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Validity and efficiency of a smartphone-based electronic data collection tool for operative data in rotator cuff repair

Sambit Sahoo, MD, PhD[a], Jill Mohr, BS[b], Gregory J. Strnad, MS[c], Jose Vega, MA[c], Morgan Jones, MD, MPH[c], Mark S. Schickendantz, MD[c], Lutul Farrow, MD[c], Kurt P. Spindler, MD[c], Joseph P. Iannotti, MD, PhD[c], Eric T. Ricchetti, MD[c], Kathleen A. Derwin, PhD[a,*]

[a]*Department of Biomedical Engineering, Cleveland Clinic, Cleveland, OH, USA*
[b]*Northeast Ohio Medical University, Rootstown, OH, USA*
[c]*Department of Orthopaedic Surgery, Cleveland Clinic, Cleveland, OH, USA*

Background: This study tested validity and efficiency of Orthopaedic Minimal Data Set (OrthoMiDaS) Episode of Care (OME).
Methods: We analyzed 100 isolated rotator cuff repair cases in the OME database. Surgeons completed a traditional operative note and OME report. A blinded reviewer extracted data from operative notes and implant logs in electronic medical records by manual chart review. OME and electronic medical record data were compared with data counts and agreement between 40 variables of rotator cuff disease and repair procedures. Data counts were assessed using raw percentages and McNemar test (with continuity correction). Agreement of categorical variables was analyzed using Cohen κ (unweighted) and of numerical variables using the concordance correlation coefficient (CCC). Efficiency was assessed by median time to complete.
Results: OME database had significantly higher data counts for 25% (10/40) of variables. A high level of proportional and statistical agreement was demonstrated between the data. Among 35 categorical variables, proportional agreement was perfect for 17%, almost perfect ($0.81 \leq \kappa \leq 1.00$) for 37%, substantial ($0.61 \leq \kappa \leq 0.80$) for 20%, moderate ($0.41 \leq \kappa \leq 0.60$) for 14%, fair ($0.21 \leq \kappa \leq 0.40$) for 6%, and slight ($0.0 \leq \kappa \leq 0.20$) for 6%. Of 5 numerical variables, agreement was almost perfect (CCC > 0.99) for 20% and poor (CCC < 0.90) for 80%. Median OME completion time was 161.5 seconds (interquartile range, 116-224.5).
Conclusion: OME is an efficient, valid tool for collecting comprehensive, standardized data on rotator cuff repair.

Institutional Review Board approval (No. 06-196) was obtained before initiation of the study.

*Reprint requests: Kathleen A. Derwin, PhD, Department of Biomedical Engineering, ND-20, Lerner Research Institute, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195, USA.
E-mail addresses: derwink@ccf.org; stojsab@ccf.org (K.A. Derwin).

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As health care in the United States continues to transition from volume-based to value-based compensation models, it is increasingly important to provide services that maximize value, which is defined as quality divided by cost.[17-19] Consequently, research will continue to focus on identifying which interventions provide the best outcomes (high quality), and at what cost, so that value can be accurately assessed. For surgical procedures, defining value necessitates identifying specific variables that are associated with quality outcomes (eg, preoperative health status, operative technique, intraoperative disease) as well as the cost associated with the procedure, including implant costs and other costs associated with the episode of care.

Rotator cuff repair is one of the most common orthopedic procedures performed, and multiple studies have demonstrated a significant increase in the rate of rotator cuff repair in the last few decades.[6,11,25] Whereas most patients report clinical improvement with the procedure,[3,10,14] the factors responsible for poor outcomes in the proportion of patients who remain dissatisfied with their outcome are not well defined.[14] This includes the surgical technique of rotator cuff repair itself as there is currently no ''gold standard'' repair method. There is also no consensus on the most effective and least costly way to repair a torn rotator cuff,[3] and costs vary by the surgical techniques employed. Thus, defining the true value for rotator cuff repair merits continued research regarding outcomes, predictors of outcomes, and economic analyses.

Historically, collecting such data has relied almost exclusively on manually reviewing operative notes and patient charts and abstracting the desired data.[7,8] Like the rest of the electronic medical record (EMR), operative notes regularly under-report quantitative information and lack standardization.[18,22] Furthermore, manual abstraction of data is associated with error rates between 8% and 23%, depending on clinical site, area, surgical specialty, and medical provider.[15] Reducing such errors by increasing quality assurance measures and a more thorough data review increases time and cost.[15] In contrast, large, structured data sets can serve to catalogue variables that potentially have an impact on outcomes or costs and allow multivariable analysis to determine the primary predictors of interest, particularly when these variables are uniformly defined and collected. However, many existing structured data sets, such as Medicare, Nationwide Inpatient Sample, and American College of Surgeons National Surgical Quality Improvement Program, are not disease specific, consistent, or standardized, thus creating incomplete data sets and limiting the ability to conduct high-quality studies. To our knowledge, no large database currently exists that has been designed to capture high-quality, prospective, standardized data surrounding rotator cuff repair techniques.[3,20]

To address this need, the Cleveland Clinic has developed the Orthopaedic Minimal Data Set (OrthoMiDaS) Episode of Care (OME) system, a prospectively designed electronic data collection tool to enable cost-effective, scientifically valid, and scalable data collection of patient- and surgeon-reported data surrounding a surgical episode for elective knee, hip, and shoulder surgery. The purpose of this study was to demonstrate the validity and efficiency of the OME system for collecting comprehensive and standardized data on rotator cuff repair. The authors hypothesized that compared with a data set constructed by manual abstraction of data from traditional narrative operative notes, the OME system would demonstrate higher completion rates for clinically relevant variables with at least substantial agreement with the operative note while not burdening surgeons with lengthy completion times.

Methods

OME system design

The OME system was designed by a multidisciplinary team consisting of software developers, orthopedic surgeons, and orthopedic administrators. It is a software-as-a-service system that builds on the Research Electronic Data Capture (REDCap) platform to enable cost-effective, scientifically valid, and scalable data collection of patient- and surgeon-reported data surrounding a surgical episode, wherein data collection is integrated within the existing workflow.[9,24] Patients undergoing elective knee, hip, and shoulder surgery systematically enter demographic data and patient-reported outcome measures (PROMs) immediately before surgical intervention and at 1 year postoperatively; their surgeons receive an e-mail link for each operation on the day of surgery. The data are entered prospectively with surgical procedural details using a smartphone, laptop, or desktop computer within 48 hours of the operation. Procedural details include past surgical history, examination under anesthesia findings, and commonly cited operative note parameters and key predictors of operative outcomes for the type of surgery being performed (such as rotator cuff repair) as identified from the literature or by expert opinion of the clinicians involved in the system's design.[23] OME was launched at Cleveland Clinic in February 2015, and by February 2018, OME had successfully captured baseline data (PROMs and surgeon-entered variables) on 97% of 21,500 eligible elective

orthopedic knee, hip, and shoulder surgical procedures. OME's design and implementation were approved by Cleveland Clinic's Institutional Review Board, and the system was vetted by the Information Security Department.

Selection of patients

This study included Cleveland Clinic patients representing the first 100 cases of isolated rotator cuff repair (arthroscopic or open) that were collected into the OME database starting in February 2015. Patients with commonly associated procedures (subacromial decompression, biceps tenotomy or tenodesis, distal clavicle excision) were included; those undergoing another major repair or reconstruction, including labral repair, shoulder arthroplasty, and fracture fixation, were excluded.

OME data collection

Specifically for rotator cuff repair, OME collects data on patients' demographics, rotator cuff disease and repair procedures, and additional disease and surgical procedures performed (Table I). Built-in branching logic is used to accelerate data entry, showing only fields applicable to each disease and procedure, which prevents surgeons from having to answer irrelevant or unnecessary items. When rotator cuff repair is selected as an operation within OME, the surgeon views fields with choices for rotator cuff tendons repaired and tear size, type of rotator cuff tear (ie, partial thickness vs. full thickness), and type of repair performed (ie, single-row vs. double-row repair techniques). Based on the repair type, branching logic presents the surgeon with the next group of applicable fields, including specific manufacturers and types of implants or devices used. Incomplete forms cannot be submitted within OME, which ensures that a standardized and complete data set is obtained for every patient's operation. Total time required to complete the surgical form is also collected to measure caregiver burden. For rotator cuff repair, a total of 40 variables related to rotator cuff tendon disease and repair procedures were extracted for comparison with data from the EMR (Table I; Table S1).

EMR data collection

The surgeons' narrative operative notes and the implant logs were obtained from Epic EMR system (Epic Systems, Verona, WI, USA) for this cohort of patients and queried for the same 40 variables extracted from OME by an examiner blinded to the OME data. When information about implanted anchors was not specifically stated in the operative note (eg, number, manufacturer, type), the information was obtained from the implant log. When the specific type of partial rotator cuff tear (articular or bursal sided) was not explicitly stated in the operative notes, tear type was determined from the description of the arthroscopy procedure. When information on a variable was not present in the operative note, it was considered absent in reporting data counts but an implied negative for agreement analysis (ie, surgeons intentionally omitting nonapplicable information with the implicit understanding that the item was negative or not present). Specifically, an implied negative was assumed when the operative note was silent on the past surgical history of the left or right shoulder or graft augmentation of the rotator cuff repair because it was thought that surgeons would more likely than not mention these points in the operative notes if they were applicable.

Statistical analysis

Before the EMR and OME data sets were statistically compared, discrepancies between the two data sets were identified, and all unmatched data were rechecked and verified. Subsequently, the EMR and OME data were analyzed for data counts and agreement. Data counts were analyzed by comparing raw percentages as well as with McNemar test (with continuity correction). Agreement of categorical variables was analyzed using Cohen κ (unweighted)[12] and of numerical variables using the concordance correlation coefficient (CCC).[13] A 95% confidence interval was calculated for all values of agreement. In addition to these formal agreement metrics, the raw proportion of records for each variable showing agreement was also used to assess raw proportional agreement. Data were analyzed with R software (R version 3.3.3; R Foundation for Statistical Computing, Vienna, Austria).

Results

The first 100 cases of isolated rotator cuff repair (arthroscopic or open) were entered into the Cleveland Clinic's OME database by 10 surgeons between February 2015 and May 2015. The median time to complete OME surgery data entry for these 100 cases was 161.5 seconds (interquartile range, 116-224.5 seconds).

Data counts

EMR and OME data counts of the 40 variables assessed are listed in Table I. OME demonstrated significantly higher counts in 10 (25%) of the variables assessed ($P < .05$). Notably, superior-posterior rotator cuff tendon tear size was mentioned in 54 of 100 cases in EMR but in all 100 cases in OME. Similarly, subscapularis tendon tear size was mentioned in 3 of 100 cases in EMR and in 25 of 100 cases in OME. Furthermore, repair of the subscapularis tendon was mentioned in 19 of 100 cases in EMR but in 25 of 100 cases in OME. In 30 variables, there were no significant differences in data counts between EMR and OME.

A survey of the cases in which data were recorded less frequently in the EMR than in OME did not reveal any bias or pattern in the absent data (eg, it was not that only "minor" or "less severe" occurrences were not mentioned in the EMR). For example, of the 46 cases for which data on superior-posterior rotator cuff tendon tear size were absent in the EMR, the corresponding OME data from those patients revealed that 5 small, 11 medium-sized, 13 large, and 12 massive tears were not mentioned in the EMR.

Table I Electronic medical record (operative note and implant log) and Orthopaedic Minimal Data Set Episode of Care data counts

Variable	EMR	OME	*P* value
Operative limb	100	100	>.99
Left shoulder past surgical history	4	100	<.001
Right shoulder past surgical history	8	100	<.001
Subscapularis			
Status	65	100	<.001
Tear type	19	25	.041
Tear size	3	25	<.001
Repaired	19	25	.041
Reason not repaired	2	7	.074
Repair type	17	18	>.99
Repair approach	17	18	>.99
Repair rows	17	18	>.99
Fixation	17	18	>.99
No. of anchors	17	17	>.99
Implant manufacturer	17	17	>.99
Implant make and model	17	17	>.99
Augmentation	0	18	<.001
Superior-posterior			
Status	100	100	>.99
Tear type	98	100	.48
Supraspinatus involved	100	100	>.99
Infraspinatus involved	100	100	>.99
Teres minor involved	100	100	>.99
Tear size	54	100	<.001
Repaired	100	100	>.99
Reason not repaired	3	3	>.99
Repair type	97	97	>.99
Repair approach	96	97	>.99
Repair rows	90	97	.023
Double-row repair type	47	46	>.99
Fixation	97	97	>.99
No. of superior-posterior anchors	43	46	.371
Implant manufacturer	43	46	.371
Implant make and model	43	46	.371
No. of medial-row anchors	47	46	>.99
Medial-row implant manufacturer	46	46	>.99
Medial-row implant make and model	46	46	>.99
No. of lateral-row anchors	47	46	>.99
Lateral-row implant manufacturer	46	46	>.99
Lateral-row implant make and model	46	46	>.99
No. of superior-posterior sutures	3	5	.48
Augmentation	5	97	<.001

EMR, electronic medical record; *OME*, Orthopaedic Minimal Data Set (OrthoMiDaS) Episode of Care.

Data agreement

Agreement proportions and associated Cohen unweighted κ values for each of the 35 categorical variables collected are listed in Table II. Proportional agreement >90% was observed in 77% (n = 27) of the categorical variables. Agreement was perfect for 17% (n = 6), almost perfect ($0.81 \leq \kappa \leq 1.00$) for 37% (n = 13), substantial ($0.61 \leq \kappa \leq 0.80$) for 20% (n = 7), moderate ($0.41 \leq \kappa \leq 0.60$) for 14% (n = 5), fair ($0.21 \leq \kappa \leq 0.40$) for 6% (n = 2), and slight ($0.0 \leq \kappa \leq 0.20$) for 6% (n = 2) of variables.

The CCCs for each of the 5 numerical variables compared between the operative note and OME are listed in Table III. Agreement was almost perfect (CCC > 0.99) for 20% (n = 1) and poor (CCC < 0.90) for 80% (n = 4) of the numerical variables.

Discussion

The purpose of this study was to demonstrate the validity and efficiency of OME for collecting comprehensive and

Table II Agreement between the electronic medical record (operative note and implant log) and Orthopaedic Minimal Data Set Episode of Care among categorical variables

Measure	Records used	Proportional agreement	κ	95% confidence interval
Operative limb	100	0.98	0.960 [AP]	(0.905-1.000)
Left shoulder past surgical history	100	0.94	0.545 [M]	(0.193-0.898)
Right shoulder past surgical history	100	0.93	0.596 [M]	(0.307-0.885)
Subscapularis				
Status	65	1.00	1.000 [AP]	(1.000-1.000)
Tear type	19	0.74	0.379 [F]	(−0.088 to 0.846)
Tear size	3	0.67	0.400 [F]	(−0.560 to 1.000)
Repaired	19	1.00	1.000 [AP]	(1.000-1.000)
Reason not repaired	2	1.00	1.000 [AP]	(1.000-1.000)
Repair type	17	1.00	N/A*	N/A
Repair approach	17	1.00	N/A*	N/A
Repair rows	17	1.00	N/A*	N/A
Fixation	17	0.94	0.000 [SL]	(−1.000 to 1.000)
Implant manufacturer	16	1.00	1.000 [AP]	(1.000-1.000)
Implant make and model	16	0.62	0.518 [M]	(0.212-0.823)
Augmentation	18	1.00	N/A*	N/A
Superior-posterior				
Status	100	1.00	N/A*	N/A
Tear type	98	0.93	0.809 [SU]	(0.672-0.945)
Supraspinatus involved	100	0.88	0.760 [SU]	(0.633-0.888)
Infraspinatus involved	100	1.00	1.000 [AP]	(1.000-1.000)
Teres minor involved	100	1.00	1.000 [AP]	(1.000-1.000)
Tear size	54	0.78	0.703 [SU]	(0.554-0.851)
Repaired	100	1.00	1.000[AP]	(1.000-1.000)
Reason not repaired	1	1.00	N/A*	N/A
Repair type	97	0.96	0.693 [SU]	(0.398-0.988)
Repair approach	96	1.00	1.000 [AP]	(1.000-1.000)
Repair rows	90	0.97	0.933 [AP]	(0.859-1.000)
Double-row repair type	45	0.49	0.161 [SL]	(−0.079 to 0.400)
Fixation	97	1.00	1.000 [AP]	(1.000-1.000)
Implant manufacturer	42	0.98	0.927 [AP]	(0.787-1.000)
Implant make and model	42	0.71	0.661 [SU]	(0.499-0.823)
Medial-row implant manufacturer	44	1.00	1.000 [AP]	(1.000-1.000)
Medial-row implant make and model	44	0.75	0.668 [SU]	(0.498-0.838)
Lateral-row implant manufacturer	44	0.98	0.896 [AP]	(0.695-1.000)
Lateral-row implant make and model	44	0.98	0.896 [AP]	(0.695-1.000)
Augmentation	97	0.99	0.663 [SU]	(0.006-1.000)

N/A, not applicable.
Implied negatives were assumed in the EMR for 3 variables: past surgical history on left/right shoulder and graft augmentation of the subscapularis/superior-posterior tendon repair.
[AP] Almost perfect agreement based on the κ statistic.
[SU] Substantial agreement based on the κ statistic.
[M] Moderate agreement based on the κ statistic.
[F] Fair agreement based on the κ statistic.
[SL] Slight agreement based on the κ statistic.
* Agreement statistics cannot be calculated in situations in which the operative note and OME are in complete agreement with only 1 variable appearing in each data source.

standardized data on rotator cuff repair. Our reporting shows that OME allowed collection of preoperative and intraoperative data relevant to rotator cuff repair in a comprehensive and time-efficient manner. Data on patients' demographics, rotator cuff disease and repair procedures, and additional disease and surgical procedures performed were captured by the surgeon on average in <3 minutes per case.

Compared with the EMR (operative note and implant log), OME demonstrated greater counts of data capture for 25% of surgical variables relevant to rotator cuff repair. In addition, absent data in operative notes appeared to be

Table III Agreement between electronic medical record (operative note and implant log) and Orthopaedic Minimal Data Set Episode of Care among numerical variables

Measure	Records used	Proportional agreement	CCC	95% confidence interval
No. of subscapularis anchors	16	0.88	0.448 [P]	(−0.267 to 1.000)
No. of superior-posterior anchors	42	0.93	0.881 [P]	(0.789-0.934)
No. of superior-posterior medial-row anchors	45	0.96	0.889 [P]	(0.807-0.937)
No. of superior-posterior lateral-row anchors	45	0.82	0.755 [P]	(0.595-0.857)
No. of superior-posterior sutures	3	1.00	1.000 [AP]	N/A

CCC, concordance correlation coefficient; *N/A*, not applicable.
[AP] Almost perfect agreement based on the CCC.
[P] Poor agreement based on the CCC.

generalized and systematic across multiple categories. Notably, superior-posterior rotator cuff tendon tear size was mentioned in 54 of 100 cases in EMR but in all 100 cases in OME. Similarly, subscapularis tendon tear size was mentioned in 3 of 100 cases in EMR and in 25 of 100 cases in OME. The absence of a key variable like tear size for a large proportion of a rotator cuff repair cohort in the EMR demonstrates why retrospective research and quality assessment from the EMR are particularly challenging and reveals the advantage of using a prospectively designed and standardized database like OME. Templates have been previously used to generate operative notes, but these lack the streamlining features of branching logic and do not always require key variables to be entered into the data set.[16] The branching logic implemented in OME allows efficient yet relevant and complete surgical documentation by streamlining the operative note process and capturing data on a prospectively designed set of clinically relevant variables. The discrete data collection format of OME, because of its underlying REDCap platform, also allows efficient data extraction and retrieval, in contrast to manual data abstraction from operative notes that is associated with high error rates and increased time and cost.[15]

The validity of data captured in OME was demonstrated by a high level of proportional and statistical agreement between data that existed in both data sets. This was true particularly for the categorical variables, for which 77% of the variables demonstrated >90% proportional agreement and 74% demonstrated at least substantial statistical agreement (Cohen unweighted $\kappa \geq 0.61$) between the 2 data sources. With regard to numerical variables, OME data demonstrated poor statistical agreement with EMR data as 80% of the variables assessed had CCC below 0.90. Because all of the numerical variables exhibited >80% proportional agreement, the corresponding low CCC indicates that when discrepancies did occur, they tended to be large.

Discrepancies between EMR and OME could arise for multiple reasons. For example, many of the discrepancies can be explained by lack of standardized content and verbiage in the surgeons' dictated operative notes, whereas standardized responses were mandated in the prospectively designed OME database. For example, some surgeons dictated detailed descriptions of lesions and treatment using identical vocabulary and quantitative measurements as contained in OME. Other surgeons used vernacular, such as, ''tear of approximately $^{2}/_{3}$ -$^{3}/_{4}$ of the width of supraspinatus'' or ''a very large rotator cuff tear.'' Such descriptions did not align with OME documentation, which requires the surgeon to enter the data using standardized categories and defined variables and lists tear size in centimeters corresponding to small, medium, large, or massive tears.[1]

The study has several limitations. First, there is a potential for implicit bias in data collection. Surgeons are required to enter a standardized data set in OME, whereas there are no requirements as to what must be included in the operative notes. Second, although the OME database is relatively comprehensive, it is not exhaustive and will be limited by its predefined classifications for certain variables. Third, the study was based on data captured during the early implementation phase of OME and may have been influenced by initial unfamiliarity of the participating surgeons. Fourth, for agreement analysis, we assumed missing data in the operative notes as implied negatives in case of 3 variables; however, it is possible that some other variables that were missing could also have been implied negative by the surgeon, but the retrospective nature of the study does not allow us to determine the accuracy of our assumption. At present, the operative note is the most widely used method of recording surgical data; however, it is neither prospectively designed nor standardized, and so there is no real gold standard of operative documentation. Consequently, it is difficult to fully compare OME data with the actual surgical record, and therefore it is challenging to fully gauge the true accuracy of the OME database.

The OME system allows a detailed, efficient, and comprehensive method of surgical documentation and data capture for rotator cuff repair and various other orthopedic procedures, including anterior cruciate ligament and meniscus repair and shoulder and hip surgery including total joint arthroplasty.[2,4,21] As of February 2018, OME is

used by 57 surgeons at 10 sites within the Cleveland Clinic Health System to document surgical details and PROMs on 97% of 21,500 elective knee, shoulder, and hip operations. Validation studies for OME in total knee arthroplasty,[21] total hip arthroplasty,[4] and anterior cruciate ligament and meniscus repair have demonstrated excellent performance of this new system in point-of-care implant documentation. Having developed and now validated the OME system for data collection, one of our future objectives is to use the OME system to create a standardized operative report and to integrate with EMR systems to replace the existing methods of creating operative reports. Implementing the streamlining features of branching logic and discrete data collection format of OME in an operative note template is expected to be challenging and will require significant programming and cost.

The widespread collection of standardized prospective data captured in an electronic format in OME will allow investigation of the relationships between patient, disease, and surgical factors and patient-reported outcomes.[2,5,26] The underlying structure of OME as a secure REDCap database also provides the ability to use this unique data collection tool across institutions in the future for prospective multicenter cohort studies or clinical trials. The OME system is currently being used in multicenter research collaborations, and the technology has also been licensed to a company for development of commercial applications. Improvement in orthopedic outcomes research will become increasingly important as health care economics dictates justification of elective repair based on efficacy and outcomes.[2,10] Future areas of research may include OME data capture validation studies for other orthopedic diseases and use of OME data to investigate the relationship between patient, disease, and surgical factors and PROMs for various orthopedic diseases.

Conclusion

The prospectively designed, electronic data entry system (OME) is a valid and efficient tool for collecting comprehensive and standardized data on rotator cuff repair.

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Supplementary data

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