Unified Decontamination and Prep: Streamlining Prep Process Across Partnered Processors

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Background:

In response to the inefficiencies and potential contamination risks posed by our tissue processor partners, our Tissue Recovery Team here at Versiti endeavored to try to find potential solutions to help decrease our tissue contamination rates. Recognizing the challenges associated with training employees on multiple prepping and draping policies and the associated risk of heightened contamination, a strategic decision was made to implement a singular, standardized preparation method across all our processors. Following collaborative discussions and unanimous approval from all three partnered processors involved, the transition to a unified prepping and draping process was executed.

Most of our initial contamination rates were deemed above our processors benchmarks; however, a collective decision to further enhance our standards prompted a thorough examination of our practices. Recognizing the imperative to eradicate bioburdens, we meticulously evaluated the impact of our standardized approach. The outcome surpassed expectations, as the consolidated preparation method not only bolstered efficiency but also facilitated a significant reduction in bioburdens, thus fortifying our commitment to bring our contamination rates below set benchmarks.

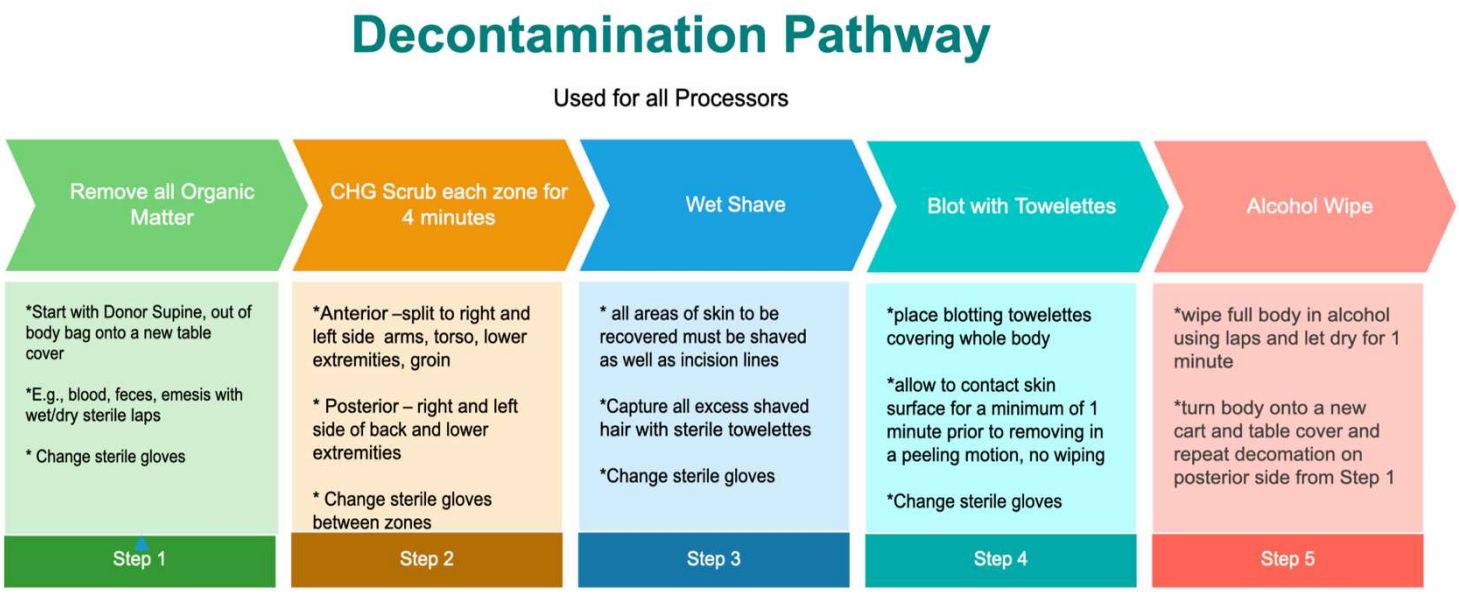
Hypothesis:

In hypothesizing the adoption of a singular standard preparation protocol, we aimed to surpass existing benchmarks and achieve lower contamination rates within our sphere of influence. Our previous contamination rates, standing at 68%. bioburden negative, exceed our target benchmark of 65% bioburden negative, necessitating decisive action to realign our practices because as a company we would like to hold ourselves to a higher standard. Consolidating our preparation procedures into a singular, meticulously crafted protocol promises to propel us towards our desired benchmark, where we currently stand at 80% bioburden negative, thereby optimizing tissue graft yields across all our partnered processors.

To assess the efficacy of this shift, we plan to conduct a comparative analysis between the contamination rates observed in Quarters 3 and 4 preceding the implementation of this singular preparation protocol, and those recorded over the last six months post-implementation.

Methods:

The approach undertaken to evaluate our hypothesis involved conducting thorough research to find an optimal sequence and selection of prep solutions for the prepping and draping procedures. Through research, it was determined that a combination of 4% CHG (Chlorhexidine Gluconate), 70% Isopropyl alcohol, and chloraprep (comprising 2% CHG and 70% Isopropyl alcohol) represents the best practice for reducing contamination rates. The diagrams below shows our current prepping and draping procedure starting with our decontamination process following with our Standard Prep Pathway.



Below is our current SOP for Prepping and Drapping the posterior and anterior sides including the steps after the team scrubs in to do final draping before recovery.

10.0 Posterior Prep and Draping

10.1 Perform an antibacterial wash utilizing Chlorhexidine Gluconate 2-4%, (Hibiclens, etc.) on all skin surfaces to be recovered to thoroughly remove any debris for a minimum of 4 minutes.

10.1.1 Antimicrobial wash is performed by utilizing a sponge/ brush sponge surface to scrub the donor for all zones to be recovered, neckline to the feet.

10.1.2 The torso, and each leg is a separate 4 minute scrub.
10.2 Apply alcohol for a minimum of 1 minute using lap sponges (or equivalent) to wipe

the donor, ensuring all antibacterial solution, loose hair or debris are removed. Allow

to dry for a minimum of 2 minutes
10.3 Don sterile gloves
10.4 Place a sterile barrier under all areas of the body to be recovered, being careful not to

compromise sterility of your gloves/gown by coming into contact with the donor or table.

10.4.1 If sterile gloves come into contact with a non-prepped area or excessively dirty area, the gloves must be discarded and new gloves donned.

10.4.2 Ensure that any non-sterile areas of the donor and table are covered. 10.5 Change sterile gloves

10.6 Apply alcohol for a minimum of 1 minute using laps or equivalent to the donor and allow it to dry for a minimum of 2 minutes.

10.7 Change sterile gloves
10.8 Apply Chloraprep (2%CHG/70% Isopropyl Alcohol). Allow to dry a minimum of 3

minutes.
10.9 Recovery team members will perform a surgical hand scrub and don surgical attire

according to policies, *Surgical Hand Scrub* and *Surgical Attire.*
10.10 Drape the donor utilizing sterile drapes and in accordance with the tissues to be

recovered.
10.10.1 Be careful not to compromise sterility of your gloves/gown by coming into

contact with the donor/table.
10.10.2 If sterile gloves come into contact with a non-prepped area or excessive

dirty area, the gloves must be discarded and new gloves donned. 10.10.3 Cover the buttocks area with a sterile barrier.

10.11 If recovering anterior skin, turn the donor and begin the prep procedure as described in Anterior Prep and Draping procedure.

10.11.1 If recovering abdominal dermis only from the anterior side, with no lower extremity involvement, a focused prep of the abdomen may be done.

11.0 Anterior Prep and Draping

11.1 Perform an antibacterial wash, for all sites to be recovered from, utilizing Chlorhexidine Gluconate 2-4%, of all skin surfaces to thoroughly remove any debris for a minimum of 4 minutes.

11.1.1 Antimicrobial wash is performed by utilizing a sponge/brushes sponge surface to scrub the donor for all zones to be recovered, neckline to the feet (arms, torso, and legs are separate prep areas).

11.1.2 Each arm, torso, and leg is a separate 4 minute scrub.

11.2 Apply alcohol for a minimum of 1 minute using lap sponges (or equivalent) to wipe

the donor, ensuring all antibacterial solution, loose hair or debris is removed. Allow to

dry for a minimum of 2 minutes
11.3 Don sterile gloves.
11.4 Place a sterile barrier under all areas of the body to be recovered, being careful not to

compromise sterility of your gloves/gown by coming into contact with the donor or table.

11.4.1 If sterile gloves come into contact with a non-prepped area or excessively dirty area, the gloves must be discarded and new gloves donned.

11.4.2 Ensure that any non-sterile areas of the donor and table are covered.

11.5 Change sterile gloves.

11.6 Apply alcohol for a minimum of 1 minute using laps or equivalent to the donor and allow it to dry for a minimum of 2 minutes.

11.7 Change sterile gloves
11.8 Apply appropriate sterile skin prep solution according to manufacturer's instructions to all exposed skin surfaces. Allow to dry a minimum of 3 minutes.
11.8.1 The sterile skin prep solution should be applied circumferentially to the legs.

11.9 Recovery team members will perform a surgical hand scrub and don surgical attire according to policies, *Surgical Hand Scrub* and *Surgical Attire.*

11.10 Drape the donor utilizing sterile drapes and in accordance with the tissues to be recovered.

11.10.1 Be careful not to compromise sterility of your gloves/gown by coming into contact with the donor/table.

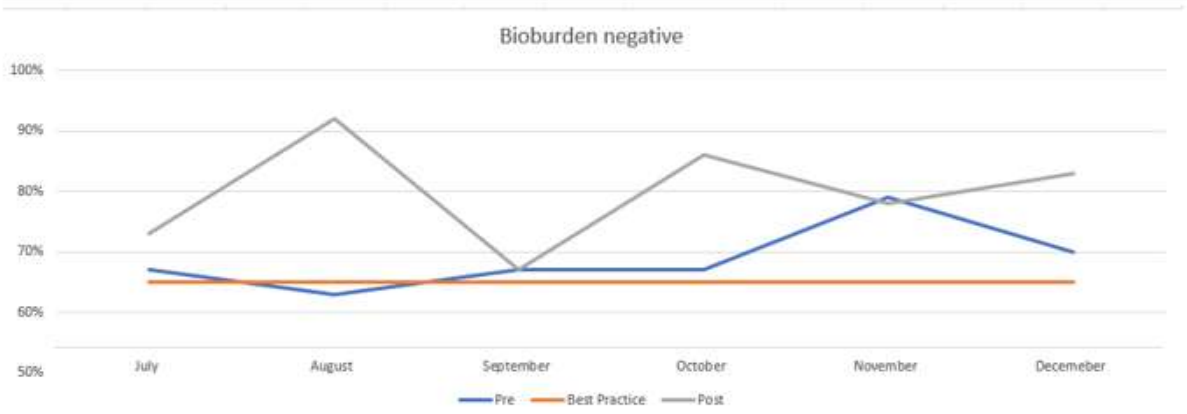
11.10.2 If sterile gloves come into contact with a non-prepped area or excessive dirty area, the gloves must be discarded and new gloves donned.

11.10.3 Cover the groin area with sterile barrier. 11.11 Change sterile gloves

11.12 Apply the third layer of sterile drapes.
11.12.1 Place U-drape under the legs
11.12.2 Place upper U-drape to cover all areas that will not be part of the recovery

sterile field.
11.13 Cover the chest/arms, hands/abdomen, legs, and feet with Steri-drape.

Results:



The graph illustrates our best practice benchmark at 65% bioburden negativity, denoted by the orange line. Pre-implantation data from quarters 3 and 4 under the

standard preparation pathway average at 68% (blue), while post-implementation data from the first year's quarters 3 and 4 average at 80% (grey).

Conclusions:

Through the efforts our Tissue Recovery Team has made, these results would show how many additional donors were saved due to the reduced bioburden metrics. Our pre implementation state put Versiti at a 32% positive bioburden resulting in 32 lost donors per 100. After getting the latest quarter 3 and 4 reports, we stand at a 20% positive bioburden out of 100. With the difference between pre and post donors saved per 100 and having 567 Versiti Tissue donors last year- can estimated that roughly 68 donors were saved due to this change. This achievement underscores the effectiveness of our efforts, marking a significant success. We continue to make this a priority for our team to continue their great efforts and to one day be able to have an even lower rate of negative bioburden on our processed tissue,

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Goal: Our Tissue Recovery Team here at Versiti looked for potential solutions to decrease our tissue contamination rates.
Challenges: Training employees on multiple prepping and draping policies and the associated risk of heightened contamination.

Decontamination Pathway

Used for all Processors

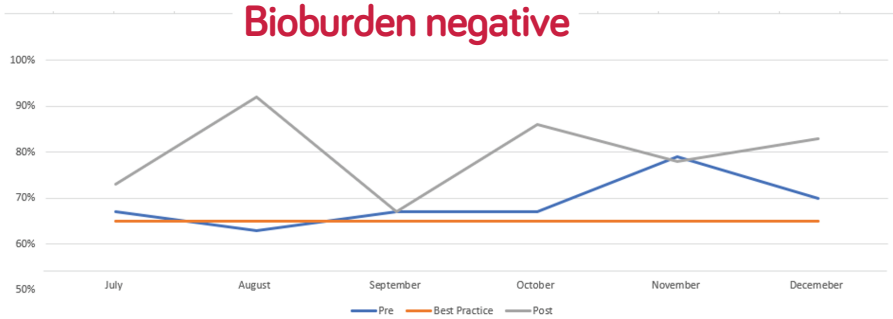
Step 1	Step 2	Step 3	Step 4	Step 5
Remove all Organic Matter	CHG Scrub each zone for 4 minutes	Wet Shave	Blot with Towelettes	Alcohol Wipe
• Start with Donor Supine, out of body bag onto a new table cover • E.g., blood, feces, emesis with wet/dry sterile laps • Change sterile gloves	• Anterior –split to right and left side arms, torso, lower extremities, groin • Posterior – right and left side of back and lower extremities • Change sterile gloves between zones	• All areas of skin to be recovered must be shaved as well as incision lines • Capture all excess shaved hair with sterile towelettes • Change sterile gloves	• Place blotting towelettes covering whole body • Allow to contact skin surface for a minimum of 1 minute prior to removing in a peeling motion, no wiping • Change sterile gloves	• Wipe full body in alcohol using laps and let dry for 1 minute • Turn body onto a new cart and table cover and repeat decontamination on posterior side from Step 1

Standard Prep Pathway

Used for all Processors

Step 1	Step 2	Step 3	Step 4	Step 5
CHG Sponge each zone for 4 minutes	Alcohol wipe full donor	Apply First Set of drapes and anoher alcohol wipe	Apply Second set of drape	Apply Chloraprep
• Once decontamination has been complete, start with sterile gloves • Anterior –split to right and left side arms, torso, lower extremities, feet • Posterior – right and left side of back and lower extremities • Change sterile gloves between zones	• Wipe full body in alcohol using laps and let dry for 2 minutes • Change sterile gloves	• Place sterile drapes under top and bottom half of donor • Change sterile gloves • Wipe full body in alcohol using laps and let dry for 2 minutes • Change sterile gloves	• Place sterile drapes under top and bottom half of donor • Change sterile gloves • Wipe full body in alcohol using laps and let dry for 2 minutes • Change sterile gloves	• Apply 3 Chloraprep sticks per left and right side of donor • One stick on upper half, one stick lower half and one stick for incision lines • Let dry for 3 minutes • Prep is now complete and team can fully scrub and begin with recovery

Bioburden negative



Orange Line: Best practice benchmark at 65% bioburden negativity,
Blue Line: Pre-implantation data from quarters 3&4 average at 68%
Grey Line: Post-implementation data from the first year's quarters 3&4 average at 80%

A strategic decision was made to implement a singular, standardized preparation method across all our processors. Following collaborative discussions and unanimous approval from all our partnered processors involved, the transition to a unified prepping and draping process was executed.

Conclusion: Our pre implementation state put Versiti at a 32% positive bioburden resulting in 32 lost donors per 100. After getting the latest quarter 3 and 4 reports, we stand at a 20% positive bioburden out of 100. With the difference between pre and post donors saved per 100 and having 567 Versiti Tissue donors last year - we can estimate that roughly 68 donors were saved due to this change. This achievement underscores the effectiveness of our efforts, marking a significant success. We continue to make this a priority for our team to continue their great efforts and to one day be able to have an even lower rate of negative bioburden on our processed tissue.

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