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Authors

Shapiro, Lauren

Chang, James

Fox, Paige

et al.

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# The Development and Validation of Data Elements and Process Steps for an Electronic Health Record for Hand Surgery Outreach Trips

Lauren M. Shapiro<sup>1</sup> James Chang<sup>2</sup> Paige M. Fox<sup>2</sup> Scott Kozin<sup>3</sup> Kevin C. Chung<sup>4</sup>  
George S.M. Dyer<sup>5</sup> Duretti Fufa<sup>6</sup> Fraser Leversedge<sup>7</sup> Julie Katarincic<sup>8</sup> Robin Kamal<sup>9</sup>

<sup>1</sup>Department of Orthopaedic Surgery, University of California San Francisco, San Francisco, California, United States

<sup>2</sup>Division of Plastic and Reconstructive Surgery, Stanford University, Palo Alto, California, United States

<sup>3</sup>Department of Orthopaedic Surgery, Shriners Children's Philadelphia, Philadelphia, Pennsylvania, United States

<sup>4</sup>Section of Plastic Surgery, University of Michigan, Ann Arbor, Michigan, United States

<sup>5</sup>Department of Orthopaedics, Harvard Combined Orthopaedics Residency Program, Massachusetts General Hospital, Boston, Massachusetts, United States

Address for correspondence Lauren M. Shapiro, MD, MS, Department of Orthopaedic Surgery, University of California San Francisco, 1500 Owens St., San Francisco, CA 94158, United States (e-mail: lauren.shapiro@ucsf.edu).

<sup>6</sup>Department of Orthopedic Surgery, Hospital for Special Surgery, New York, New York, United States

<sup>7</sup>Department of Orthopaedic Surgery, University of Colorado Anschutz, Aurora, Colorado, United States

<sup>8</sup>Department of Orthopaedic Surgery, University Orthopedics, Rhode Island, United States

<sup>9</sup>Department of Orthopaedic Surgery, VOICES Health Policy Research Center, Stanford University, Redwood City, California, United States

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## Abstract

**Background** The surgical burden in low- and middle-income countries (LMICs) as reported by the number of surgical cases per capita is great. To improve global health and help address this burden, there has been a rise in surgical outreach to LMICs. In high-income countries, an electronic health record (EHR) is used to document and communicate data critical to the quality of care and patient safety. Despite this, there is little guidance or precedence on the data elements or processes for utilizing an EHR on outreach trips. We validated data elements and process steps for utilizing an EHR for hand surgery outreach trips.

**Methods** We conducted a literature review to identify data elements collected during surgical outreach trips. A future-state process map for the collection and documentation of data elements within an EHR was developed through literature review and semistructured interviews with experts in global outreach. An expert consortium completed a modified RAND/University of California at Los Angeles Delphi process to evaluate the importance and feasibility of each data element and process step.

**Results** In total, 65 data elements (e.g., date of birth) and 24 process steps (e.g., surgical site marking) were validated for use in an EHR for hand surgery outreach trips to LMICs.

**Conclusion** This validated portfolio of data elements/process steps can serve as the foundation for pilot testing of an EHR to document and communicate critical patient data on hand surgery outreach trips. Utilization of an EHR during outreach trips to LMICs may serve to improve the safety and quality of care provided. The validated data elements/process steps can serve as a guide for EHR development and implementation of other surgical specialties.

## Keywords

- ▶ data collection
- ▶ electronic health records
- ▶ global outreach
- ▶ hand surgery
- ▶ quality improvement

## Introduction

Five billion people lack access to safe and affordable surgical and anesthetic care.<sup>1</sup> To address this burden, organizations from the United States sponsor more than 6,000 short-term medical trips costing over \$250 million annually.<sup>2,3</sup> Growth in outreach trips, however, has outpaced the development of measurement systems and technology to use during trips to ensure safety and quality of care—systems commonly utilized in high-income countries (HICs). For example, despite the emphasis on surgical process measures (e.g., surgical timeout), in low- and middle-income countries (LMICs) the collection and tracking of process steps (e.g., completing a timeout, documenting follow-up) does not routinely occur during outreach trips. Similarly, important patient data, such as outcomes and complications, are collected sporadically.<sup>4,5</sup> Tracking and evaluation of such data are key to accountability, quality measurement, and improvement.<sup>6</sup>

In a landmark publication by the Lancet Global Health Commission, authors demonstrate the problem of systemic quality deficits with care delivery in LMICs.<sup>6</sup> The authors highlight that the burden of mortality is more greatly attributed to poor quality care than the lack of access and they demonstrate that eight million lives could be saved by quality improvements.<sup>6,7</sup> To ensure quality, the Commission called for countries to (1) invest in health systems that enhance health, (2) provide services valued by people, and (3) remain accountable for delivering high-quality care<sup>6,9</sup> and emphasize the importance of the collection of data through electronic health records (EHRs).<sup>6,10</sup>

In HICs, data collection of process steps through EHR is a foundation to safety, quality, and efficiency. For example, in the United States, EHR use was promoted by the Health Information Technology for Economic and Clinical Health Act, incentivizing electronic data collection by providing reimbursement incentives. These initiatives are based on the ability of EHR data collection to prevent communication errors and improve quality. Benefits are numerous—from improving neonatal mortality and adherence to evidence-based guidelines to reducing adverse drug reactions and rates of reordered tests.<sup>11–16</sup> Despite such benefits in HICs, they are not routinely implemented during surgical outreach trips to LMICs.

Kruk et al and the Lancet Global Health Commission identified priorities for a high-quality health system as (1) measuring and analyzing quality (e.g., developing and validating quality measures), (2) improving quality (e.g., evaluating educational innovations), and (3) methods and tools (e.g., developing measurement surveys).<sup>6</sup> This research agenda was made feasible by a context-specific, low-cost, and agile EHRs. Prior work has demonstrated that data collection during outreach trips to LMICs is primarily conducted through handwritten paper charts that limit the meaningful use of data not only for patient care but also for informing policy, quality improvement efforts, and resource allocation.<sup>1,17,18</sup> Although some organizations leading outreach trips have recognized the benefits of EHRs and have demonstrated the feasibility and effectiveness of data

collection in LMICs,<sup>17,19</sup> the evidence guiding implementation and real-time use of EHRs on outreach trips is lacking. We set out to systematically develop and validate data elements and process steps for use with an EHR for hand surgery outreach trips, the results of which may be applied to health systems and related specialties across the globe.

## Methods

### Development and Implementation Framework

Based on the unique challenges of implementing technology in LMICs,<sup>20,21</sup> our work was guided by a framework described by Pettigrew that has been used to guide EHR development and implementation in HICs.<sup>22,23</sup> The Pettigrew framework requires understanding the content, process, and context of implementation. The content is composed of the what of the EHR system (data elements), the process represents the how of the EHR system (process steps), and the context represents the why (understanding the system in which the technology will be applied). The steps we used within this framework are illustrated in ►Fig. 1. In this work, we address the content and process for EHR development, whereas the context of EHR use will require knowledge of the local health care system, culture, stakeholder beliefs (e.g., hospital administration, end users), etc.

### Catalog of Candidate Data Elements

This study was a quality improvement initiative and was institution review board exempt. A literature review was conducted by R.N.K. and L.M.S. to identify candidate data elements for inclusion in this study. Literature review focused on currently utilized and/or validated elements specific to surgical outreach with an emphasis on outcome measures, guidelines, and databases (in following with prior literature).<sup>24</sup> Further candidate data elements were added by two authors with experience in hand surgery, global health, and surgical outreach trips (R.N.K. and L.M.S.). A total of 340 candidate data elements were initially included. Duplicates were removed, and similar elements were merged (e.g., age and date of birth). Data elements that were not directly related to patient care (e.g., cost of the trip) were removed. One hundred and eleven elements were included for initial voting.

### Data Element Evaluation

Data elements were evaluated by Global Quality in Upper Extremity Surgery and Training (Global-QUEST), a consortium of 10 hand surgeons with experience and interest in promoting the delivery of safe and high-quality care to those in LMICs. Eight consortium members with extensive experience in the global delivery of hand surgery utilized a modified RAND/University of California at Los Angeles (UCLA) Appropriateness methodology to evaluate 111 data elements with regard to their importance and feasibility (two consortium members facilitated the discussion process and did not vote). This methodology is frequently applied to develop appropriateness criteria that have face, construct, and predictive validity.<sup>25–27</sup> Consortium members were provided

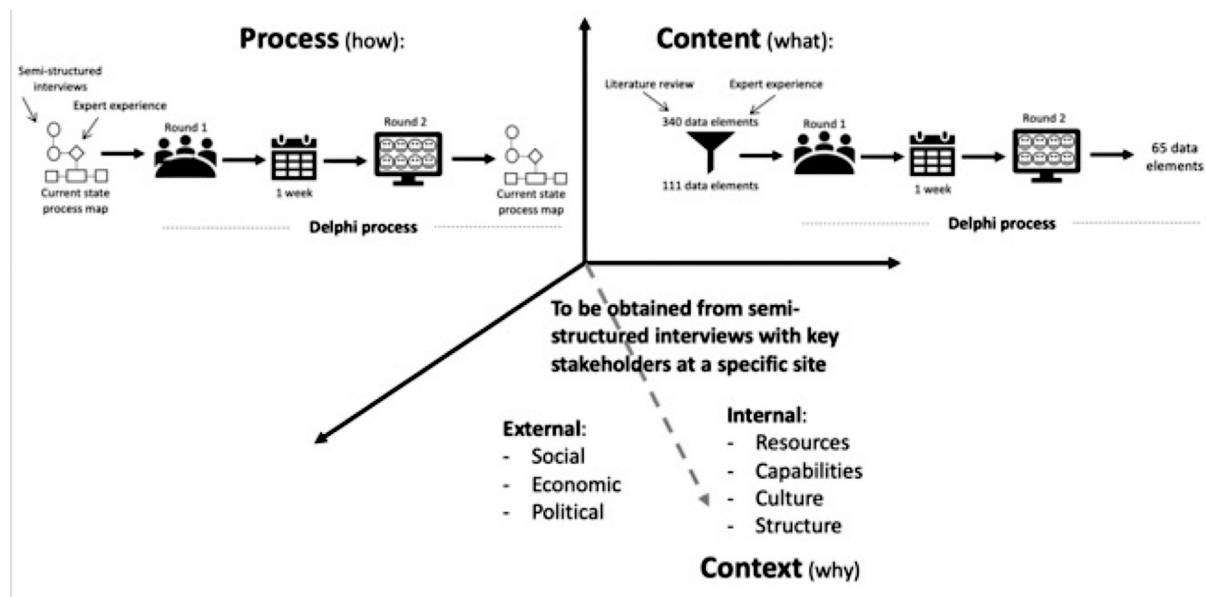


Fig. 1 Illustration of manuscript methodology within the Pettigrew framework.

Table 1 Quality indicators with definitions

Term	Definition
Importance	Measures an important aspect of data collection in which considerable variation exists that is subject to provider or health system control.
Feasibility	It is possible to apply the element accurately, completely, and affordably in practice without significant burden.

Source: Definitions of importance and feasibility are adapted from *Guidance for Using AHRQ Quality Indicators for Public Reporting or Payment: Appendix B and the National Quality Forum*.

with a definition table based on the Agency for Healthcare Research and Quality Criteria (→Table 1) in addition to the candidate data elements. Each consortium member independently rated each measure.

**Creation of a Future-State Process Map**

A process map is a visual flow diagram of activities, tasks, and decisions that are conducted or made within a workflow. The items within the map can be accompanied by a responsible party and/or include how this particular step interacts with the broader system. Borrowed from the field of business, process maps help one to gain a better understanding of a particular process to improve communication about and efficiency of such process or as a foundation upon which to implement improvement initiatives.<sup>28</sup> Process mapping has been used previously in health care not only to improve the value of surgical systems and processes<sup>29,30</sup> but also to improve surgical infection prevention in resource-constrained settings.<sup>31</sup>

We constructed a current state process map of the care provided for patients on hand surgery outreach trips from

the initial patient evaluation stage through the patient’s follow-up. The creation of this process map was guided by semistructured interviews with hand surgery global health experts and by the barriers and challenges described by the World Health Organization.<sup>32</sup> A future- (or ideal) state process map was derived from this current state process map by adding previously validated quality measures (unpublished data), further semistructured interviews with hand surgery and global health experts, and findings from a literature review on EHR implementation and best practices.<sup>23,33</sup>

**Data Process Evaluation**

Data processes were evaluated by the Global-QUEST consortium through a modified RAND/UCLA Appropriateness methodology with regard to their importance and feasibility (two consortium members facilitated the discussion process and did not vote). Consortium members also voted on who (e.g., surgeon and administrator) and how (e.g., dictation and templated note) each process could be conducted.

**Modified RAND/UCLA Delphi Scoring**

The modified RAND/UCLA Delphi process requires two rounds of independent ratings of (1) EHR data elements and (2) EHR process elements (preliminary and final). Qualitative feedback and additional candidate data elements were elicited during the preliminary voting round. A virtual meeting was conducted between the two voting rounds during which voting members were provided the aggregate scores to formulate a discussion. The verbiage of each data element and process element was reviewed and tailored for broad application based upon member consensus. Additional candidate data elements and process elements from the primarily voting round were added to the catalog for discussion and final voting. Qualitative feedback from the preliminary

voting round was included for discussion in the meeting. Two nonvoting consortium members facilitated a discussion regarding the validity of each data element based upon the voting criteria. The second round of voting was conducted within 1 week of the virtual meeting. The two voting rounds consisted of each member rating each candidate data element on a scale of 1 to 9 (1 = definitely not important and definitely not feasible and 9 = definitely important and definitely feasible). Data were made ordinal (1–3 are considered not important/feasible, 4–6 are of equivocal importance/feasibility, and 7–9 are considered important/feasible). We calculated the median score for each data element from the results of the second round of voting and tabulated the number of ratings for each decision that were in the same ordinal category (1–3, 4–6, or 7–9). If no more than two of the eight ratings were outside the three-point range that included the median score (1–3, 4–6, or 7–9), the panelists were considered to be in agreement. If three or more ratings of a decision were within the 1 to 3 ordinal range and three or more ratings were in the 7 to 9 ordinal range, the panelists were considered as in disagreement. Other scoring scenarios were considered indeterminate. **►Supplementary Table A1** illustrates hypothetical examples. A data or process element was considered a valid element if it received a median score of 7 or higher for all criteria with no more than two panelists rating outside of the 7 to 9 range for all criteria. These results were reported as the final consensus of the group. A nonvoting member of the consortium calculated the results and completed the analysis.

### Feasibility, Usability, and Transparency

The development and validation of the EHR followed the mobile health evidence reporting and assessment (mERA) checklist<sup>34</sup> to ensure a transparent report of its usability and feasibility. Although we have not yet implemented this EHR, we felt that following and reporting these consensus guidelines developed by the WHO would help to improve the quality of evidence reporting and encourage reproduction and implementation of our results.

### Results

In total, 65 (59%) of 111 data elements reached a consensus on validity (**►Table 2**). Examples include patient name, date of surgery, operative note, postoperative rehabilitation plan. Twenty-four (89%) of twenty-seven process steps reached a consensus on validity (**►Fig. 2**) Examples include history and physical exam and consent by local trip or local surgeons, confirmation of the correct patient by trip or local surgeon, discharge instructions with a follow-up plan, future surgical plan, and rehabilitation protocol responsibility. The responsible parties, as well as the method of input, are reported in **►Fig. 2** (data available in **►Supplementary Tables A2 and A3**).

### Discussion

As the number of surgical outreach trips to LMICs increases and the global agenda to ensure the quality of care delivery strengthens, the ability to collect critical patient data

through an EHR may improve patient safety and outcomes, adherence to clinical practice guidelines, and quality improvement efforts. We used a literature review, semistructured interviews, and a modified Delphi process to develop the data elements and process steps to collect via an EHR to promote safety and quality of care that can be applied to health systems and specialties across the globe.

At present, few outreach organizations delivering care in LMICs use EHRs and those that do frequently require manual input of data from paper charts and/or use the data as a repository and not at the point of care. For example, the use of an electronic Surgical QUality Assurance Database to collect data on patients in Uganda is detailed in a two-part Lancet Commission on Global Surgery teaching case where paper charts are converted to a digital database.<sup>19</sup> Operation Smile also adopted an electronic record system that is used to collect patient health information. Although some of the potential benefits of EHR implementation are being realized in these systems (e.g., allowing for further analysis and quality measurement), most are not used at the point of care and do not have a standardized workflow. The Lancet Global Health Commission on the quality of care in LMICs demonstrates that eight million lives could potentially be saved by high-quality health systems each year (of which, an EHR is a critical component).<sup>6,7</sup> Though guidance on the development and implementation of an EHR in countries with robust resources exist, these same guiding principles and assistance are less common in LMICs, which presents a system-wide self-improvement opportunity for organizations participating in global outreach. Understanding that the creation and validation aspects of technology are just as important as the implementation aspect and that a majority of technologies never succeed past the pilot phase,<sup>20,21</sup> we used the Pettigrew framework<sup>22</sup> to understand the critical aspects of successful and sustainable implementation that have been employed for EHR development and implementation in developed countries<sup>22,23</sup> and additionally recorded methods of personnel responsible for data collection. These data elements and processes can be used with knowledge gained about the local environment to understand how the EHR will work within a specific context (e.g., organization, country, and health system) to improve implementation success.

The data elements and process steps developed in this work have the potential to be scaled, adapted to new contexts (e.g., different countries and different specialties), and served as a framework by which to guide future EHR development and implementation. When integrated into an open-access and interoperable EHR (e.g., OpenMRS), the impact of scaling becomes broader and more impactful, for example, the integration of this system across regions, countries, and subspecialty facilitates for more streamlined patient care and an enhanced ability to draw clinical insights (e.g., creating a learning health system). Although the processes of various organizations participating in global outreach may differ by surgical specialty, the essential steps necessary for safety and quality of care are consistent across fields. Through the development of a process map that provides

**Table 2** List of validated data elements for collection and use in an EHR during patient evaluation and follow up after hand surgery

Validated data elements	
Host city/country	Procedure time (minutes)
Host institutions	Intraoperative photos (when indicated)
Organizations/trip specific medical record number	Anesthesiologist level of training (anesthesiologist officer, resident, specialist, and others)
Patient name	Anesthetic type (GA, spinal, block, GA + block, GA + spinal, local, and others)
Date of birth	Prophylactic antibiotics (type and time)
Sex	Implants used
Telephone number	Tourniquet time (when indicated)
Impact on activities of daily living (e.g., work and care taking)	Operative note
Weight	Blocked performed (yes or no)
Admission date	Block laterality
Admission diagnosis	Block complications (none, intravascular, intraneural, and failed block)
Laterality	Anesthetic used
Scheduled surgery date and time	Intraoperative complications
Time traveled for care	Postoperative diagnosis
Transfusion services available	Pathology sent (yes/no)
Preoperative photograph of surgical extremity (e.g., range of motion and burn)	Postoperative comments
Date of injury	Encounter date
Cause of injury	Surgical complications (e.g., surgical site infection and failure of fixation)
Trauma classification (blunt, penetrating, burn, and others)	
Mechanism of injury (e.g., assault, pedestrian, vehicle driver, fall, boda drive, boda passenger, vehicle passenger, and others)	Reoperation (yes/no)
Temperature	Reoperation reason
Heart rate	Discharge diagnosis
Systolic blood pressure	Outcomes (e.g., improved, critical, etc.)
Diastolic blood pressure	If death, cause

**Table 2** (Continued)

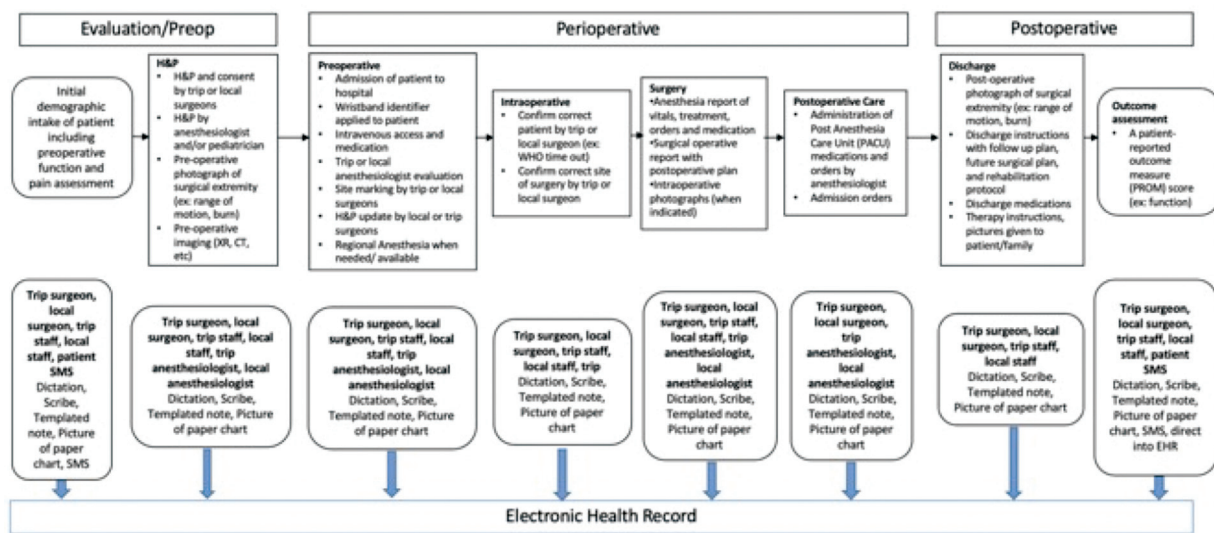
Validated data elements	
Respiratory rate	Postoperative pain
Preoperative radiographs (when indicated)	Postoperative rehabilitation plan
Past medical history	Was a caregiver instructed in home therapy (yes/no)
Date of surgery	Postoperative follow-up date/time
Urgency (elective, emergency, and urgent)	Name and contact of health care professional responsible for patient follow-up
Surgeon and level of training (intern, resident, specialist, and others)	Postoperative photograph of surgical extremity (e.g., range of motion and burn)
Assistant (training level)	Postoperative radiographs (when indicated)
ASA scores (Class I/II/III/IV)	A patient-reported outcome measure (PROM) score (e.g., function)
Diagnosis	

Abbreviations: ASA, American Society of Anesthesiologists; GA, general anesthesia.

examples of personnel who may be in charge of tracking process and outcome measures, we also strove to ensure our results and their use along with an EHR would be feasible (e.g., without a set process or set responsibilities and some aspects of care may not occur). We aim for these steps to not add to or detract from the time clinicians spend with patients but to improve their efficiency while ensuring they can treat patients safely. In keeping in line with feasibility, our group also aimed to only include data that were critical to patient care. The inclusion of too many elements may lead to data collection fatigue and decrease adoption and usability.

Limitations of this work should be noted. Given that few guidelines or frameworks exist for the development and implementation of data elements and process steps along with an EHR system for point of care use in surgical specialties in LMICs, we used multiple steps to ensure the internal and external validity of this work. First, we were guided by frequently used development and implementation frameworks (Pettigrew, mERA) and focused on previously described barriers and challenges to data collection. Second, we engaged experts in global outreach with a mean of over 15 years of outreach experience. Third, we ensured the importance and feasibility of both data collection and process steps using an established method for appropriate use criteria development and quality measure development. We recognize that while we have validated the data elements and process steps, they will require postimplementation testing (to ensure they improve quality gaps), along with contextualization for use in a specific location. Our group also appreciates the end-goal of local health systems implementing technology (e.g., EHR) and processes to improve





**Fig. 2** Ideal state process map with validated elements of patient care/touch points for EHR use.

care in an LMIC, rather than the prescribed scope of a global outreach trip. Based on our experience, promoting a culture of electronic data collection, measurement, and improvement first within the organizations participating in global outreach is a prerequisite to attempts to promote these practices in an LMIC.

This work validated data elements and the process steps to measure and improve quality and safety via an EHR that can be implemented and utilized globally. When implemented within the right context, this technology promotes more robust collection and tracking of critical patient data. This EHR and development process can serve as a guide for EHR development and implementation for surgical specialties worldwide.

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#### Conflict of Interest

D.F. reports grants from Integra and Medartis, outside the submitted work. R.K. reports grants from NIH, outside the submitted work.

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