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SPECIAL TOPIC

Creation of Nepal's First Skin Bank: Challenges and Outcomes

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Background: In Nepal, burn trauma causes more than 55,000 injuries each year. Burn-related mortality is high in Nepal, in part due to lack of allograft, leading to high infection rates. To address this challenge, our collaboration between Kirtipur Hospital, America Nepal Medical Foundation, Stanford University, and ReSurge International established Nepal's first skin bank.

Methods: We identified 3 major tasks to create a sustainable skin banking program: 1) identify and acquire the equipment and personnel needed to collect, process, store, and graft cadaveric skin for burn injuries; 2) develop safe donation protocols and documentation tools that remain feasible for low-resource settings; and 3) develop a long-term awareness program to educate the Nepali people on skin donation, a previously foreign concept.

Results: Kirtipur Hospital acquired the necessary equipment and materials for the skin bank through a combination of local and international fundraising efforts. Existing U.S. skin banking protocols were adapted for the Nepali setting and piloted on potential patients, donors, and physicians. For the first time in the hospital's history, patients with > 40% total body surface area burns were successfully treated with extensive allografts.

Conclusions: It is feasible to create a skin bank in a country with no tradition of allograft skin use. Long-term sustainability now depends on spreading awareness and education in the Kathmandu Valley to overcome religious and cultural barriers that have hindered donor recruitment. Our low-cost and high-impact skin bank provides a model to expand this system to other hospitals both within Nepal and beyond. *(Plast Reconstr Surg Glob Open 2017;5:e1510; doi: 10.1097/GOX.0000000000001510; Published online 7 November 2017.)*

INTRODUCTION

Globally, burn injuries are the fourth most common cause of trauma, accounting for 11 million injuries and over 300,000 deaths each year.[1] Low- and middle-income countries (LMIC) bear 95% of this burden of burn injuries, and access to burn treatment and follow-up care is limited by barriers including poor patient education, high cost of care, and lack of adequate health care infrastructure.[2,3] Burn injuries present a particularly significant challenge in Nepal, as they account for more than 55,000 injuries and 216 lost disability-adjusted life years per 100,000 patient-years annually.[4]

Nepal is a country in South Asia with a mountainous geography that divides the country into 3 broad regions. The country remains one of the poorest in the world, with 83% of its 27 million inhabitants living in rural areas and more than 25% of the population living below the poverty line. Kathmandu Valley is the most developed and populated area of Nepal, with a population of 3.0 million.[5] Despite the large population and high incidence of burn injuries, the capital city's hospitals are hindered by lim-

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ited burn treatment facilities, inadequate burn training for health care professionals, and gross underreporting of burn injuries.[6–8]

Whereas U.S. burn centers typically report an LA50 (the total body surface area of burns [TBSA] lethal to 50% of patients) of 70–80%, Nepali hospitals report an LA50 of 25%, and burn injuries greater than 40% TBSA have a nearly 100% mortality rate.[9,10] These rates are comparable with burn care in the United States in the pre-World War II era, before the discovery of antibiotics.[11] Nepali hospitals have the capability to debride burned tissue but lack the resources, such as cryopreserved allograft, silver dressings, or even antibiotic gauze, for definitive treatment of burn wound infections. In some instances, patients may receive only gauze dressings and intravenous antibiotics after debridement. As a result, patients with moderate-to-deep burn injuries commonly succumb to sepsis.[10]

A partnership was formed between ReSurge International, Kirtipur Hospital, the America Nepal Medical Foundation, and Stanford University to find a feasible and cost-effective solution to the challenge of preventing burn wound infection in a low-resource environment. ReSurge International is an NGO that provides year-round reconstructive surgical care primarily in postburn contractures for patients in LMICs and training for local surgical teams and therapists to build permanent local capacity. Kirtipur Hospital, located in Kathmandu, Nepal, is a 75-bed hospital that serves an underprivileged patient population and maintains a 42-bed tertiary burn referral center.

Our team worked through a user-centered design process in the Stanford Design for Extreme Affordability Program to develop and implement Nepal's first skin bank at Kirtipur Hospital. Our skin bank provides a low-cost system of collecting, processing, and storing donated cadaveric skin that can be used as temporary allograft for patients with extensive burn injuries and insufficient autograft donor sites. The use of cadaveric human skin as allograft in burn care is well described,[12–14] and the concept of skin banking has been implemented successfully in both LMICs and high-income countries.[15–17]

Our team launched the first skin bank in Nepal by designing an implementation plan outlining key funding and technical partners, a business plan, a thorough quality assurance (QA) program, an operational plan, steps to obtain legal and regulatory support, and an awareness campaign. This skin bank would directly address the need for preventing burn wound infection and would have tremendous impact on reducing the morbidity and mortality of acute burn injuries in Nepal.

METHODS

Project Framework

We identified 3 major tasks to create a sustainable skin banking program: 1) identify and acquire the equipment and personnel needed to collect, process, store, and graft cadaveric skin for burn injuries; 2) develop safe donation protocols and documentation instruments that remain feasible for low-resource settings; and 3) establish a long-term awareness program to educate the Nepali people on skin donation, a previously unknown concept.

Developing the Physical Infrastructure

Our first objective was to identify and acquire the materials and equipment required to procure cadaveric skin. Establishing this system in Nepal included a number of unique considerations, including the unreliable availability of electricity, the need for long-term storage, and cost of ongoing operations.

One of the most pervasive challenges we faced was the lack of reliable electricity throughout Kathmandu. The inconsistent electrical supply influenced decisions ranging from storage methods and patient communications to record keeping and graft procurement. Graft procurement posed a particularly difficult challenge because power sources for motorized dermatomes, such as plug-in electricity or compressed gas, cannot reliably be found in Kathmandu hospitals. Further complicating this is the custom for patients in rural Nepal to die at home—where power supplies are even more uncertain—rather than at a hospital.

Grafts can be procured with manually operated knives such as Humby or Weck. These knives offer advantages of low cost relative to electric dermatomes and no power requirements. For an untrained user though, they yield relatively narrow strips of skin with ragged edges that cannot be easily meshed. The confluence of high incidence of burns, small number of donors, and lack of alternative skin substitutes creates a need to maximize the amount of graft collected from a single donor. Therefore, cordless dermatomes were chosen as the ideal instrument, as they are battery-powered, require minimal training, and can reliably create large skin grafts. We chose to purchase 2 D80 cordless dermatomes (Humeca, Borne, The Netherlands), as we were unable to find locally manufactured devices of sufficient reliability. Although importing these dermatomes and their single-use blades from an international manufacturer created additional challenges, we believed that the high quality and relative longevity of the dermatomes warranted the additional costs.

After procurement, the tissues are immediately placed in a 50% glycerol solution and then chilled on ice for transport to the hospital for processing. At the hospital, the new grafts are kept in a separate refrigerator from usable grafts until processing is completed. Blood samples collected from the donor are tested for HIV, HBV and HCV, and portions of the graft itself are sent for bacterial and fungal testing. If all serological and microbiological tests are negative, then the grafts are transferred to a new 85% glycerol solution for permanent storage. All processing is done in ultraviolet light-sterilized biosafety cabinet.

Long-term graft storage posed a number of challenges. In developed countries, allograft is commonly cryopreserved at -70°C or lower with liquid nitrogen, dry ice, or electric refrigeration, which allows the tissue to be stored for several years with minimal loss of tissue viability.[18] However, a constant, long-term supply of either liquid nitrogen or dry ice would have been prohibitively expensive, running counter to our primary objective of establishing a low-cost program. Electric cryopreservation was similarly untenable due to the unreliable electrical supply and the high power demands of maintaining a freezer at -70°C.

Instead, we used a basic refrigeration system in which cadaveric skin is stored at 4°C in a glycerol solution. The temperature requirements can be achieved by an ordinary kitchen refrigerator, which costs substantially less and requires less power than a traditional cryopreservation system. Skin stored at these temperatures is also more tolerant to small fluctuations in temperature that result from the frequent power interruptions. Lastly, glycerol is cheap, readily available, and serves as a virucidal agent for the grafts.[19,20]

Although we recognize that these grafts may have allogeneic potential, no additional steps were taken to prevent possible immunological response in patients for several reasons. Although we expect these grafts to be rejected within several days to weeks, they offer a life-saving intervention in the interim. Given the lack of other dressing options such as cryopreserved allograft, xenograft, or acellular matrices, these skin grafts are the only available option when patients lack sufficient skin for autograft. Furthermore, the donor grafts are only used in patients with extensive burns—those with 20% TBSA or greater—who have undergone massive systemic trauma with suppressed immune function and are therefore less likely to acutely reject the allograft. The grafts are rigorously tested for pathogenic potential but are otherwise not processed or matched for host-graft immune response.

Developing the Quality Assurance Program

Our next objective was to create an end-to-end QA program, including the donation protocols, collection documents, and an ongoing monitoring program, to ensure that all future donations would be handled appropriately.

The initial framework for the donation protocol was adopted from U.S. tissue donation standards by first identifying the critical steps that must be carried out for tissue donation: donor evaluation, tissue procurement, tissue processing, and tissue storage. Our U.S.-based protocols were adapted for Nepal- and hospital-specific circumstances, such as at-home patient deaths, a paper-only record keeping system, and poor transportation infrastructure. The protocol was finalized by removing steps that would have been impractical or prohibitively expensive for the hospital to implement. A flowchart of the major steps, possible termination points, and documentation forms can be found in Figure 1. The full set of protocols and documentation can be found in appendix (**Supplemental Digital Content 1**, which displays the skin bank's full procedures and documentation, **http://links.lww.com/PRSGO/A569**).

These protocols were then tested with the skin bank team members via full-scale mock collections in Kathmandu, with the requisite equipment, materials, sterile fields, personnel, and documentation forms of an actual donation. In each exercise, the team followed the protocol instructions exactly as written to evaluate the protocol's comprehensibility and completeness, without asking for clarifying directions or adding any steps that they believed to be missing. These exercises allowed us to identify and modify potentially ambiguous elements and breakpoints where tissue samples and collection records were improperly transferred. Through iterative rounds of simulations and protocol revisions, we ultimately devised a set of simple and feasible protocols that still were comprehensive in scope.

We then turned to personnel who would be responsible for maintaining the end-to-end program. We identified one skin bank manager (B.K.), who held the critical role of maintaining the QA of the skin bank and overseeing the on-site procurements and the in-hospital maintenance of the grafts. When grafts first arrive at the skin bank, the manager is responsible for 1) storing the untested sample separately from samples that are confirmed as appropriate for grafting; 2) submitting and following up with the sample for microbiological testing; 3) completing all donor consent and tissue tracking forms; and 4) processing of the graft for storage (detailed below). When grafts are needed in a procedure, the skin bank manager was also responsible for checking that the graft has not expired and is still viable. Weekly responsibilities for the manager included monitoring the temperature of the refrigeration system and conducting hospital follow-ups with graft recipients. Given the frequent power interruptions, the skin bank manager was also responsible for testing the hospital's solar and diesel generator power supply on a monthly basis and ensuring that these backup power sources quickly restored power to the refrigeration system during outages.

Three house staff from the plastic surgery team were trained to procure donor skin. Additionally, all plastic surgery personnel were trained on the storage and use of cadaveric grafts in acute burn patients, to ensure that grafts were appropriately used. The skin bank manager then spent 4 weeks at 2 skin banks in Mumbai, India and Indore, India for training on tissue procurement and public awareness best practices.

Creating Donor Awareness

Awareness and education are key to the success of any skin bank, as an otherwise perfect skin bank without donor skin still is functionless. This has been a significant challenge of this project for several reasons. First, the concept of organ donation is not widespread in the general Nepalese population, so its benefits are not well understood. This knowledge gap first started to change in 1994 when a cornea donation service—the first of its kind in Nepal—was established in Kathmandu. Today, the Nepal Eye Bank receives more than 500 donations annually, due in large part to their extensive education and awareness efforts. Second, organ donation conflicts with Hindu religious principles, which place value in maintaining the physical wholeness of the body after death. Skin donation, along with other types of organ donation, is viewed as a Western practice that could compromise the integrity of the body.

Early awareness efforts focused on educating the general population about the prevalence of burn injuries in

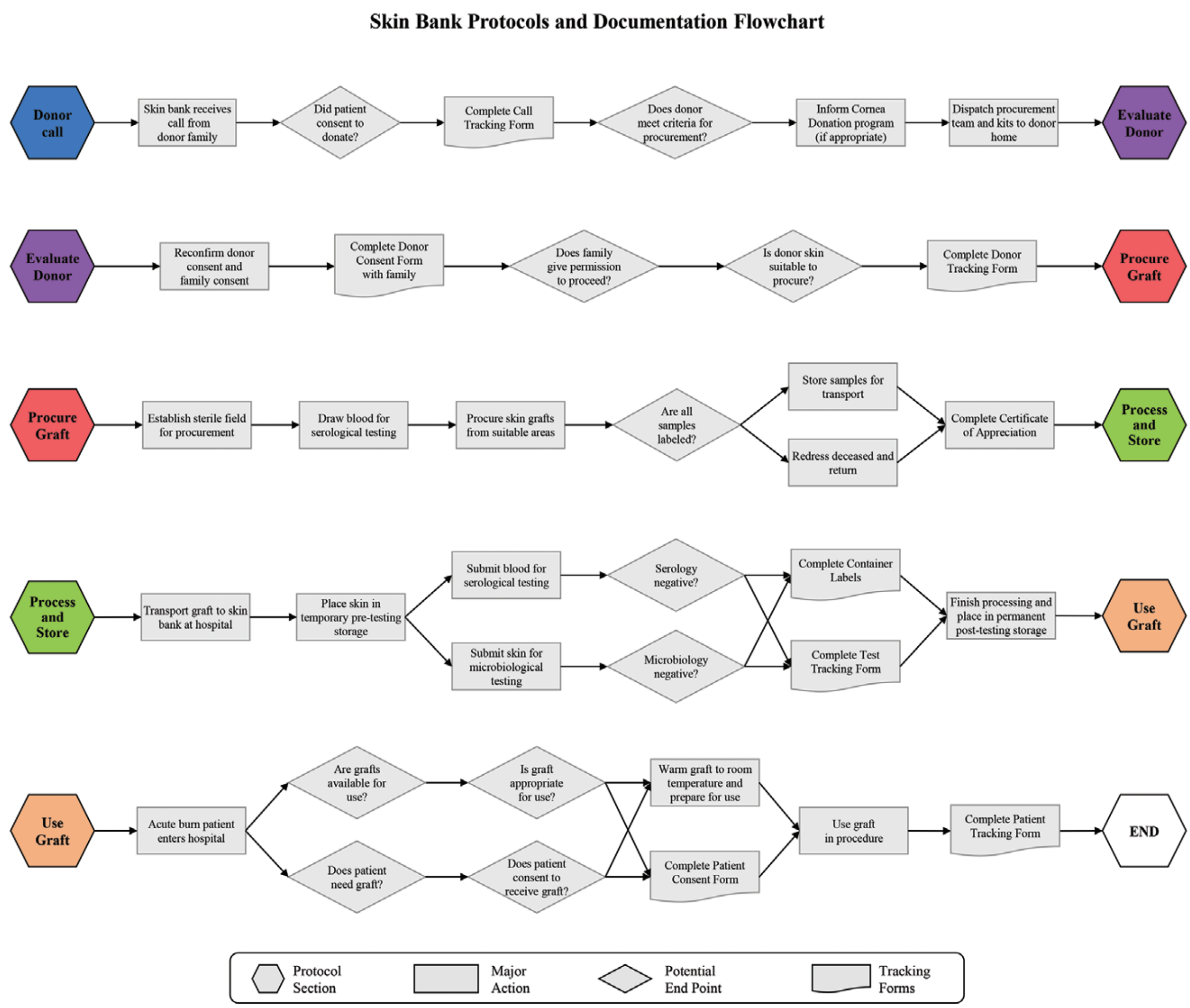

Fig. 1. Flowchart of the skin bank procurement protocol and documentation, based on overall protocol sections, major actions, potential end points, and tracking forms required.

Nepal, the role that skin grafts play in treating these acute injuries, and the concept of skin donation. In particular, we emphasized the life-saving potential that donated skin would have for severely burned patients and the karmic benefit of skin donation within the framework of Hindu religious principles. Most audiences were unfamiliar with the idea of skin donation but impressed by the benefit that a donation could provide without interrupting traditional funeral rites. Ultimately, we were able to demonstrate that skin donation was not only compatible with but also complementary to Hindu principles.

Promoting Physician Awareness

Additional awareness efforts were undertaken to address the physician knowledge gap in definitive burn treatment. Most hospitals in Nepal lack the surgical capacity for early excision and grafting and typically rely exclusively on wound dressings, even for deep partial-thickness or full-thickness burns. As such, patients who are referred to Kirtipur Hospital from rural hospitals often do not receive adequate triage care, which creates new preventable morbidities during definitive care. To address this challenge, a series of classes were offered for local physicians to teach simple interventions that could be performed before patient transfers from the periphery to Kathmandu. These classes focused on 3 critical knowledge gaps: the Parkland formula for appropriate fluid resuscitation, immediate cooling of burns with water to preserve the zone of stasis, and basic escharotomies in circumferential burns to prevent limb loss.

RESULTS

Financial Plan

Most of Kirtipur Hospital's burn patients are of low socio-economic means, even by Nepali standards, and cannot afford medical care. Treatment is heavily subsidized by domestic and international donations, so we designed a sustainable financial plan to include support from external sources, rather than relying solely on internal revenue streams from patient payments.

The start-up costs cover the one-time investments for the full suite of equipment necessary to operate a skin bank (Table 1). In procuring equipment, we sought local manufacturers whenever possible, due to the substantially lower costs and lack of import tariffs. However, experience has shown that more sophisticated instruments (such as motorized dermatomes and skin meshers) may be of lower quality when purchased from local manufacturers and may incur significant repair and replacement costs. In these cases, we sought U.S.- or European-made equipment that ultimately would be cheaper in the long term. In total, start-up costs were approximately $18,000.

The operating costs cover the cost of supplies for each donation, maintenance of equipment, and labor (Table 2). Unlike complex medical equipment, basic medical supplies could be sourced reliably from local manufacturers without quality concerns, so all cost estimates were from local business partners. Supplies cost approximately $120 per donation. Labor costs were estimated based on the expected number of donations in a year and the amount of manpower required to collect, process, and maintain that graft over its lifetime.

Individual costs for start-up equipment, supplies, personnel, and awareness programs were combined to provide an approximate annual operating budget (Table 3). Based on our estimates, the skin bank would require $35,000 in its first year to purchase capital equipment, supplies for 10 donations, and resources to continue expanding the awareness campaign. In subsequent years, we expect the program to require $10,000 to $15,000 to continue operations, primarily for equipment maintenance and replacement, procurement supplies, and awareness efforts. As a point of comparison, an ICU bed without mechanical ventilation in the United States costs an average of $4,500 per day.

Table 1. Start-Up Costs for Equipment

Expenses	Cost/Item (USD)	No. Items	Total Cost (USD)
Dermatome	$4,000.00	1	$4,000.00
Freezer	$700.00	2	$1,400.00
Solution shaker	$1,000.00	1	$1,000.00
Ice box	$30.00	1	$30.00
Mesher	$1,500.00	1	$1,500.00
Laminar flow cabinet	$3,500.00	1	$3,500.00
Autoclave	$6,000.00	1	$6,000.00
Incubator	$600.00	1	$600.00
Scalpel	$5.00	2	$10.00
Scissors	$10.00	2	$20.00
Ruler	$5.00	1	$5.00
Kidney dish	$50.00	3	$150.00
Thermometer	$4.00	1	$4.00
Total			**$18,219.00**

Table 2. Material Costs Per Donation

Expenses	Cost/Item (USD)	No. Items	Unit	Total Cost (USD)
Sterile gloves	$2.00	4	Pair	$8.00
Surgical gowns	$2.00	2	Pair	$4.00
Surgical masks	$0.10	2	—	$0.20
Iodine or betadine	$0.10	8	Fluid ounce	$0.80
Sponges	$0.50	4	—	$2.00
Gauze	$0.50	2		$1.00
Ice	$0.20	1	Pound	$0.20
Dressing	$3.00	3	Sq. meter	$9.00
Glass vials	$1.00	5	Jars	$5.00
Blood draw kit (kit)	$10.00	1	Kit	$10.00
Paraffin (skin lubricant)	$1.00	2	Ounce	$2.00
Shaving razor blade	$0.50	1	Blade	$0.50
Hepatitis B testing kit	$12.00	1	Kit	$12.00
Hepatitis C testing kit	$12.00	1	Kit	$12.00
HIV testing kit	$20.00	1	Kit	$20.00
Skin microbe testing kit	$20.00	1	Kit	$20.00
Scalpel blade	$0.10	1	Blade	$0.10
Glycerol	$0.10	32	Fluid ounce	$3.20
QA labeling materials	$0.10	2	—	$0.20
Certificate of recognition	$2.00	1	—	$2.00
Consent forms	$0.50	2	—	$1.00
Saline solution	$0.05	32	Fluid ounce	$1.60
Penicillin	$1.00	1	Gram	$1.00
Streptomycin	$3.00	1	Gram	$3.00
Total				**$118.80**

Patient Results

Since its inception, the skin bank program has made large strides in improving burn care in Nepal. Monetary donations from international NGOs and private foundations allowed Kirtipur Hospital to acquire all the necessary equipment and materials to establish a skin bank. The ongoing awareness efforts have reached several thousands of individuals in Kathmandu, leading over 200 people to register as donors for the skin bank and commit to donating their skin after death.

During its first year of operation, the skin bank received no donations, in large part due to a lack of public awareness. During the second year of operation, 6 patients with an average TBSA of 40% (20–55%) received allograft from the skin bank. These patients received allografts that covered 10–30% TBSA and relied upon autograft for the remaining burn area. Of note, these cases mark the first time that patients with a TBSA of greater than 40% were successfully treated with skin grafts and survived. All 6 patients demonstrated good graft take and early signs of graft neovascularization at 7 days postoperatively. Two patients' grafts began to reject on postoperative day 7 and 10 and required debridement and new allograft for the rejected areas. Two patients demonstrated persistent allograft take at 30 days; no follow-up data were available for these patients beyond 30 days. Superficial skin infections were seen in 4 of the 6 patients. However, this is in keeping with the burn unit's baseline infection rate of ~50%. Al-

Table 3. Total Costs for Year 1, Year 2, and Subsequent Years

(USD in '000s)	Year 1	Year 2	Year 3+
Start-up investment			
Equipment and supplies	$18.50	$—	$—
Ongoing operations			
Key supplies	$2.00	$4.00	$5.00
Equipment maintenance	$2.00	$3.00	$3.00
People (FTEs)	$—	$4.50	$6.30
Awareness program			
Design	$8.00	$2.00	$—
Implementation	$5.00	$7.00	$10.00
Annual total	$35.50	$20.50	$24.30
Cumulative total	$35.50	$56.00	$80.30

FTE, full-time equivalents.

Fig. 2. A 17-year-old woman who sustained 20% TBSA burns to her lower extremities. Pictured are the initial injury before debridement and grafting (A), initial allograft with cadaveric skin from the skin bank at 7 days postinjury (B), partial rejection of the allograft at 20–25 days postinjury (18 days postgraft) (C), and with allograft excision and permanent autograft at 28 days post injury (D).

though high by U.S. standards, this infection rate is in line with standard of care in Nepal and can be attributed to several factors, including lack of individual patient rooms, lack of adequate antibiotics, and limited availability of surgeons, anesthesiologists, and operating room time. A case study with representative preoperative and postoperative photographs can be found in Figure 2. Two patients ultimately expired due to graft rejection, lack of sufficient autograft, and subsequent sepsis.

From these early donations, we have seen that simply registering donors is not enough to guarantee an eventual donation. Donors' family and community members also must be educated and engaged in the donation process. In most high-income countries, patients typically expire in the hospital, and even after death, autonomy remains with the patients; family members cannot override patients' explicitly stated wishes after death. In contrast, Nepali patients typically pass away at home in the presence of family members, and after death, autonomy transfers to the senior family members who ultimately make the decision regarding skin donation. Thus, donations cannot proceed without agreement from the family members, even if the donor expressly stated his/her desire to donate skin after death. Additionally, the death of a family member requires the family leader to contact religious leaders, community leaders, and close friends for funeral rites. Given that skin must be collected within a warm ischemia window of 6 hours to remain viable, family members must treat skin donation as a high priority and incorporate the tissue procurement team into the funeral proceedings. The long-term sustainability of this program ultimately depends on educating patients and spreading awareness to overcome the cultural and religious barriers. Of note, the 4 surviving allograft recipients have served as key local community advocates for the importance of skin banking.

CONCLUSIONS

It is feasible to create a skin bank in a low-income country with no history of allograft skin use, as demonstrated by the successful establishment of Nepal's first allograft skin bank at Kirtipur Hospital in October 2014. During its first 2 years of operation, the skin bank registered over 200 donor pledges and received 4 allograft skin donations. These allografts were used in extensive skin grafting procedures in 6 burn patients with ≥ 20% TBSA, 4 of whom eventually recovered from their injuries. These cases marked the first time that patients with 40% TBSA burn injuries were treated successfully at Kirtipur Hospital. The positive response from the Nepali community suggests that future efforts should focus on continuing to develop public awareness for the previously unknown concept of cadaveric skin donations.

New partnerships with Nepal- and U.S.-based tissue distribution organizations continue to provide mentorship and guidance for growth. Collaboration with the Nepal cornea donation program—one of Nepal's oldest and highly trusted tissue donation programs—has provided an additional avenue of spreading awareness by associating skin donation with cornea donation. When a family contacts the cornea program for a donation, the family also is educated about the need for skin donation and asked to consent to donating skin in addition to the corneas.

Nepal's first skin bank still has many hurdles to overcome before it can fully meet the substantial demand for skin grafts. However, with the help of our many partner organizations, we believe our goal is possible. The need for such a skin bank both in Kathmandu and beyond is enormous and the impact equally so. Given the country's tremendous burden of burn injuries, the life-saving potential of a skin bank offers a sustainable, cost-effective, and feasible solution for reducing mortality in acute burn injuries. This skin bank also provides a model for similar centers to be established throughout Nepal and eventually in other resource-limited countries where the burden of burn injuries remains the greatest. At Kirtipur Hospital alone, an estimated 70 patients die each year from burn wound infections, many of whom potentially could be saved with allograft from a skin bank. Looking forward, we plan to scale this skin bank program up to serve a network of hospitals in the greater Kathmandu area.

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