Surgical Innovation

Minimum Specifications for a Lifebox Surgical Headlight for Resource-Constrained Settings

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What Is the Innovation?

Safe surgery requires reliable, high-quality lighting. In low- and middle-income countries (LMICs), electricity outages are disruptive, dangerous, and ubiquitous.[1] Inadequate surgical lighting due to inconsistent or poor illumination results in delays and cancellations of surgery, as well as patient harm.[2] In LMICs, surgical headlights are unaffordable, lack in-country suppliers, and are unsuitably designed for austere environments. An affordable, rechargeable, built-for-purpose surgical headlight could help address this surgical safety issue. Lifebox (https://www.lifebox.org/), a charity focused on improving surgical safety globally, undertook a process to identify the essential elements of a fit-for-purpose surgical headlight for use in resource-constrained settings.

After reviewing the existing market of rechargeable LED (light-emitting diode) headlights, we procured 8 unique models and quantified light quality and longevity and generated qualitative data on overall design features and usability. We measured illumination intensity 40 cm from the light source hourly using a digital lux meter until complete discharge of the battery and measured maximum and minimum spot size; full battery recharge time was subsequently quantified. We performed controlled illuminance testing to determine maximum and minimum acceptable light intensity under no light, ambient light, and overhead surgical light conditions. From May 1, 2017, to January 31, 2018, we field-tested these lights during surgery at 3 hospitals in Ethiopia and 1 in the United States. Participating surgeons provided standardized feedback on lighting quality, mounting, battery charge, overall fit, and general use. We also shadowed surgeons in Ethiopia to better understand charging, storage, and transport of the headlight outside of the operating room and developed a target product profile (**Table**).

What Are the Key Advantages Over Existing Approaches?

Backup generators are the most common solution for power outages[2]; in prior studies of infrastructure in sub-Saharan Africa, however, less than 30% of backup generators were functional.[3] Limited fuel and maintenance staff, as well as prohibitive cost, undermine the usefulness of backup generators. Other lighting options include lights on mobile telephones, flashlights, natural window light, and headlights. In a previous study of surgeons in LMICs, 29% relied on lights on mobile telephones, with only 9% reporting using a headlight; barriers cited were unaffordability and poor in-country suppliers.[2] Some have described using recreational headlights during surgery but report problems of poor design, improper light quality, and inconsistent battery life.[4] A portable, comfortable, robust surgical headlight with appropriate duration and illuminance can provide illumination when lighting has failed or is inadequate.

How Will This Affect Clinical Care?

More than 125 million operations are performed annually in LMICs[5]; electricity is unreliable in up to 30% of these surgical facilities owing to power cuts.[1,3] Assuming a gradation of electricity failure across countries ranging from 10% for upper-middle-income countries to 30% for lower-income countries, we estimate that at least 24 million patients annually are at risk of harm from loss of lighting during surgery.

In 2015, LMICs—representing 71% of all countries and 82% of the global population—were served by 1 010 000 surgical professionals: 720 000 surgeons and 290 000 obstetricians.[6] Based on prior field work,[2] we estimate that at least 40% of surgical professionals in LMICs operate with inadequate or substandard surgical lighting, equating to an estimated 404 000 surgical professionals (288 000 surgeons and 116 000 obstetricians). This market estimate does not account for clinical officers performing many medical procedures or for future expansion of the surgical workforce.

Is There Evidence Supporting the Benefits of the Innovation?

Eighty percent of surgeons in LMICs reported that their current lighting presents a patient safety risk; 18% have direct knowledge of a patient harmed owing to poor surgical lighting.[2] Many operating room lights in resource-constrained settings are of inferior quality and may be poorly functioning from the start. Providing an affordable, rechargeable, high-quality surgical headlight would ensure consistent lighting for both clinicians and patients in these settings.

What Are the Barriers to Implementing This Innovation More Broadly?

Economics and logistics prevent widespread distribution and use of a surgical headlight. Navigating international customs and regulations, forming relationships with professional organizations, and developing a globally accepted standard of care are activities familiar to Lifebox. Through our safer anesthesia program, we established pulse oximeter standards and, working with a commercial manufacturer, we have procured and distributed more than 18 000 purpose-built devices to 110 countries worldwide to address the global gap in oximetry. This Lifebox headlight project will challenge the market to provide a fit-for-purpose surgical headlight.

In What Time Frame Will This Innovation Likely Be Applied Routinely?

Next steps include partnering with a manufacturer, development and testing, procurement, and distribution. As many devices are

Table. Lifebox LED Surgical Headlight Minimum Specifications

Component and Category	Specification	Rationale
LED lighting[a]		
Acceptable illuminance (12-cm spot diameter at working distance)	Adjustable between ≤8000 lux and ≥35 000 lux at end of battery pack run time	Provide proper illumination to visualize critical structures in a variety of ambient light settings ranging from no light to high quality overhead OR lights
Light color	4500-6500K;CRI,≥90andCRIR9,≥90	Range of color temperature most similar to full-spectrum sunlight best for distinguishing between red and blue colors typical of anatomical structures
Illumination spot size	Adjustable with ideal diameter of 12 cm with narrowest diameter ≤7 cm at working distance	Most common essential operations and lower lighting conditions tend to benefit from a larger diameter of 12 cm, not currently offered in some surgical headlights; smaller spot size used with surgical loupes are not essential given low use in LMICs
Light component quality	Device shall maintain the LED within manufacturer-recommended temperature limits at the full range of required operating temperatures	The light must function in LMIC ORs that do not have temperature or humidity control systems
Light housing	Adjustable by at least +5° and -60° in cranial-caudal direction measured from the bottom edge of headband around circumference of the head	Illuminate the full range of common surgical operations including cesarean delivery and obstetric fistula repair
Light uniformity	Lux measurements shall not vary ≥25% over illumination field	Uneven illumination common in recreational headlights can lead to the inability to distinguish important anatomical structures
Mounting		
General	Durable material, such as plastic, that will not stretch significantly during device lifetime, with padding and 2 points of adjustment (circumference and depth)	Durable for operating in LMIC setting, where replacement parts and biomedical technicians are not readily available
Weight	<300 g on the head	Device must be light enough for surgeons to use for extended periods of time
Battery		
Quality	High quality from a manufacturer either with ISO 9001 certification or a history of products with CE marking	Ensure a high-fidelity device built for providing light, regardless of OR equipment or regulatory environment
Run time	2 Batteries with ≥3 h run time; optional battery available with ≥6 h run time	Support surgeons working long shifts where down time is not sufficient for recharge; support surgeons performing multihour operations.
Charging	Compatible with 100-240 VAC and 50-60 Hz	Accommodates the variety of electricity infrastructures from LMICs and enables continuous charging during modest power dips and surges
Recharge time	>90% Charge attained in time less than or equal to battery pack run time	Battery should be fully charged before the second battery is fully discharged.
Fixation	Independent from head mounting; placed on waistband or hip pocket	Can decrease weight of head mount to ensure minimal surgeon neck fatigue
Lifetime	2 Batteries last for a total of 3500 h of use including 1200 charging cycles each	Should continue to function for 2 y when used an average of 6 h/d
Durability		
Impact	Operates according to specification after a drop from 1-m height onto concrete	Similar to rechargeable telephones, dropping can occur with concrete as one of the most common building materials in LMICs
Water and particulate resistant	Splash resistant, dust protected, ideally attaining IP54 rating	Occasionally, device may be splashed with bodily fluids; in addition, many LMIC ORs do not have air filtration systems so device will be exposed to particulate matter
Charging stability	Withstand frequent power surges; automatically continue charging whenever power is in specified range	Power outages are common in LMICs, ideal to have unit continue to function automatically on return of power to ensure it will be ready for use
Temperature demands	Operate according to specification at 10°-40°C and 30%-90% relative humidity	ORs in LMICs may not be climate controlled, requiring a device to function in a variety of temperatures and humidity

Abbreviations: CE, Conformité Européene; CRI, color rendering index; IP, Ingress Protection Marking; ISO, International Organization for Standardization; LED, light-emitting diode; LMIC, low- and middle-income country; OR, operating room; VAC, volts, alternating current.

[a] Working distance defined as 40 cm from light source.

close to our target product profile, we anticipate rapidly developing a prototype that can be distributed for field testing and feedback. We are optimistic that our surgical headlight will be ready for distribution in 2019. Distribution will capitalize on our already substantial capacity to engage partners and professional societies around the world.

ARTICLE INFORMATION

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Submissions: Authors should contact Justin B. Dimick, MD, MPH, at jdimick@med.umich.edu if they wish to submit Surgical Innovation papers.

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