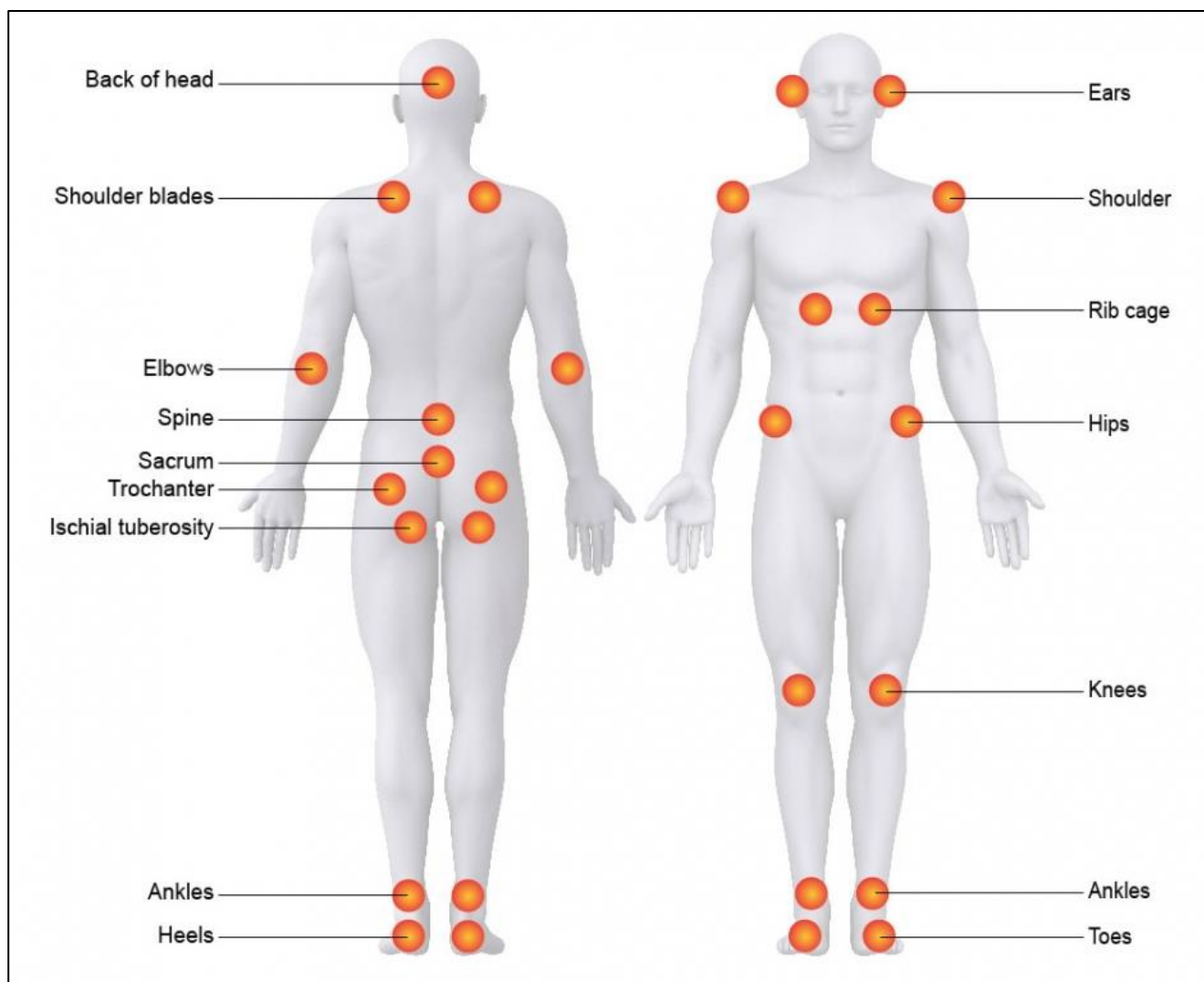


Figure 1 – Pressure points on the body susceptible to decubitus ulcers ^[5].

The following table lists the 6 visual diagnoses of pressure ulcers.

Table 1 – Stages 1 through 4 increase in severity. The 5th and 6th row are stages difficult to diagnose due to slough and eschar ^[4].

Stage 1 Pressure Injury	Skin with reduced blood flow, will appear as a red or pink bruise. Patient sensation reduced. May feel firmer, warmer, or colder than surrounding skin to touch.
Stage 2 Pressure Injury	Skin deteriorated showing some flesh. Surrounding area will still be pink to red. Surrounding area and wound will be moist.
Stage 3 Pressure Injury	Wound deep enough to see fatty tissue. Depth varies by location on body. Slough and eschars does not affecting visibility.
Stage 4 Pressure Injury	Skin is lost. Bone and tendons are visible. Slough and eschar may be visible. If these obscure vision, then not a stage 4.
Unstageable Pressure Injury	Stage 3 or 4 wound with slough or eschar obscuring view of depth and affected physiology.
Deep Tissue Pressure Injury	Maroon to purple skin covers the wound. May have temperature change based on bacterial infection. Stage 3 or 4 below skin.

Complications

DU complications include cellulitis, septic arthritis, and per urethral fistula ^[4]. Mortality rates have been recorded as 67% where pressure ulcers are the underlying cause ^[6].

Cellulitis is a bacterial dermis and muscle infection mostly identified in pressure ulcers by an increase in temperature surrounding the wound. It causes expansion in affected area and severity as it may infect healthy surrounding tissue and the circulatory system ^[7].

Septic arthritis is a bacterial infection of a joint. 30% of these cases become chronic, and 40% of these cases leave permanent joint damage ^[8, 9].

Per urethral fistula occurs from DUs where an abscess or series of abscesses open the urethra to the surface resulting in bladder leakage ^[10]. This increases further risk of infection and maceration.

EXISTING SOLUTIONS

Mattress Products

Current mattress solutions include alternating pressure technology or fluid, foam, or gel based lining; however, recent studies have failed to provide evidence of a dominant material based solution ^[11]. Product prices range from \$50 to \$6000 based on functionality, materials used, and life of product.

FDA regulations require identification of methods used to reduce the risk of fire and explosion among oxygen based devices within 510(k) application ^[12]. In response, control box designs have been made with fire retardant, medical PVC.

Hydraulic mattresses consider fluid pressure to reduce capillary collapse. Higher end beds use a maximum of 32 mmHg; others range 60-150 mmHg. Higher pressure mattresses are used as inserts between the patient and previous mattress. To prevent further bedsores formation, pressure points are oscillated through air pockets; refer to Figure 2.

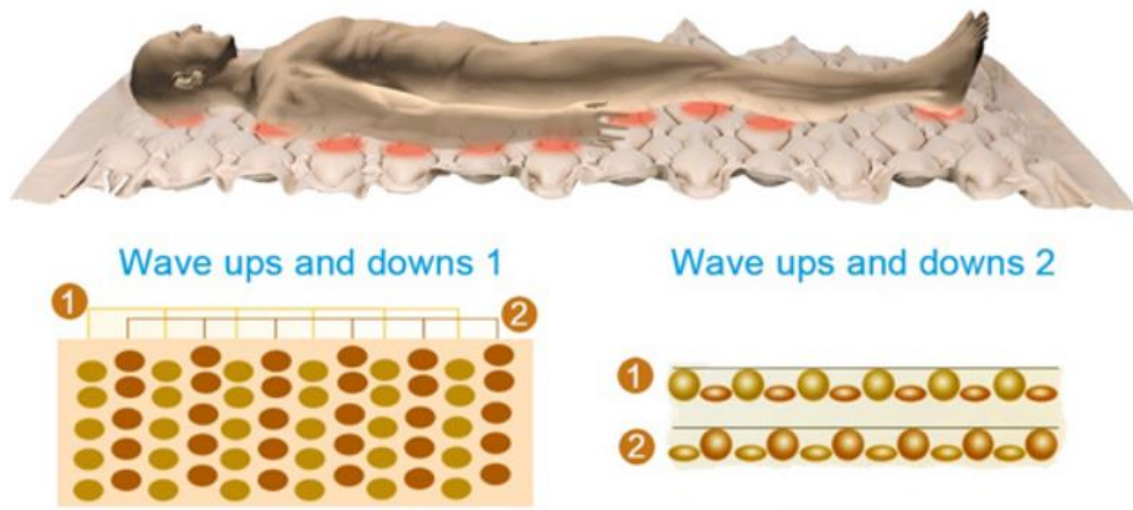


Figure 2 – air pocket oscillation bed ^[13].

Patients may be repositioned in bed to the upright position. As their weight shifts to their sacrum, patients may bottom out on low pressure beds. To prevent this, additional air is automatically into the mattress. See Figure 3 for a bed in the upright position ^[14].



Figure 3 – Higher end bed in the upright position ^[14].

Care Procedures

To prevent a DU from occurring, the patient should be turned every 2-3 hours where DUs can form within 2-6 hours of laying stagnant ^[15]. This procedure is done manually by nurses as seen in figure 4.

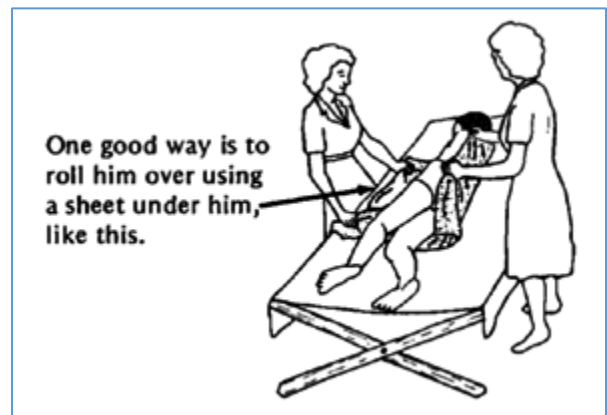


Figure 4 – Nurses rolling patient on bed ^[16].

Upon identifying an ulcer it is critical that patients do not obstruct further blood flow to the wounded area. Wounds are cared for with bandages. Ulcer stages are diagnosed visually using the guide above; however, to identify the extent of an infection, a surface swab should be used over a needle aspiration ^[17]. This may require removing eschar and slough over the wound.

Gaps in Existing Solutions

Based on the solutions above, there is an inverse relationship between product price and capillary occlusion. There is a gap to provide cost effective solutions while promoting ideal blood flow.

An optimal turning schedule to prevent ulcer formation has not been developed ^[15]. Future solutions such as a mathematical model may consider measurable variables such as patient weight, supporting surface area, and blood pressure to indicate an ideal schedule per patient.

There is a gap in existing solutions to consistently identify early signs of ulcer formation among darker skin tones where this population segment has a higher ulcer incident rate ^[18]. Again, a model may be used to identify high risk patients to prompt more thorough body exams.

Many hydraulic beds are sold with patch kits. This indicates anticipation of product failure by either fatigue or lack of durability. Solutions may consider more robust materials that do not obstruct weight distribution.

STAKEHOLDERS

Care Cycle Approach

- ***Elderly Patients***
 - Patient at risk of contracting disease; potential solutions should reduce incident rate.
 - Contraction of ulcers prolong care time at the hospital and may be detrimental to state of life outside of the hospital.
- ***Family of patient***
 - Additional injuries to patients may incite emotional distress to family members.
- ***Health Care Facility***
 - Decubitus ulcers prolong patient's stay which delays bed openings amongst over population in hospital.
 - Nurses routinely turn patients to reduce risk of decubitus ulcers. Potential solutions could simplify or complicate their role in the care cycle.
 - Physicians are tasked with resolving complications. Reducing incident rate could reduce work load.

Cash Flow Approach

- ***Elderly Patients***
 - Ulcer care accrues supplemental expenses which may become a financial burden if not covered by insurance.
- ***Health Care Facilities***
 - Over 17,000 lawsuits are filed over decubitus ulcers annually which causes hospital administration a financial burden regardless of outcome in court ^[19].
 - Additional funding spent on nurses, physicians, and technicians to care for patient.
- ***Insurance companies***
 - Patients with decubitus ulcers accrue an addition \$43,000 to their care to be covered by insurance ^[19].

Product Development Approach

- ***Patient***
 - Investigate patient perspective to implement functions into product.
- ***Health Care Facilities***
 - Investigate nurse and physician experience to implement functions into product.
- ***Family of patient***
 - Consider ease of interface for outside of hospital usage.

- ***Food and Drug Administration***
 - Make design comply with pre-established regulations.
 - Perform tests for 510(k) application. May need to argue product is a non-novel solution depending on solution route.
- ***Patent Office***
 - Will need to hire an intellectual property attorney
 - Will need to prove novel solution to receive patent.
- ***Insurance companies***
 - Product price must be within acceptable cost bounds set by insurance company to ensure use of product is covered.

MARKET ANALYSIS

Market Size

In the United States alone, decubitus ulcers add approximately \$43,000 to the cost of a hospital stay ^[19]. The aggregate cost of pressure ulcers was reported to be \$11 billion in 2006; this is approximately 4% of all aggregate medical costs ^[20]. Two-thirds of pressure ulcer cases occur in elderly over the age of 60 ^[21]. This is over 80,000 incidences in this population annually within the hospital setting.

Excluding maternal care, patients over the age of 65 are the primary age group to be discharged from the emergency department or overnight stays as an inpatient; this is shown in Figures 5 and 6, respectively. Although both show population decline, it is negligible to market opportunity.

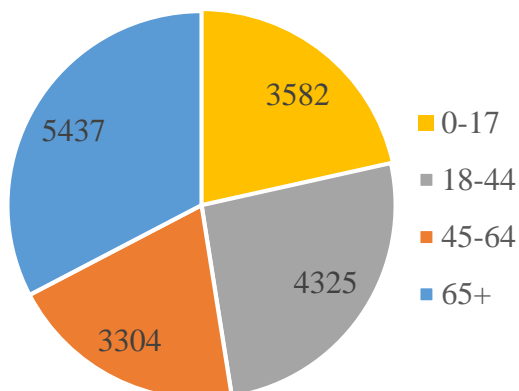
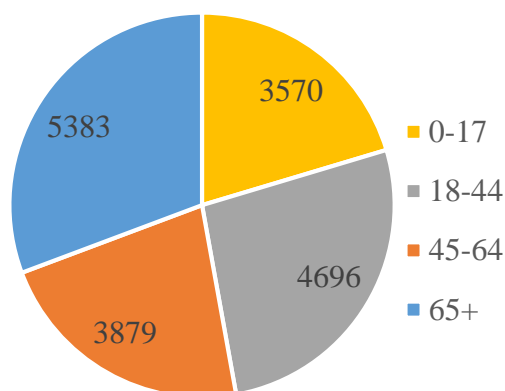
ED Visits per 10,000 Population
(2006)ED Visits per 10,000
Population (2014)

Figure 5 – Emergency department visits per 10,000 population per age segment for 2006 and 2014 [22].

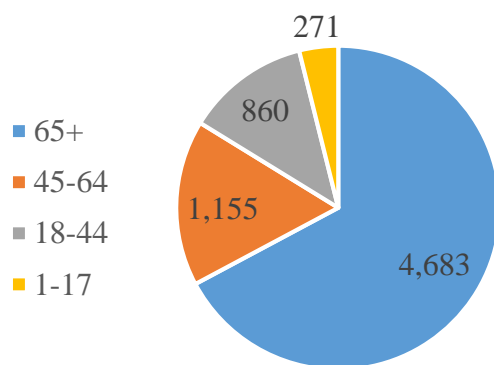
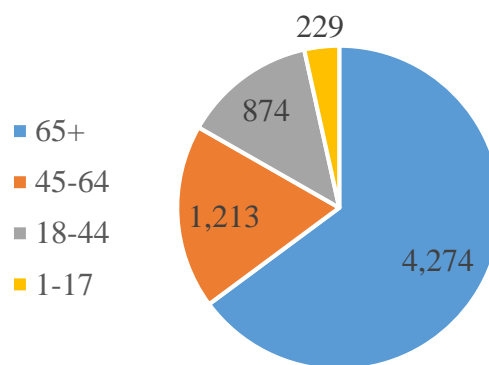
Stays per 10,000 Population
(1997)Stays per 10,000 Population
(2009)

Figure 6 – Prolonged stay discharge per 10,000 population per age segment for 1997 and 2009 [23].

Market Segments

African Americans and other patients with darker pigmented skin tones are more likely to develop a DU, where African Americans' had 1.3% higher incidence rate than white patients ^[15]. This may be attributed to difficulty in identifying early stage DUs on the skin surface. DU mortality rate has been reported higher in African Americans over whites as well ^[24].

Other population segments such as gender are negligible above the age of 65. There are no correlations between incidence rate and geographic location within the US.

SWOT Analysis

A Strength, Weakness, Opportunity, Growth (SWOT) Analysis identifies potential in implementing a project.

<p>STRENGTHS</p> <p>Value: Increasing patient comfort, decreasing likelihood of further injuries, and decreasing risk of death.</p> <p>Advantage: Problem is still prevalent regardless of past solutions, indicating demand.</p> <p>“30,000 foot view”: Preventing bed sores reduces risk of death in elderly patients.</p> <p>Testing: PMA testing no required.</p>	<p>WEAKNESS</p> <p>Financial: Difficult to show hospitals benefit of new model bed or technology.</p>
<p>OPPORTUNITIES</p> <p>4% of medical aggregate cost sourced from pressure ulcers ^[20].</p>	<p>THREATS</p> <p>Patent Office: Difficult to prove novelty.</p> <p>Large competition and market already exists.</p>

NEED CRITERIA

Absolute Criteria

- *Financial*
 - Must be financially competitive with other solutions.

- ***Functional***
 - Reduce DU incidence rate in long term, elderly patients over the age of 65.
 - Reduce friction and shear on bodies while rolling patient to new position.
- ***Geometric***
 - Must be compatible with current hospital hallway and doorframe constraints.
- ***Interface***
 - Must be practically integrated into current nursing systems.
- ***Performance***
 - Reduce external forces on pressure points to be less than venous pressures to allow constant blood flow.
 - Predict pressure DU formation 30 minutes prior.

Optional Criteria

- ***Functional***
 - Observe or control skin moisture to reduce maceration.
 - Identify abnormal temperature gradients on skin to locate cellulitis in early stage DU.
 - Must be a mobile system to reduce ulcer formation during transport.
- ***Interface***
 - Provide more competent diagnosis on darker pigmented patients.
 - Must be user friendly to be used in home care settings.
 - Must be compatible with other brand technologies.
- ***Manufacturing***
 - Produce and easily manufacture product or solution.

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