

A Physician Delphi Panel to Determine Clinical Significance Thresholds in Burn Care Products Aiming to Replace or Minimize Autograft

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Thresholds for a clinically significant reduction of harvested donor skin in adult patients established by an expert panel:

- Moderate burn wounds (DPT or FT, 10-20% TBSA): 50% reduction
- Major burn wounds (mixed DPT and FT, 20-50%TBSA): 35% reduction

Significance Statement

There is currently no consensus of what constitutes a clinically significant reduction (CSR) in the amount of harvested donor skin (HDS) with innovative therapies. The aim of this Delphi consensus panel was to provide a research-based definition of CSR thresholds for the percentage reduction in HDS, thereby improving outcomes in severely burned patients.

Population

15 expert panelists meeting the following inclusion criteria took part:

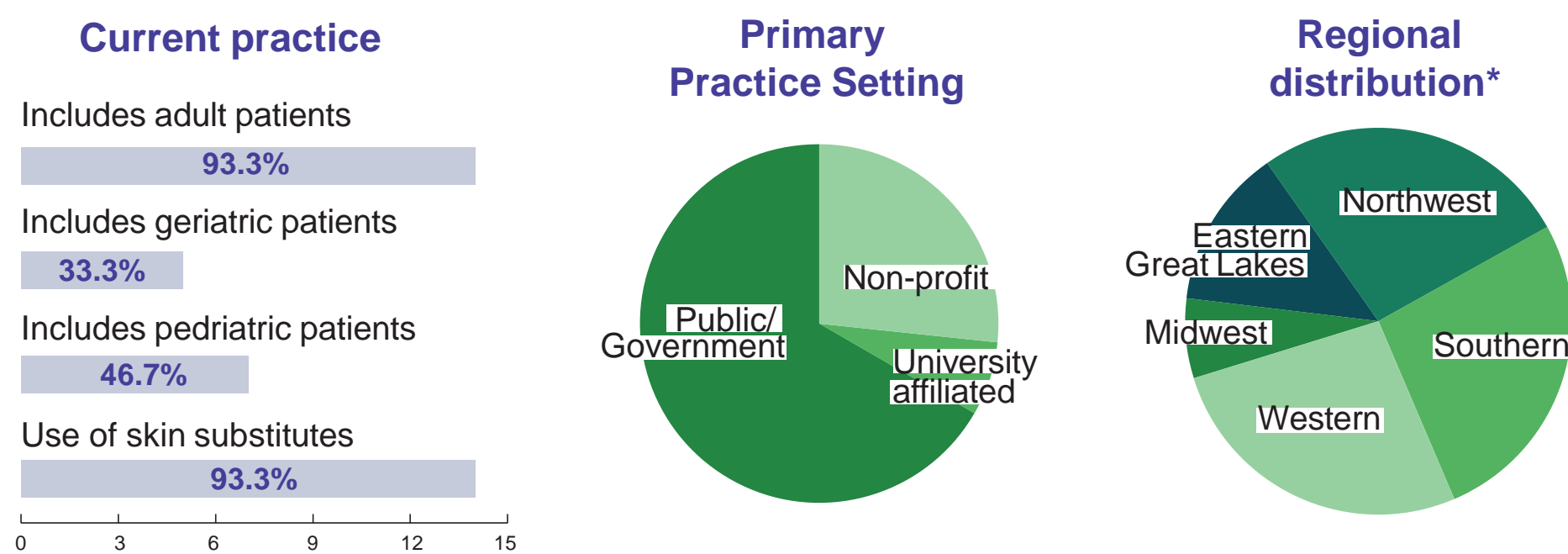


3+ years
post-residency
experience



Experience as part of a burn team:
Care for **1,000+** patients OR
Care for **500+** patients and work in
a unit with 200+ annual admissions

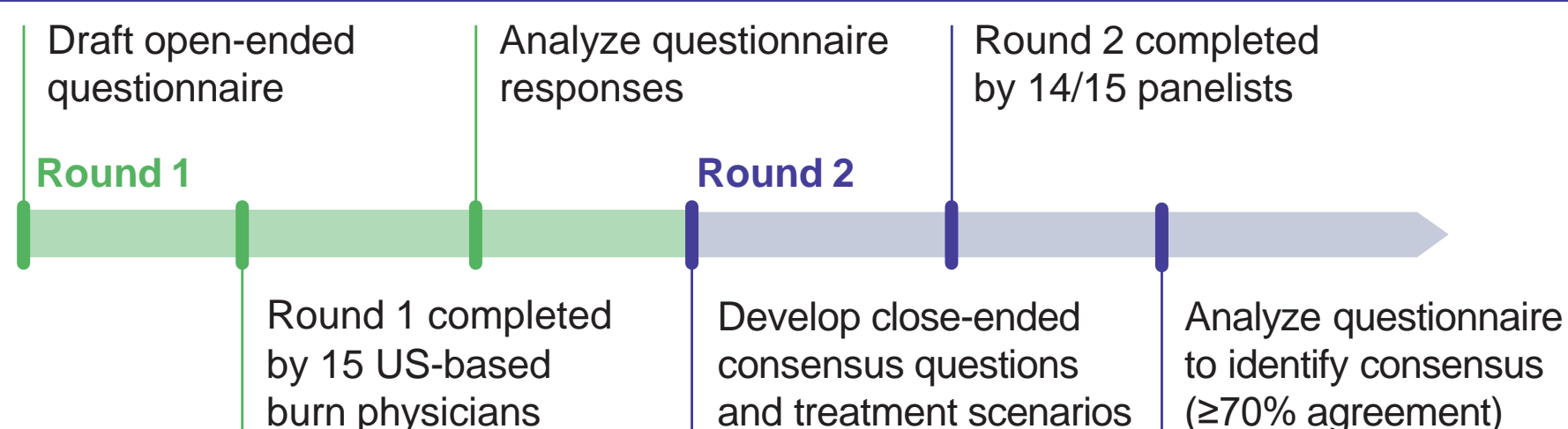
Figure 1. Panelist Background Characteristics



Data Source

A two-round Delphi Panel was administered online using controlled questionnaires (Fig, 2). Fourteen (of 15) panelists completed both rounds (93.3%).

Figure 2. Delphi Panel Process



Round 1 Questionnaire: open-ended questions about what could be considered a CSR threshold in HDS, and the effect of burn types, patient types, and burn and donor site on the threshold.

Round 2 Questionnaire: panelists were asked to agree/disagree with thresholds identified in round 1. Panelists were then given short treatment scenarios and asked whether the percentage reduction in each was a CSR.

Funding source: this study was funded by Mallinckrodt Pharmaceuticals.

Results

In Round 1, panelists stated that:

- They were more likely to use skin substitutes for treatment of patients with larger percentage total burn surface area (TBSA), either as a temporary measure or to improve graft take and promote healing.
- It is important to reduce the amount of required donor skin for both DPT (n = 10; 66.7%) and FT (n = 9; 60%) burns.

Table 1. Minimum clinically meaningful reduction in harvested donor skin (Round 1, n=15)

	Range	Median	Mean
DPT burns	10%-50%	35%	33.5%
FT burns	10%-50%	30%	30.7%

Figure 3. Round 2 Consensus Statements (n=14)

Scar quality/cosmesis, reduction in functional limitations and time to healing are the three most important patient outcomes after definitive wound closure

78.6%

The three most important patient outcomes after definitive wound closure are the same for FT and DPT burns

100%

Increased pain is the patient outcome most affected by the amount of donor skin harvested

85.7%

The importance of reducing the amount of donor skin harvested change when considering extremes of ages (very young/old patients)?

92.9%

A CSR in the amount of donor skin required for autograft would facilitate wound management and decrease donor site morbidity experienced by patients?

100%

0 8 10 12 14
Number of Panelists that agree

Table 2. Treatment scenarios and percentages of panelist agreement: Are reductions in required donor skin clinically meaningful? (n=14)

Treatment scenarios (all in adult patients)	Panelist Agreement n (%)	Consensus
<ul style="list-style-type: none"> • Risk factors for hypertrophic scarring • Approximately 20% TBSA burned • Burns are primarily DPT and require autograft • Use of innovative cellular and/or tissue product (CTP) would allow for 50% reduction in HDS 	13 (92.9%)	YES
<ul style="list-style-type: none"> • Approximately 10% TBSA burned • Burn is primarily FT and across a joint • Use of innovative CTP would allow for 25% reduction in HDS 	7 (50%)	NO
With 50% HDS reduction		
<ul style="list-style-type: none"> • Approximately 45% TBSA burned • Burn injury is mixed (DPT and FT) mainly on upper body in non-cosmetically sensitive areas • Use of innovative CTP would allow for 35% reduction in HDS 	12 (85.7%)	YES
<ul style="list-style-type: none"> • Approximately 45% TBSA burned • Burn injury is mixed (DPT and FT) mainly on upper body in non-cosmetically sensitive areas • Use of innovative CTP would allow for 35% reduction in HDS 	14 (100%)	YES

Lessons Learned

- Clinical consensus can be achieved in a 2-round Delphi consensus panel with careful analysis of qualitative responses.
- Panelists agree that a clinically significant reduction in harvested donor skin would improve patient outcomes in terms of wound management and donor site morbidity. However, the responses of the selected panel may not be representative of all experts in the field of burn care.