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Review

Benefits and Disadvantages of Electronic Patient-reported Outcome Measures: Systematic Review

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Abstract

Background: Patient-reported outcome measures (PROMs) are important in clinical practice and research. The growth of electronic health technologies provides unprecedented opportunities to systematically collect information via PROMs.

Objective: The aim of this study was to provide an objective and comprehensive overview of the benefits, barriers, and disadvantages of the digital collection of qualitative electronic patient-reported outcome measures (ePROMs).

Methods: We performed a systematic review of articles retrieved from PubMED and Web of Science. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed during all stages. The search strategy yielded a total of 2333 records, from which 32 met the predefined inclusion and exclusion criteria. The relevant ePROM-related information was extracted from each study.

Results: Results were clustered as benefits and disadvantages. Reported benefits of ePROMs were greater patient preference and acceptability, lower costs, similar or faster completion time, higher data quality and response rates, and facilitated symptom management and patient-clinician communication. Tablets were the most used ePROM modality (14/32, 44%), and, as a platform, Web-based systems were used the most (26/32, 81%). Potential disadvantages of ePROMs include privacy protection, a possible large initial financial investment, and exclusion of certain populations or the "digital divide."

Conclusions: In conclusion, ePROMs offer many advantages over paper-based collection of patient-reported outcomes. Overall, ePROMs are preferred over paper-based methods, improve data quality, result in similar or faster completion time, decrease costs, and facilitate clinical decision making and symptom management. Disadvantages regarding ePROMs have been outlined, and suggestions are provided to overcome the barriers. We provide a path forward for researchers and clinicians interested in implementing ePROMs.

Trial Registration: PROSPERO CRD42018094795; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=94795

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KEYWORDS

electronic patient-reported outcome measures; paper-based patient-reported outcome measures; systematic review; advantages; pitfalls

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Introduction

In patient-centered care, patient-reported outcome measures (PROMs) are the gold standard for efficiently evaluating patients' feelings, thoughts, and complaints about a clinical intervention or disease [1].

Clinicians use PROMs to guide and audit routine care and support patient-centered care. Standard intake procedures already include many questionnaires such as generic quality of life questionnaires administered before arthroplastic surgeries [2]. At the patient level, the data can be used to monitor individual progress, investigate the effects of medical and surgical interventions [2], and improve communication between patients and caregivers [3]. On a larger scale, PROM data can be used to screen for health problems, compare outcomes between populations, and assess quality of care. They are widely implemented in clinical research [1,4], with positive effects on patient-clinician communication and mutual decision making. PROMs are traditionally measured using pen-and-paper questionnaires. We aimed to investigate whether pen-and-paper methods are the best option because unsupervised paper-based PROM data collection in clinical trials has resulted in unreadable, missing, or faulty data [5].

The growth of electronic health (eHealth) technologies provide unprecedented opportunities to systematically collect information via PROMs. Patients of all ages and sociodemographic backgrounds worldwide are comfortable using digital networks and services [6]. Furthermore, smartphones and lightweight computers or tablets with touchscreens are omnipresent. Supposed advantages of electronic PROMs (ePROMs) include more complete data capture and lower cost but it is unknown if the advantages of ePROM outweigh the disadvantages. Various research groups in different medical fields have investigated the use of electronic questionnaires in different patient groups; however, the benefits and disadvantages of ePROM collection have not yet been systematically explored. When transferring questionnaires from paper to electronic format, comparability is questioned. Many individual studies and several meta-analyses [7-10] have concluded that scores derived from ePROMs are equivalent to their original paper versions. In other words, scores derived from a computerized measure do not differ from scores derived from the pencil-and-paper version. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) reported 3 levels of modification (minor, moderate, and substantial) for the migration from original paper-based PROM to ePROM. The ISPOR also provides an effective strategy for testing measurement equivalence (reliability and validity). Minor modification means simply placing a paper-based scale form into a screen-based format without changing font size or altering items. Then, only a cognitive interview with 5-10 patients and a usability test is recommended. Moderate modifications are changes such as splitting single items into multiple screens, requiring the patient to use a scroll bar to see all the items or responses, or changing the order of items. With moderate modifications, equivalence testing with a randomized parallel group or randomized crossover design is advised in addition to usability testing. Major changes include removing items. With

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major modifications, full psychometric evaluation and large-scale usability testing in the target population are required [11]. However, recent evidence suggests that previous usability evidence in a representative group is sufficient to assume equivalence [12].

The ISPOR's electronic patient-reported outcome (ePRO) System Validation Task Force also developed recommendations on the validation of electronic systems used to collect PRO data in clinical trials [13]. This report enhances the understanding of different steps needed to develop ePROM. Both reports, based on expert opinion, give important insights in the development of ePROM based on the paper-version counterpart.

Hence, there is growing emphasis on ePROMs with a clear shift towards electronic data capture driven by regulatory and practical considerations [14], and patients seem motivated to use these tools as long as they provide added value and quality of care [15]. While a number of reviews have summarized the equivalence of digital questionnaires, none of these reviews systematically assessed the benefits and disadvantages of ePROM. Since more people have gained access to the internet via many types of devices, many opportunities have arisen in the eHealth ecosystem. Weighing the advantages against the disadvantages is necessary and imperative for clinical practice and research purposes. This systematic review aimed to evaluate the scientific evidence for the use of digital questionnaires to assess PROMs and more particularly describe the benefits and disadvantages.

Methods

The protocol for this review was accepted in the PROSPERO systematic review database (ID: CRD42018094795) [16]. This systematic review was conducted and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [17].

Inclusion and Exclusion Criteria

The PICO model was used to define the criteria to assess study eligibility. To be included in this review, studies had to report about questionnaires that evaluated PROMs. These questionnaires had to be in digital format (ie, tablet, computer, or mobile app). The criteria did not include a comparison; both studies comparing digital against paper formats and studies solely reporting about a digital questionnaire were included. The outcome measures described either benefits or disadvantages of digital questionnaires. This systematic review focused on the use of digital questionnaires. The scope of digital questionnaires was broad, including any web-, tablet-, computer-, or mobile-based method to assess PROMs.

To be included, articles had to evaluate ePROMs, preferably those used by general practitioners, doctors, occupational therapists, physiotherapists, or other health care workers; assess questionnaires in a digital format; compare a digital questionnaire with a paper-based method; describe either benefits or disadvantages of a digital questionnaire; or describe a randomized controlled trial or cohort, case-control, longitudinal, descriptive, or qualitative research.

Articles were excluded when the questionnaire was not used in the health care setting, it did not describe one of the listed aspects or clinical parameters mentioned in the keywords, or it described a review, meta-analysis, case study, or case report.

Information Sources and Search Strategy

A systematic computerized search strategy was performed in PubMed and Web of Science in October 2017. Additionally, manual screening of reference lists of relevant published literature occurred in November 2017. Neither filters nor limitations on the query were used. We searched for articles using the keywords patient related outcomes, self-management, self-reported, self-administered, questionnaire, survey, PRO, ePRO, PROM, ePROM, electronic, web-based, tablet-based, and digital questionnaires in combination with the keywords advantages, disadvantages, benefits, efficacy, acceptability, feasibility, validity, reliability, reproducibility, and response rate.

Study Selection

Two reviewers (JM and NH) searched and screened the identified records based on the eligibility criteria. Screening and selection were performed first on the title and abstract and second on the full text. Only published full-text articles in English were included.

Data Collection

The following relevant information was extracted: study description, examined ePROMs, outcome measures, and main results.

Methodological Quality

Two researchers (NH and JM) independently assessed the methodological quality. Both researchers were not aware of the other's evaluation before holding a consensus meeting. Methodological quality of the experimental studies was assessed with a 10-item checklist provided by the Dutch Cochrane Centre [18]. Observational studies were assessed with the 14-item Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies [19]. Studies with high methodological quality were given more value when making final conclusions about the advantages and disadvantages of ePROMs.

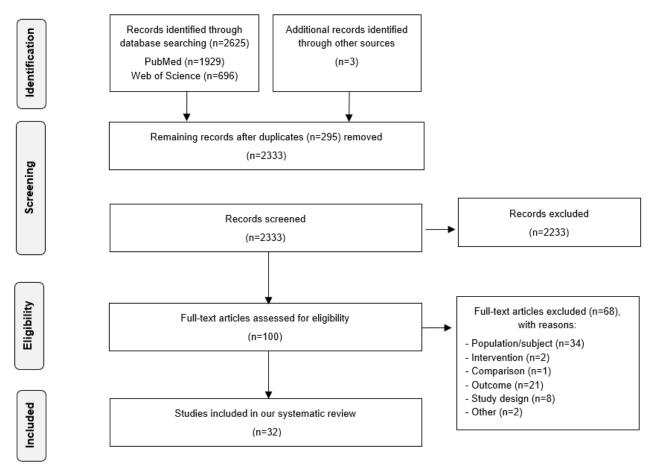
Results

Study Selection

The results of the literature search and study selection are shown in Figure 1. In summary, 2333 records were identified after removing duplicates. After screening the titles and abstracts, 100 eligible studies remained, and the full-text versions were screened. After reading the full text, 32 articles that met the predefined inclusion and exclusion criteria were included in this systematic review. Two reviewers (NH and JM) screened the identified records using the eligibility criteria. Screening was first performed based on the titles and abstracts. Full-text articles were retrieved when a record was assessed as eligible. Each full-text article was once again assessed against the inclusion criteria. Disagreements were discussed between the researches, and consensus was always achieved. The intervention of a third reviewer (UVD) was not necessary.



Figure 1. Flow diagram of the study selection process.



Study Characteristics

The results of this systematic review are based on 14 observational studies [20-33] and 18 experimental studies [34-51]. The retrieved experimental studies either compared an ePROM

versus a paper-based PROM in two separate groups [23,35,39,41,44,48,50] or compared the two modes of administration within the same groups, after randomizing in which order the modes of administration were completed [36-38,40,42,43,45-47,49,51].

The populations varied from healthy people [31,36,39,44,49] to patients with a certain condition or disease [20-22,24-30,32-35,38,40,41,43,45,51]. We did not differentiate the results by population since the goal was to systematically evaluate all possible advantages and disadvantages of ePROMs

regardless of the population. Most articles were found in the field of cancer research (9/32) and musculoskeletal research (10/32).

Overall, the included studies represented 11,006 individuals (mean age 49 years, range 13-93 years) exposed to an ePROM or asked their opinion about it. Not all studies [30,31,38,51] reported the ratio between male and female participants, meaning the sex of 3038 of the 11,006 participants was unknown. Based on the available data, 61% (4827/7968) of the subjects were female, and 39% (3141/7968) were male.

The different ePROM modalities were personal digital assistants (2/32, 6%), smartphones (2/32, 6%), tablets (14/32, 44%), computers (9/32, 28%), or not specified (5/32, 16%). Web-based systems were used the most (26/32, 81%).

The characteristics of the studies are presented in Table 1, and the results are presented in Table 2.



Table 1.	Characteristics of the studies included in the systematic review.

Study	Risk of bias score ^a	Level of evidence ^a	Population	Sample size, n (male/fe- male)	Age (years), mean (range)	Setting
[46] ^b	6/10	A2	Patients with a skin condi- tion	104 (45/59) 57 (29/28; group 1) 47 (16/13; group 2)	51.5 (20-89) 51.5 (19.3 ^c ; group 1) 51.4 (18.2 ^c ; group 2)	Outpatient clinic
[20] ^d	9/14	С	Patients post-major gyneco- logic cancer surgery	49 (0/49)	56 (23-74)	_h
[45] ^b	6/10	В	Cardiology patients	-	-	Outpatient clinic
[<mark>31</mark>] ^d	6/14	С	People from Andalucia	2493	_	At home
[41] ^b	3/10 B	В	Patients who had under- gone hand surgery	468 (216/270)	48.3 (18-91)	Private practice
[23] ^b	4/10	В	Patients in a cardiac, pul- monary, occupational, or cancer rehabilitation pro- gram	126 (56/70)	56.3	Prior to rehabilita- tion at home
[49] ^b	7/10	В	Healthy aging adults	49 (13/36)	64 (57-71)	Research center
[28] ^d	10/14	В	Patients with a cancer diag- nosis	1484 (607/877)	56.3	Inpatient reference center
[47] ^b	6/10	В	Patients with rheumatoid arthritis	40 (17/23)	65 (44-83)	In the clinic
[26] ^d	9/14	В	Patients with adjuvant and metastatic breast cancer	202 (0, 202)	54 (20-85)	Outpatient visit
[34] ^d	7/14	С	Patients with cancer pain	-	_	Outpatient oncolog clinic
[43] ^b	4/10	В	Patients with lung cancer	148 (84/64)	67 (35-81)	Community center
[29] ^d	9/14	В	Patients with sickle cell disease	15 (9/6)	26 (16-54)	At home
[25] ^d	8/14	С	Patients with multiple sclerosis	55	46.3	At home
[51] ^b	6/10	В	Patients with asthma or rhinitis	116	17-65 ^e	Clinic visit
[48] ^b	5/10	В	Patients with THR ^f or TKP ^g	100 (41/59)	67 (36.7-88)	Outpatient clinic
[32] ^d	7/14	A2	Patients with THR or TKP	565 (198/367; THR) 387 (126/261; TKR)	65.9 (10.6 ^c ; THR) 68.9 (9.7 ^c ; TKR)	At home
[50] ^b	8/10	A2	Healthy women referred for mammography	533 (0/533)	20-67 ^e	At home
[<mark>21</mark>] ^d	7/14	С	Patients with epilepsy	502 (272/230)	27.98 (15-73)	At home
[44] ^b	7/10	A2	Healthy adolescents	591 (272/319)	14 (13-17)	At school
[27] ^d	9/14	С	Geriatric patients (>70 years) with gastrointestinal cancer	37 (17/20)	77 (70-89)	Outpatient institute
[<mark>39</mark>] ^b	7/10	A2	Adolescents	933 (432/501)	14.7 (13-17)	At school
[33] ^d	9/14	С	Ambulatory neurological patients	323 (134/190)	32.2	Ambulatory clinic
[42] ^b	6/10	A2	Patients with rheumatoid arthritis, lupus, or spondy- loarthritis	153 (47/106)	45.7	Outpatient care cer ter

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Study	Risk of bias score ^a	Level of evidence ^a	Population	Sample size, n (male/fe- male)	Age (years), mean (range)	Setting
[40] ^b	6/10	A2	Patients with rheumatoid arthritis	87 (29/58)	14.7 (34-83)	Outpatient clinic
[37] ^b	6/10	В	Patients with axial spondyloarthritis	55 (45/10)	51 (34-63)	Outpatient clinic
[<mark>30</mark>] ^d	6/14	С	Dialysis patients	66	66 (36-91)	Home dialysis units
[22] ^d	10/14	С	Patients with HIV	42 (28/14)	50 (26-66)	Outpatient clinic and at home
[35] ^b	7/10	A2	Orthopedic patients (upper extremity, spine, or arthro- plasty)	483 (235/248)	55.7 (14-93)	Three subspecialty services during out- patient visits
[38] ^b	6/10	A2	Patients from an orthope- dic clinic (spine, upper ex- tremity, and trauma)	308	-	Outpatient clinic
[36] ^b	7/10	A2	Healthy volunteers	147 (68, 79)	62.7 (49-75)	At home
[24] ^d	8/14	С	Cancer patients	158 (116/42)	51.9 (22-81)	clinic and home

^aBased on the Dutch Centraal BegeleidingsOrgaan-classificatiesysteem (CBO) [52].

^bExperimental study.

^cMean (SD).

^dObservational study.

^eRange.

^fTHR: total hip replacement.

^gTKR: total knee replacement.

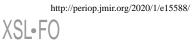
^hNot applicable.



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Table 2. Results of the studies included in the systematic review.

Study	Electronic	delivery method	ePROM ^a , outcome, and resu	ults
	Web/PC ^b	Device		
[<mark>46</mark>]	Web	Tablet	DLQI ^c	
			Preference	76% prefer electronic
			Completion time	Electronic took 9 s longer than pencil and paper (P =.008), older participants took longer (r^2 =.257, P =.012)
			Agreement	ICC ^d =.98, CI 0.97-0.99
[20]	Web	-	EORTC ^e , QLQ-C30 ^f	
			Completion rate	92% completed the first measurement, 74% completed the 6-month measurement, 82% completed ≥4 of 7 sessions
			Satisfaction and other outcomes	92% found it easy to use, 85% continued using it, 85% recommended it
[45]	Web	PC	SAQ ^g , SF-36 ^h	
			Preference	82% preferred electronic, there was no effect on preference with age, sex, race computer use, education, visual impairment, or reading level
			Completion rate	No differences in the completion rate
			Completion time	SAQ completion time: 5.53 min electronic, 4.78 min paper (P <.05); SF-36 completion time: 6.76 min electronic, 5.44 min paper (P <.05); the log-on procedure was not significantly different
			Agreement between electronic and paper	For the 5 SAQ domains $r=0.84-0.93$; for the 8 SF-36 subscales: $r=0.54-0.75$
[31]	Web	PC	-	
			Preference	83.6% preferred pencil and paper, 14.4% preferred internet
			Data completion	Unanswered questions: 9.3% pencil and paper, 4.9% internet (== t =14.85, P =.01)
			Data missing	Internet answers were more detailed than pencil and paper answers in 4 of 5 questions (P <.05)
[41]	Web	Tablet	DASH ⁱ	
			Data completion	24% of questions were unscorable with pencil and paper, compared with 2% for electronic (P <.001); electronic was more likely to be scorable (OR^{j} =13.4 P <.001)
			Data missing	Mean (SD) of 2.6 (4.4) with pencil and paper vs 0.1 (0.8) with electronic (P <.001), electronic format had an inverse relationship with omitted question (beta=-0.358, P <.001)
[23]	Web	-	PAM-13 ^k , MacNew ^l , FQ ^m	, EORTC, QLQ-C30, HADS ⁿ
			Demographic factors	Preferred electronic over paper: younger age (P =.008), married/cohabitating (P =.004), internet available (P <.001), educated (P =.092)
			Preference	77.8% prefer web-based forms
			Completion time	Web-based, ~9.5 min; paper-based, ~24 min
			Data completion	Inadequate responses did not exist for the web version due to the system desig
			Data missing	Fewer total data points missing on paper-based forms than on web-based form $(P < .001)$
[<mark>49</mark>]	Web	Tablet	PASE ⁰ , BARSE ^p , PSQI ^q	
			Demographic factors	Factors affecting preference of electronic vs paper: daily computer use, per- ceived ease of use, reported anxiety while completing the digital questionnai (all P <.05)
			Preference	Electronic preferred over pencil and paper (z=4.96, SE 3.428, P<.001)



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Study	Electronic	delivery method	ePROM ^a , outcome, and resu	lts
	Web/PC ^b	Device		
[28]	PC	Tablet	EORTC, QLQ-30	•
			Completion rate	Completion rate 43%-58% from 2005-2010, <20% since 2011 (ePRO ^r)
			Adherence and compli- ance	Pencil and paper associated with non-completion (OR=2.72, <i>P</i> <.001) and poor adherence (OR=2.23, <i>P</i> <.001), male sex associated with poor adherence (OR=1.69, <i>P</i> =.010)
[47]	PC	PC	RAQoL ^s	
			Satisfaction	Electronic > P-P (P =.003)
			Preference	64% prefer electronic
			Completion time	Pencil and paper, 6 min; electronic, 5 min P =.194
			Agreement between electronic and paper	ICC=.982
[26]	Web	Tablet	EORTC, QLQ-C30	
			Attitude/ willingness	92.3% of those exposed to both electronic and paper vs 59% of those exposed only to paper (P =.001) were willing; patients exposed only to paper more likely to report barriers: data privacy (P =.003), technical knowledge (P =.02), discomfort using technology (P =.02), no internet (P =.05)
[34]	Web	Tablet	-	
			Adherence	Patient adherence: 76.8% for pain monitoring, 50.4% for medication monitoring, and 100% for education
			Satisfaction	Limited effort, comfortable, education session appreciated, added value with self-management, medication overview with reminders was supportive
			Experience	Measured using a Likert scale, mean (SD): learnability, 4.8 (0.4); usability, 4.8 (0.5); desirability, 4.6 (0.4); and would recommend app, 4.8 (0.4)
[43]	PC	PDA ^t	LCSS ^u	
			Satisfaction	98% of patients reported it acceptable and easy to use, 80% learned it in $<\!\!3$ minutes, 100% of nurses and 86% of physicians said it's easy to use
			Completion time	Electronic, 2.2 min; pencil and paper, 3-5 min
			Agreement between electronic and paper	Pearson $r=0.92$, ICC=.92, Lin's CCC ^v =.92
[29]	Web	iPhone, iPad, or iPod	Pain VAS ^w	
			Completion rate, adher- ence, compliance	Compliance decreases over time, >35 years old had increased compliance (P <.05), compliance greater with iPad than iPhone (P <.0025), technical difficulties decreased compliance (P <.0025),
			Demographic factors	Information technology comfort level had no impact on adherence
			Agreement	iPhone, ICC=.99 (95% CI 0.92-1.00); iPad, ICC=.97 (95% CI 0.88-0.99)
[25]	Web	-	MSIP ^x , MSQoL-54 ^y , MFIS	S-5 ^z , LMSQoL ^{aa}
			Other symptom insights	46% have greater insights into symptoms; 18% feel better able to handle symptoms; 65.4% feel it's important for other health care professionals to have access; advantages include availability, overview of symptoms, gain insights, forced to reflect, look back on history; disadvantages include it's tiring, lot of work, complicated, repeated questions, grammatical errors, no space for free text, monthly completion, login problems, not used friendly, data aren't used by physician
[51]	Web	PDA	AQLQ ^{bb} , ACQ ^{cc} , RQLQ ^{dd}	1
			Agreement between electronic and paper	AQLQ (<i>P</i> =.009), ACQ (<i>P</i> =.12), RQLQ (<i>P</i> =.05)
[<mark>48</mark>]	Web	Tablet	WOMAC ^{ee} , FJS-12 ^{ff}	



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Study	Electronic	delivery method	ePROM ^a , outcome, and resu	lts
	Web/PC ^b	Device		
		•	Completion time	WOMAC: pencil and paper 170 s, electronic 117 s (<i>P</i> <.001); FJS-23: pencil and paper 22 s, electronic 37 s (<i>P</i> <.001)
[32]	Web	-	SF-36	
			Preference	THR ^{gg} 81.8% preferred pencil and paper (CI 78.8-84.7), TKR ^{hh} 86.8% pre- ferred pencil and paper (CI 83.1-89.8)
			Demographic factors	Preferred electronic over paper: younger age (P <.001), male sex (P <.001), higher education level (P <.001), higher BMI (P =.004)
[50]	Web	PC	SF-36, MFI-20 ⁱⁱ , HADS	
			Completion rate	73.2% with pencil and paper vs 17.9% with internet: difference of 55.3 (48.3-62.3); after a reminder: 76.5% with pencil and paper vs 64.2% with internet: difference 12.2 (4.5-20)
			Preference	55.4% prefer pencil and paper
			Data completion, miss- ing data	63.4% data completion with pencil and paper vs 97.8% with internet (P <.001): difference 34.5 (26.6-42.3)
[21]	Web	Smartphone	MMAS-8 ^{jj}	
			Demographic factors	Preferred electronic over paper: younger age (P =.002), live in the city (P <.001), higher education level/stable employment (P <.001), more seizures (P =.01), lower medication adherence and own a smartphone (P =.001)
			Attitude/willingness	65.5% would use it if it was free, 72.3% if it was easy to operate, 59% think it decreases medical visits and related costs, 71.7% say privacy must be protected
[44]	Web	PC	KIVPA ^{kk}	
			Preference	Mean (SD) pleasantness: 2.7 (0.9) for pencil and paper vs 3.0 (0.8) for internet (P <.01); mean (SD) difficulty: 3.6 (0.7) for pencil and paper vs 3.9 (0.7) for internet (P <.01)
[27]	PC	Tablet	CSGA ^{II}	
			Feasibility in older pa- tients	≥50% unable complete without assistance (reason: computer illiteracy)
[<mark>39</mark>]	Web	PC	CHQ-CF ^{mm}	
			Data completion, miss- ing data	0.54% with paper vs 0.04% with internet (P <.01)
[33]	Web	PC and tablet	EQ-5D ⁿⁿ , PHQ-9 ⁰⁰	
			Satisfaction	92.3% found it easy to use, 87.6% thought it time appropriate, 77.3% saw a perceived benefit
			Other factors affecting perception of benefit	Provider review (OR 6.56, P<.001)
[42]	Web	Tablet	FFbH ^p , BASDAI ^{qq} , SF-36	
			Experience	Older age requires more support
			Preference	62.1% prefer electronic, especially those of younger age and with increased computer knowledge (P <.01)
			Data completion	Significantly greater with electronic
			Agreement between electronic and paper	r=0.87-0.98; P>.05
[<mark>40</mark>]	PC	PC	VAS GH, VAS Pain, VAS P	PGA ^{rr} , ROAD ^{ss} , TJC ^{tt}
			Preference	86% prefer electronic
			Completion time	Electronic 7.3 min, pencil and paper 7.9 min (P =.006); older age requires greater time for both (electronic: P =.02, pencil and paper: P =.005)

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Study	Electronic	delivery method	ePROM ^a , outcome, and resu	ePROM ^a , outcome, and results		
	Web/PC ^b	Device				
			Agreement between electronic and paper	No difference between methods and high correlation (all <i>P</i> >.05, CCC>.849)		
[37]	PC	Tablet	BASDAI, BASFI ^{uu} , NRS ^{vv}			
			Preference	83.4% prefer the tablet		
			Completion time	Tablet 5.1 min, paper 7.9 min (<i>P</i> =.04)		
			Agreement	ICC>0.9 (P<.0001)		
[30]	Web	Tablet	KDQOL-36 ^{ww} , ESAS ^{xx}			
			Logistics	Internet/cellular access, link to electronic health records		
			Infection control	Hand sanitizer, stylus		
			Financials	Financial support necessary?		
			Design	Minimalistic, large font, black writing on white background, no distracting graphics, adapted to population		
[22]	Web	-	Symptom self-management	t tool for PLWH ^{yy}		
			Symptoms diminish with targeted strategies	Decreased frequency (effect size=.37) and intensity (effect size=-8.41) over time for all symptoms except diarrhea		
[35]	Web	Tablet	EQ-5D, ODI ^{zz} , NDI ¹ , HOC	OS ² , KOOS ³ , QuickDASH ⁴		
			Completion rate	No differences in unanswered questions (P>.05)		
			Preference	Satisfaction similar; however, 41.4% prefer the tablet (P<.001); total 60.38%		
			Data completion	No difference in completion rate (P=.208)		
			Completion time	No difference in the completion time (<i>P</i> >.05)		
[38]	Web	Tablet	PSS ⁵ , FFI ⁶ , ODI			
			Preference	68% prefer electronic		
			Data completion	Pencil and paper 14 times greater completion (PSS, <i>P</i> =.008), 260 times greater completion (FFI, <i>P</i> <.001), 11 times greater completion (ODI, <i>P</i> <.001)		
			Agreement between electronic and paper	Differences in patient-reported outcomes scores not significant (P>.05)		
[36]	Web	PC	Nutrinet Sante			
			Preference	92.2% prefer web; web considered more acceptable (P =.002) and with fewer barriers (P =.03)		
			Data completion	No data missing in web		
			Completion time	No significant differences in completion time		
			Cost	For a cohort of 500,000 subjects: paper €4,965,833 (€9.94/subject); web-based tool €150,000 (€0.3/subject)		
			Agreement between electronic and paper	Agreement ICC=.86-1.00 qualitative variables; ICC=.69-1.00 for 18 qualitative variables (height, weight, hip circumference, waist circumference were all different)		
[24]	Web	Tablet	EORTC			
			Preference	65.98% prefer electronic		
			Habits and attitudes	64.4% of the clinic ePROM group and 91.1% of the home ePROM group found it useful and adequate for QOL; 82.2% would appreciate discussing results with a physician		

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-		delivery method	ePROM ^a , outcome, and resu	115
Web/	PC ^D	Device	· · ·	
			Feasibility and sugges- tions	Perceived benefits included that it was always available, feeling well cared a home, and low cost; the disadvantages included that it was too impersonal an technical issues; suggestions included adjustable font size
^a ePROM: electro	nic p	atient-reported of	utcome measure.	
^b PC: personal co	mpute	er.		
^c Dermatology Li	-			
dICC: interclass		-		
^e EORTC: EORT	C: Eu	ropean Organiza	tion for the Research and Treat	ment of Cancer.
fQLQ-C30: Qual				
^g SAQ: Seattle Ai	•	-		
^h SF-36: Short Fo	•	-		
ⁱ DASH: Disabilit			der, and Hand.	
^j OR: odds ratio.	100 01			
^k PAM-13: Patien	t Act	vation Measure	short form.	
			lth-related Quality of Life ques	stionnaire
^m FQ: Fatigue Qu			and related Quarty of Elic ques	
ⁿ HADS: Hospita			ion Scale	
^o PASE: Physical		•		
^p BARSE: Barrier		•	Elderry.	
^q PSQI: Pittsburg		-		
^r ePRO: electronic				
	-	-	of Life Questionnaire.	
		-	of Life Questionnaire.	
^t PDA: personal d	-			
^u LCSS: Lung Ca			•	
VCCC: concordat			ient.	
WVAS: visual ana	-			
^x MSIP: Multiple		-		
^y MSQoL-54: Mu				
^z MFIS-5: Modifi				
aaLMSQoL: Lee		1		
^{bb} AQLQ: Asthm				
^{cc} ACQ: Asthma		-		
	5		of Life Questionnaire.	
			faster Universities.	
ffFJS: Forgotten.				
^{gg} THR: total hip				
^{hh} TKR: total kne	-			
ⁱⁱ MFI-20: Multid	imens	sional Fatigue In	ventory.	
^{jj} MMAS-8: Mori	•			
			t voor Psychosociale Problema	tiek bij Adolescenten.
^{ll} CSGA: Cancer-	Speci	fic Geriatric Ass	essment.	
^{mm} CHQ-CF: Chi	ld He	ealth Questionnai	ire-Child Form.	
ⁿⁿ EQ-5D: Europ	ean Q	uality of Life-5 I	Dimensions (General Health).	
^{oo} PHQ-9: Patient		-		
^{pp} FFbH: Hannov	er Fu	nctional Ability	Questionnaire.	
^{qq} BASDAI: Bath	Ank	ylosing Spondyli	tis Disease Activity Index.	
^{rr} PGA: Patient G	lobal	Disease Activity	·.	
^{ss} ROAD: Recent	-Onse	et Arthritis Disab	ility Index.	
ttTJC: tender joir	it cou	nt.		
^{uu} BASFI: Bath A	nkyle	osing Spondylitis	Functional Index.	
^{vv} NRS: numeric	-			

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wwKDQOL-36: Kidney Disease Quality of Life Instrument.

^{xx}ESAS: Edmonton Symptom Assessment System.

^{yy}PLWH: people living with HIV/AIDS.

^{zz}ODI: Oswestry Disability Index.

¹NDI: Neck Disability Index.

²HOOS: Hip Disability and Osteoarthritis Outcomes Score.

³KOOS: Knee Injury and Osteoarthritis Outcomes Score.

⁴QuickDASH: abbreviated version of Disabilities of the Arm, Shoulder, and Hand.

⁵PSS: Perceived Stress Scale.

⁶FFI: Foot Function Index.

⁷None mentioned in particular.

Methodological Quality

The risk of bias scores and the level of evidence, based on the classification of the Dutch Centraal BegeleidingsOrgaan-classificatiesysteem [52], are reported in Table 1. Scores ranged from 3/10 to 8/10 for the experimental studies and from 6/14 to 10/14 for the observational studies. Level A2 evidence was determined for 10 studies [32,35,36,38-40,42,44,46,50], level B for 12 studies [23,26,28,29,37,41,43,45,47,51], and level C for 10 studies [20-22,24,25,27,30,31,33,34].

Benefits for Patients

Preference and Satisfaction

The preferred modality (electronic vs paper) was reported in 14 studies [23,25,31,32,35-38,40,42,45,50], and electronic

Figure 2. Preferred mode of form administration.

administration preferred in 11 studies was [23,25,35-38,40,42,45-47]. One study reported a significantly greater preference for the tablet-delivered questionnaires (z=4.96, SE 3.428, P<.001) [49]. Another study asked patients to rate which mode of administration was the most pleasant and least difficult to use with a Likert scale [44]. Overall, of the 16 studies that reported user preference [23,24,31,32,35-38,40,42,44-47,49,50], a preference for ePROM was reported in 13 studies [23,24,35-38,40,42,44,49]. An overview of the reported percentages can be found in Figure 2.

Additionally, 4 [23,32,42,49] of the 16 studies reported sociodemographic variables that significantly influenced the preference for electronic administration (Table 3).

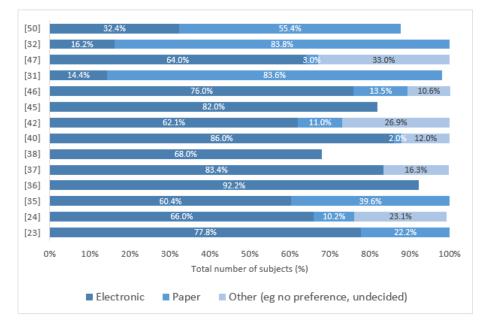




Table 3. Sociodemographic variables influencing the preference for electronic patient-reported outcome measures.

Study	Population	Significantly preferred electronic patient-reported outcome measures
Engan et al 2016 [23]	Patients in cardiac, lung, occupational, and cancer rehabilitation programs	Younger age (P =.008), married/cohabitating (P =.004), internet availability (P <.001)
Richter et al 2008 [42]	Patients with rheumatoid arthritis, lupus, or spondyloarthritis	Younger age, better computer knowledge (P<.01)
Keurentjes et al 2013 [32]	Patients post-THR ^a or TKR ^b	Younger age (P <.001), men (P <.001), higher education level (P <.001), higher BMI (P =.004)
Fanning et al 2014 [49]	Healthy aging adults (n=47)	Daily computer use (r_s =.42, P <.05), perceived ease of use (r_s =.665, P <.001), reported anxiety while completing digital questionnaires (r_s =.552, P <.001)

^aTHR: total hip replacement.

^bTKR: total knee replacement.

The satisfaction with and attitude towards ePROMs were reported in 7 studies. Most patients who were exposed to an ePROM found it easy to learn, easy to use, would recommend it to other patients, and would like to continue using it [20,21,33,34,43,47]. In a feasibility and acceptability study of a smartphone app for seizure self-management, patients with epilepsy thought ePROMs would reduce medical visits and health-related costs. Positive satisfaction levels with ePROMs were found for people who were younger (P=.002), lived in a city (P<.001), had higher education levels (P=.001), had stable employment (P<.001), had more frequent seizures (P=.01), had poor medication adherence, and owned a smartphone (P=.001) [21]. In breast cancer patients, willingness to use ePROM was higher in the group with previous experience with ePROM than in the group with previous experience with only paper PROM (92.3% and 59%, respectively, P=.001) [26]. Finally, reviewing the results with a health care professional was associated with

6.6-fold increased odds (P<.001) of perceiving systematic ePROMs as a benefit [33].

Completion Time

Time to complete electronic and paper-based questionnaires was reported in 9 studies [35-37,40,43,45-48], and 3 of these studies reported no significant differences in completion time [35,47]. In one study, however, subjects reported that the completion time for the electronic variant was more acceptable (P=.02) and was perceived as less of a barrier (P=.003) compared to the paper version [36]. Significantly lower times for the electronic variant were reported in 3 other studies [37,40,43]. Only 2 of the 9 studies reported significantly lower completion times for the paper version [45,46], owing to the longer log-on procedure required for the ePROM [45]. One study was indecisive. A detailed overview of the completion times for ePROMs were at least equal to or faster than those for paper forms.

Table 4. Completion times for electronic questionnaires, compared with the paper-based counterpart.

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Study and instrument	Time for electronic com- pletion, mean	Time for paper comple- tion, mean	P value	Remarks	
Shah et al 2016 [35]				N/A	
EQ-5D ^a	88 s	81 s	.105		
ODI ^b	145 s	143 s	.869		
NDI ^c	124 s	117 s	.716		
HOOS ^d	247 s	238 s	.829		
KOOS ^e	255 s	259 s	.916		
QuickDASH ^f	111 s	117 s	.723		
Touvier et al 2010 [36]					
NutriNet-Sante anthropometric questionnaire	v	_	.07	Time for electronic considered more accept- able (P =.02) and less a barrier (P =.003)	
Salaffi et al 2013 [37]					
BASDAI ^g , BASFI ^h , NRS ⁱ	5.1 min	7.9 min	.04	Computer skills, age, and education had no impact (<i>P</i> >.05)	
Salaffi et al 2009 [40]					
VAS ^j GH ^k , VAS Pain, VAS PGA ^l , ROAD ^m , TJC ⁿ	7.3 min	7.9 min	.006	Older age was associated with slower times for both electronic (P =.02) and paper (P =.005)	
Hollen et al 2013 [43]					
LCSS ^o	2.2 min	3-5 min	N/A	N/A	
Bliven et al 2001[45]				Not significant without the time for the log- on procedure	
SAQ ^p	5.53 min	4.78 min	<.05		
SF-36 ^q	6.76 min	5.44 min	<.05		
Ali et al 2017 [<mark>46</mark>]					
DLQI ^r	78 s	73 s	.008	Older age was associated with longer time $(r^2=.257, P=.012)$	
Greenwood et al 2006 [47]					
RAQol ^s	5 min	6 min	.194	N/A	
Kesterke et al 2015 [48]				When data entry is added, WOMAC elec- tronic signature was faster (<i>P</i> <.001) and no difference for FJS (<i>P</i> =.169)	
WOMAC ^t	117 s	170 s	<.001		
FJS ^u	37 s	22 s	<.001		

^aEQ-5D: EQ-5D: European Quality of Life-5 Dimensions (General Health).

^bODI: Oswestry Disability Index.

^cNDI: Neck Disability Index.

^dHOOS: Hip Disability and Osteoarthritis Outcomes Score.

^eKOOS: Knee Injury and Osteoarthritis Outcomes Score.

^fQuickDASH: abbreviated version of Disabilities of the Arm, Shoulder, and Hand.

^gBASDAI: Bath Ankylosing Spondylitis Disease Activity Index.

^hBASFI: Bath Ankylosing Spondylitis Functional Index.

ⁱNRS: numeric rating scale.

^jVAS: visual analogue scale.

^kGH: global health.

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¹PGA: Patient Global Disease Activity.
^mROAD: Recent-Onset Arthritis Disability Index.
ⁿTJC: tender joint count.
^oLCSS: Lung Cancer Symptom Scale.
^pSAQ: Seattle Angina Questionnaire.
^qSF-36: Short Form-36.
^rDLQI: Dermatology Life Quality Index.
^sRAQoI: Rheumatoid Arthritis Quality of Life Questionnaire.
^tWOMAC: Western Ontario and McMaster Universities.
^uFJS: Forgotten Joint Score.
^vNo statistically significant difference between ePROMs and paper PROMs in unanswered questions or complete questionnaires.

Benefits for Health Care Workers or Centers

Cost

Engan et al [23] calculated and compared the human resource (HR) costs, specifically the time spent by an employee preparing, receiving, and handling data, of web-based and paper-based questionnaires. The mean HR cost for the web version was 9.5 minutes, whereas the mean HR cost for the paper version was 24 minutes.

Based on a cohort of 500,000 subjects [36], the financial costs of a paper-based questionnaire were calculated, including printing, mailing, returns, and double data entry. In total, it cost €4,965,833 (⊕.94/subject) to use a paper-based version. In comparison, the development of a web-based tool by professionals was estimated to cost only €150,000 (€0.3/subject) or just 3% of the amount of the paper version.

Overall, these results indicate that digital data collection is less expensive, especially with large sample sizes, and it reduces HR-related costs.

Data Quality and Completion

Of the 10 studies [23,31,35,36,38,39,41,42,45,50] that reported on missing and incomplete data, 7 studies [23,31,36,38,39,41,50] indicated that electronic methods are associated with less missing data and more complete data. Integrated controls embedded in their ePROM administration was reported by 3 articles [23,35,36]. When a question wasn't answered, an alert message provided the option to revise the answer prior to submission. As such, data entry mistakes in the form of missing, inconsistent, or abnormal values could theoretically be reduced to zero [23,36]. Regarding unanswered questions or incomplete questionnaires, 2 studies reported no statistically significant differences between ePROMs and paper PROMs [35,45]. One study [42] found significantly more missing items in the electronic version. And, one study reported that the answers were more detailed in 4 of 5 open questions on their electronic questionnaire (P < .05) [31]. Details of these results can be found in Table 5. Based on these results, we conclude that data quality is higher with ePROMs.

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Table 5. Data quality of electronic questionnaires compared to their pencil-and-paper counterpart.

Study and missing data, unanswered questions, or	meompiete	lorms		
Instrument and outcome unit	Electronic	Paper	P value	Remarks
Engan et al 2016 [23]				
PAM-13 ^a , MacNew ^b , FQ ^c , EORTC ^d , QLQ	2-C30 ^e , HAD	Sf		
Mean number of missing answers per patient	0.55	2.15	<.001	No inadequate responses in the web version due to integrated controls
Shah et al 2016 [35]				No difference in unanswered questions
EQ-5D ^g				
Mean number of unanswered questions	1.08	1.30	.083	
ODI ^h				
Mean number of unanswered questions	1.14	1.23	.619	
NDI ⁱ				
Mean number of unanswered questions	1	1.75	.541	
HOOS ^j				
Mean number of unanswered questions	6.7	5.5	.788	
KOOS ^k				
Mean number of unanswered questions	1.5	3.8	.220	
QuickDASH ¹				
Mean number of unanswered questions	1	1	1	
Couvier et al 2010 [36]			N/A ^m	Non-existent in web-based version due to integrate
			10/11	controls
NutriNet Sante questionnaire				
Data entry mistakes	0	82		
Missing values	0	60		
Inconsistent values	0	57		
Abnormal values	0	3		
Smith et al 2016 [38]				
PSS ⁿ				
Incomplete forms	3	29	<.001	14 times more likely to be incomplete
FFI ⁰				
Incomplete forms	0	20	<.001	260 times more likely to be incomplete
ODI				
Incomplete forms	1	10	<.001	11 times more likely to be incomplete
Raat et al 2007 [39]				
CHQ-CF ^p				
Mean % missing answers per item	0.04%	0.54%	<.01	N/A
Dy et al 2012 [41]				
DASH ^q				
Mean number of missing questions	0.1	2.6	<.001	N/A
Richter et al 2008 [42]				
FFbH ^r , BASDAI ^s , SF-36 ^t				

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Study and missing data, unanswered questions, or incomplete forms								
Instrument and outcome unit	Electronic	Paper	P value	Remarks				
Number of missing items	NR ^u	NR	<.05	N/A				
Bliven et al 2001 [45]								
SAQ ^v								
Incomplete forms	5	5	N/A	N/A				
SF-36								
Incomplete forms	4	4	N/A	N/A				
De Rada et al 2014 [31]								
SAQ								
% unanswered questions	4.9%	9.3%	<.01	N/A				
Kongsved et al 2007 [50]								
SF-36, MFI-20 ^w , HADS								
% complete forms	97.8%	63.4%	<.001	N/A				

^aPAM-13: Patient Activation Measure short form.

^bMacNew: MacNew Heart Disease Health-related Quality of Life questionnaire.

^cFQ: Fatigue Questionnaire.

^dEORTC: European Organization for the Research and Treatment of Cancer.

^eQLQ-C30: Quality of Life Questionnaire Core 30.

^fHADS: Hospital Anxiety and Depression Scale.

^gEQ-5D: European Quality of Life-5 Dimensions (General Health).

^hODI: Oswestry Disability Index.

¹HOOS: Hip Disability and Osteoarthritis Outcomes Score.

^jKOOS: Knee Injury and Osteoarthritis Outcomes Score.

^kQuickDASH: abbreviated version of Disabilities of the Arm, Shoulder, and Hand.

¹BASDAI: Bath Ankylosing Spondylitis Disease Activity Index.

^mN/A: not applicable.

ⁿPSS: Perceived Stress Scale.

^oFFI: Foot Function Index.

^pCHQ-CF: Child Health Questionnaire-Child Form.

^qDASH: Disabilities of the Arm, Shoulder, and Hand.

^rFFbH: Hannover Functional Ability Questionnaire.

^sBASDAI: Bath Ankylosing Spondylitis Disease Activity Index.

^tSF-36: Short Form-36.

^uNR: not reported.

^vSAQ: Seattle Angina Questionnaire.

^wMFI-20: Multidimensional Fatigue Inventory.

Response Rate, Adherence, and Compliance

A retrospective cohort analyzed the annual data from PROM non-completers. PROM monitoring was completed via paper until 2010, and in 2011, ePROMs were implemented. The initial rate of PROM non-completers was 43%-58%. This decreased to less than 20% since the implementation of ePROMs in 2011 [28]. One randomized controlled trial reported response rates of 17.9% in the internet group and 73.2% in the paper group. After sending a reminder, response rates were 64.2% and 76.5%, respectively (risk difference 12.2%, P=.002) [50]. Another study found no differences in completion rates between ePROMs and paper PROMs (P=.208) [35].

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There is conflicting evidence on the effect of electronic data collection on response rates and adherence. Adherence to ePROM declines over time [20,29]. The opportunity to send automated reminders (eg, email or notification) to subjects can improve response rates and compliance [20,50].

Other Benefits

The role of ePROMs in symptom management and decision making was acknowledged in multiple studies. Andikyan et al [20] and Schnall et al [22] reported that electronic symptom self-reporting was important in clinical decision making. Automated data collection and processing via ePROM can generate automated alerts to health care professionals when a

patient reports disturbing or severe symptoms [20]. It allows early detection of complications, immediate action, and potentially reduction in symptom burden, complications, and readmissions to the hospital. Furthermore, it empowers patients and improves patient-clinician communication [22,24,42]. This is facilitated by the opportunity to plot results visually with a graph or visual aids and gives both the patient and clinicians better insight in the evolution of the patient's health status [25,34,43].

ePROMs have the advantage of always being available [24,25]. There is no paper waste [34,41], and ePROMs are portable and can be used to measure across multiple devices [42,46,49]. These reported 'other benefits' originate from studies with the lowest methodological quality.

Disadvantages

As of May 25, 2018, all European organizations are expected to be compliant with the General Data Protection Regulations. This is reassurance for patients that the law is on their side when it comes to the use of their personal health data. All included articles and studies were performed before the implementation of the General Data Protection Regulations. However, privacy concerns were reported in 2 studies [21,26]. Liu et al [21] reported that the majority of patients (71.7%) thought their privacy should be adequately protected. In another study, patients were asked whether there were any barriers related to privacy and technology that would negatively influence their willingness to use ePROMs, and 30% were concerned about privacy issues. The study showed that barriers can be overcome by exposing the patients to an ePROM, which significantly influenced the willingness to participate in electronic assessments [26].

Disadvantages due to technical issues were addressed in 5 articles. The difficulty of or problems with login procedures were addressed in 3 studies [24,45]. Furthermore, technical difficulties adversely impacted compliance; patients who experienced technical difficulties completed fewer daily symptom entries (41.0%) than those who did not (76.0%) [29]. In another study, the needs and possible technological support structures were investigated. The importance of different possible support services to help complete a web-based questionnaire was assessed. Onsite support services were rated

as being moderately or highly important by 38%. Technical telephone support was rated as moderately important or very important by 52%. At least 61% would appreciate receiving direct feedback after using the ePROM app [26].

Electronic data collection may require a large initial financial investment (eg, to purchase tablets or computer infrastructure and software, equipment costs, hiring computer programmers, or accessing cellular internet) [30,36,45].

A major disadvantage of ePROM is the potential of a 'digital divide'. People who are computer illiterate, are older, or have no access to infrastructure could be disadvantaged. One study reported that more than 50% of >70 year olds were not able to complete the electronic version without assistance due to computer illiteracy; less assistance was required for patients completing the paper version [27]. In a second study, patients who needed support were significantly older [42]. The digital divide was also illustrated in another study with cancer patients. Patients who refused ePROM or chose phone calls over (home-based) ePROMs were approximately 10 years older. Patients may differ in terms of available internet, user experience, and affinity for new media. Older or computer-illiterate patients need opportunities to familiarize themselves with the devices [24]. Older patients with poorer health-related quality of life and fewer pre-existing technical skills reported barriers for ePROMs more frequently [26]. Wintner et al [24] reported that patients found ePROMs too impersonal.

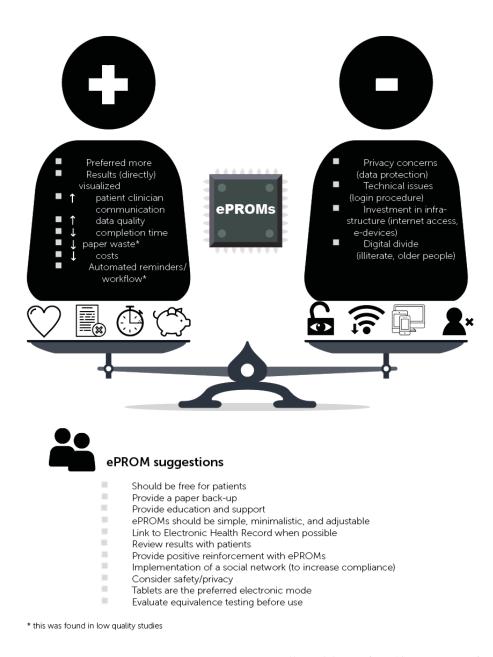
Suggestions

Suggestions and tips for ePROM apps were extracted from 12 studies [20,21,24,27,29,30,32-35,38,42]. ePROMs should be free, simple, and minimalistic. They should have a good design, good user experience, adjustable font size, and adaptable user interface. When you start implementing ePROMs, provide educational sessions or support, think of the link with electronic health records, and review the results of the ePROMs with the patients because of the increased perception of benefit. ePROMs should provide positive reinforcement for the patients. Based on our results and discussion, we created a comprehensive overview of the benefits, disadvantages, and suggestions for ePROMs (see Figure 3).



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Figure 3. Comprehensive overview of the benefits of, disadvantages of, and suggestions for electronic patient-reported outcome measures (ePROMs).



Discussion

Principal Findings

The goal of this systematic review was to systematically and critically summarize the evidence on the use of ePROMs and find the potential benefits and disadvantages. We conclude that ePROM collection is feasible and accepted in healthy people and a wide range of patients with different conditions. Taking into account the results from the strongest methodological studies and the items that were reported in multiple studies, electronic data collection is preferred over paper-based collection, costs less, improves data quality, results in similar or faster completion times, and requires less administration time. Clinical decision making in combination with adequate symptom management can be facilitated. Expressed opinions reflected positive thoughts and attitudes towards ePROMs.

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Overall, participants found it easy to use, found it easy to learn, and would recommend it to others.

Strengths and Limitations

Although our findings are generally favorable towards ePROMs, we cannot ignore the potential disadvantages. Aspects to consider are privacy protection, the one-time large financial investment, and exclusion of certain populations. Patients may be unwilling or unable to complete ePROMs due to higher age or computer illiteracy. Some patients have no internet access, do not have technological devices, or are not acquainted with technological devices. These reported disadvantages and barriers need to be considered when implementing a digital data collection tool in any population. Potential solutions may include an educational session on the use of the digital app and providing sufficient support [24,27,42]. It is also useful to at least provide back-up pen-and-paper data collection to avoid excluding

segments of the population from receiving the best possible health care [20,32]. Several suggestions to keep in mind when creating an ePROM are also mentioned in this literature review, which could increase patient experience, usability, and acceptability.

Considering the influence of age, 2 studies suggest that it is an important factor that could potentially increase completion time [40,46]. In contrast, one study found no relationships between completion time and computer skills, age, or education [37]. Older people in particular have reservations concerning modern computer technology and need to be properly approached, especially since we found that younger people had a significantly greater preference for ePROMs [23,32,42]. In our systematic review, we found that various groups of patients with a chronic disease preferred ePROMs over paper versions. On the aspect of completion time, only the time for the patient to complete the questionnaire was measured in the included articles. However, one of the greatest reported advantages of electronic data collection is automated data processing [36,38,41-43,45,49], which subsequently reduces HR time [23], and data are less prone to administration errors. Clinical-based decision-making models using daily registration of PROMs can thus be created.

The strengths of this literature review are that 32 studies concerning the research question were retrieved. Not all studies were comparative trials but assessed patient satisfaction or attitude towards a single ePROM [21,24,25,32,33]. These studies, although not methodologically the strongest, provided capital insights for the research question.

In this systematic literature search, we only searched two databases. It is, therefore, possible that we missed some clinical studies. Moreover, the limited methodological quality of some of the included studies diminished the power of the recommendations.

The overall methodological quality of the included articles was moderate. Disadvantages were a lack of blinding of participants, heterogeneity of outcome measures, heterogeneity of patient populations, different ePROM questionnaires, and different ePROM modalities/formats. Generalizing or comparing results is therefore more difficult, and the results should be interpreted with caution.

The most frequently used screen-based device was tablets. This may be because tablet screens are larger than traditional handheld devices, are easy to use, and can be used for device-based systems. They can provide access to web-based portals or can be used with downloadable apps, which makes them the primary platform for site-based (ie, hospital, care centers) ePROM collection. On the contrary, desktops usually lack touch screen functionality and require the use of a keyboard and/or mouse to respond to questions [14]. Different electronic modes were used in the different articles. The advantages and disadvantages of the different electronic modes are difficult to conclude from this study. Contrasting evidence was found in previously published literature. Two reviews reported their concerns of equivalence between different electronic modes [8,10]; however, White et al [10] found small differences in the correlations, which were not significant regardless of the electronic mode used. In clinical trials, multiple modes of

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administration may be used, and new findings may be compared to findings that used a different electronic mode of data collection. Further research is warranted regarding the influence of the electronic mode on measurement equivalence. Our findings predominantly complement those from other published literature. Belisario et al [53] conducted a review to assess the impact of apps on the quality of survey questionnaire responses and reported contradictory results regarding completion times but acknowledged that apps might improve data completeness with more complete records than paper administration. Similar to our findings, they reported that there is not enough evidence that apps impact adherence to sampling protocols. Muehlhausen et al [9] conducted a meta-analysis on the equivalence of electronic and paper administration of PROMs and showed that ePROMs yielded comparable results to those of the paper-based variant. Their findings also confirmed the ISPOR taskforce's conclusion that full psychometric testing of new ePROMs is not necessary for migrations with minor changes only [12]. For researchers and sponsors, this is a clinically and financially reassuring aspect that might facilitate the decision-making process to migrate from paper to digital data collection. The bring-your-own-device (BYOD) approach for ePROM data collection shows potential. BYOD allows participants to use their own computer device (eg, smartphone, tablet, laptop) to access and complete ePROMs [14]. However, there are still a number of issues (eg, software, security, ownership) that need to be resolved before BYOD becomes widely used.

Future Work

The importance of PROMs is widely accepted. Collecting PROMs with paper-based questionnaires requires many subsequent time-consuming steps [45] that hamper wide implementation in daily care. Electronic collection of PROMs overcomes many of these steps. The potential to collect, score, analyze, visualize, and almost instantly review the results may facilitate workflow. Clinically, we believe ePROMs will improve the interchangeability of information between health care workers, patient-clinician communication, and patient care due to its always available nature. In addition, automated data processing in combination with targeted strategies (eg, automated alerts when patients report disturbing symptoms) has major clinical implications. Clinicians and researchers will also benefit from digital data collection since it reduces administration time. Furthermore, integration of ePROMs into electronic health records may be fundamental to advancing clinical care to improve patient engagement and health outcomes.

Conclusion

Based on this study, we found multiple advantages for the use of ePROMS in several fields of care. ePROMs are preferred over paper-based forms, cost less, improve data quality, result in similar or faster completion times, reduce administration times, and facilitate clinical decision making in combination with adequate symptom management. Subjects expressed positive thoughts and attitudes towards electronic data collection. Potential disadvantages have been mapped but they are not of the magnitude to disregard ePROMs. Furthermore, suggestions have been provided to counteract the disadvantages.

This review allows researchers and clinicians to consider both the advantages and disadvantages of selecting one mode over the other. While electronic modes offer advantages for all involved parties (eg, patients, hospitals, government), implementing (new) ePROMs requires careful considerations of the implications on the study population and may require additional steps (eg, provision of internet access, acquiring electronic devices) to include participants who would be excluded otherwise.

Conflicts of Interest

None declared.

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Abbreviations

ACQ: Asthma Control Questionnaire AQLQ: Asthma Quality of Life Questionnaire BARSE: Barriers Self-Efficacy Scale BASDAI: Bath Ankylosing Spondylitis Disease Activity Index BASFI: Bath Ankylosing Spondylitis Functional Index CBO: Centraal BegeleidingsOrgaan-classificatiesysteem CCC: concordance correlation coefficient CHQ-CF: Child Health Questionnaire-Child Form CSGA: Cancer-Specific Geriatric Assessment DASH: Disabilities of the Arm, Shoulder, and Hand DLQI: Dermatology Life Quality Index eHealth: electronic health

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EORTC: European Organization for the Research and Treatment of Cancer ePRO: electronic patient-reported outcome ePROM: electronic patient-reported outcome measure **EQ-5D:** European Quality of Life-5 Dimensions (General Health) ESAS: Edmonton Symptom Assessment System FFbH: Hannover Functional Ability Questionnaire FFI: Foot Function Index FJS: Forgotten Joint Score FQ: Fatigue Questionnaire **GH:** global health HADS: Hospital Anxiety and Depression Scale HOOS: Hip Disability and Osteoarthritis Outcomes Score HR: human resource **ICC:** intraclass correlation coefficient **ISPOR:** International Society for Pharmacoeconomics and Outcomes Research KDQOL-36: Kidney Disease Quality of Life Instrument KIVPA: Korte Indicatieve Vragenlijst voor Psychosociale Problematiek bij Adolescenten KOOS: Knee Injury and Osteoarthritis Outcomes Score **LCSS:** Lung Cancer Symptom Scale LMSQoL: Leeds Multiple Sclerosis Quality of Life MacNew: MacNew Heart Disease Health-related Quality of Life questionnaire MFI-20: Multidimensional Fatigue Inventory MFIS-5: Modified Fatigue Impact Scale-5 MMAS-8: Morisky Medication Adherence Scale **MSIP:** Multiple Sclerosis Impact Profile MSQoL-54: Multiple Sclerosis Quality of Life-54 NDI: Neck Disability Index **NRS:** numeric rating scale **ODI:** Oswestry Disability Index **OR:** odds ratio PAM-13: Patient Activation Measure short form **PASE:** Physical Activity Scale for the Elderly PDA: personal digital assistant **PGA:** Patient Global Disease Activity PHQ-9: Patient Health Questionnaire-9 **PLWH:** people living with HIV/AIDS PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses **PRO:** patient-reported outcome **PROM:** patient-reported outcome measure **PSQI:** Pittsburgh Sleep Quality Index **PSS:** Perceived Stress Scale QLQ-C30: Quality of Life Questionnaire Core 30 QuickDASH: abbreviated version of Disabilities of the Arm, Shoulder, and Hand **RAQol:** Rheumatoid Arthritis Quality of Life Questionnaire **ROAD:** Recent-Onset Arthritis Disability Index **RQLQ:** Rhinoconjunctivitis Quality of Life Questionnaire SAQ: Seattle Angina Questionnaire SF-36: Short Form-36 THR: total hip replacement **TJC:** tender joint count TKR: total knee replacement VAS: visual analogue scale WOMAC: Western Ontario and McMaster Universities

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Original Paper

Preoperative Fasting Practices Across Three Anesthesia Societies: Survey of Practitioners

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Abstract

Background: Pulmonary aspiration of gastric contents is recognized as a complication of anesthesia. To minimize that risk, anesthesiologists advised fasting for solid foods and liquids for an often prolonged period of time. However, 30 years ago, evidence was promulgated that fasting for clear liquids was unnecessary to ensure an empty stomach. Despite a strong evidence base and the knowledge that fasting may be physiologically harmful and unpleasant for patients, the adoption of society guidelines recommending short fasting periods for clear fluids into clinical practice is uncertain.

Objective: This study aimed to determine the current practices of anesthetists with respect to fasting guidelines.

Methods: An electronic internet survey was distributed to anesthetists in Canada (CAN), Australia and New Zealand (ANZ), and Europe (EUR) during April 2014 to February 2015. The anesthetists were asked about fasting guidelines, their recommendations to patients for the consumption of clear fluids and solid foods, and the reasons and consequences if these guidelines were not followed.

Results: A total of 971 anesthetists completed the survey (CAN, n=679; ANZ, n=185; and EUR, n=107). Although 85.0% (818/962) of these participants claimed that their advice to patients followed current society guidelines, approximately 50.4% (476/945) enforced strict fasting and did not allow clear fluids after midnight. The primary reasons given were with regard to problems with a variable operating room schedule (255/476, 53.6%) and safety issues surrounding the implementation of clear fluid drinking guidelines (182/476, 38.2%).

Conclusions: Many anesthetists continue to follow outdated practices. The current interest in further liberalizing preoperative fluid intake will require more change in anesthesia culture.

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KEYWORDS

preoperative care; guideline adherence; practice guideline



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Introduction

A prescription for fasting before surgery is a topic that has been discussed in the literature since modern anesthesia started in 1847. In 1858, John Snow proposed that fasting would be helpful to avoid the unpleasantness of vomiting associated with anesthesia [1]. Following descriptions of regurgitation and pulmonary aspiration of gastric contents [2] later in the 19th century, it was proposed that fasting would help decrease the risk of such complications [3]. Seminal work by Maltby et al [4] in the 1980s and 1990s demonstrated that clear fluids are cleared from the stomach within 2 to 3 hours, thus negating the need for long periods of fasting. Recent evidence suggests that starvation—*nil per os (NPO, nothing by mouth) from midnight*—for clear liquids is not only unnecessary to allow for gastric emptying but could also have deleterious effects in the perioperative period [5].

In the 1990s, evidence and discussions led to proposals that the fasting-from-midnight dogma must be modified and liberalized. Maltby [6] lists 91 key references in summarizing the debate and the literature. The recommendations for liberal perioperative fasting guidelines in elective patients have gradually been adopted by numerous national societies, including the Canadian Anesthesiologists' Society, whose guidelines were modified in 1998 to include these liberal fasting policies (further changes were made in 2015 to include recommendations encouraging the consumption of clear fluids preoperatively) [7]. In Norway, similar guidelines were published in 1994 (further updated in 2005) [8], and the American Society of Anesthesiologists did so in 1999 [9]. With the development and implementation of many enhanced recovery after surgery protocols, which emphasize preoperative preparation, there is renewed interest in shortening the fasting period for clear fluids to less than that recommended by these guidelines, particularly in pediatric anesthesia. [10].

Despite the extensive knowledge base developed and the dissemination of society guidelines based upon the published science, literature suggests that adoption into clinical practice has been irregular. In Canada (CAN), many hospital departments appear to have policies unchanged from the traditional *NPO from midnight*, although it has been 20 years since the society guidelines were changed. Dr Maltby himself recently experienced a further variation of the reality of our imperfect system—he was allowed fluids in preparation for an elective operation; however, he then subsequently fasted for 20 hours when his elective procedure was *bumped* from the schedule in a major Canadian academic teaching hospital.

To review the current practices in preoperative fasting advice, we conducted an electronic survey on anesthetists from CAN, Australia and New Zealand (ANZ), and Europe (EUR). We wished to determine the current practices and perceptions surrounding fasting guidelines, whether the current guidelines are being followed and what could be preventing the uptake of these evidence-based guidelines.

Methods

Study Design

The study design and approval from the Research Ethics Board (FHREB number 2014-02) were obtained from the Fraser Health Authority (British Columbia, CAN, on March 12, 2014; chairman Dr Stephen Pierce).

A Web-based survey was designed and sent to anesthetists in 3 major practice regions: in CAN via provincial associations in the largest provinces, in ANZ through the Australian and New Zealand College of Anesthetists to a sample of fellows in accordance with their survey policy, and in EUR to the members of the European Society of Anesthesiology. This was a convenience sample of practices thought likely to be similar in the implementation of current liberal fasting guidelines based on recent literature. Before designing the survey, we reviewed the current fasting guidelines for the society in each region (see Table 1). Using these recommendations, a series of questions was developed by the authors and advisors (RM and RNM) to explore the currently prescribed preoperative fasting advice as well as the features about preoperative fasting such as the source of advice and why society guidelines might not be followed. A common thought is that variability in the time of access to the operating room (OR) will affect the actual fasting time; hence, we also asked whether and how often operations are actually moved earlier than the planned time.

The questionnaire was tested with 20 Canadian anesthesia trainees. It was implemented as a Web-based survey using FluidSurveys (now SurveyMonkey) for the CAN and ANZ participants and separately in SurveyMonkey for the EUR participants.

The survey included 13 questions on fasting experience and practices, each on a separate page, along with a collection of basic demographic and practice information. There were no mandatory questions and no completeness check. All the survey questions can be found in Multimedia Appendix 1.



Table 1. Current society guidelines.

Guidelines	Canada [11]	Australia and New Zealand [12]	Europe [13]
Minimum duration of fasting for meat, fried foods, or fatty foods	8 hours	No comment	All solid foods for 6 hours
Minimum duration of fasting for light meal or infant formula	6 hours	6 hours	All solid foods for 6 hours
Minimum duration of fasting for breast milk	4 hours	6 hours	4 hours
Minimum duration of fasting for clear fluids	2 hours	2 hours	2 hours
Active encouragement of clear fluid intake	Yes	No comment	Yes
Use of carbohydrate-rich beverages	No comment	No comment	Yes
Pharmacological intervention	No comment	Consider	Not routine
Gum chewing	No comment	No indication to cancel	No indication to cancel

Participants

The survey information and invitations were distributed to the anesthesiologists via email with the assistance of provincial anesthesia associations in CAN, the Australian and New Zealand College of Anesthetists, and the European Society of Anesthesiology. This occurred from April to May 2014 for CAN, from January to February 2015 for ANZ, and from December 2014 to August 2015 for EUR.

The invitation email explained the background and the aim of the survey, its ethical approval, the type of demographic and practice information that would be requested, that it was voluntary, that participation would imply consent, and that the responses would remain anonymous. The email included a URL to the survey, which was implemented as an open Web survey.

We did not track the number of invitations sent or whether individual anesthetists did or did not respond to the survey request, and no follow-up or reminder emails were sent.

Data Analysis

The extracted survey data were collated and analyzed in Microsoft Excel 2016 (Microsoft). All responses to each question were included in the analysis, including those from incomplete surveys. The data have been presented using descriptive statistics, with the number and percentage of respondents in each region. We have mainly reported data for the 3 practice regions separately but have not applied comparative statistics.

Results

A total of 1057 anesthetists participated in the survey, of which 971 completed the survey questions: CAN (n=679); ANZ (n=185); and EUR (n=107; Table 2).

Overall, in response to the simple question "Do your fasting instructions follow Society guidelines?," 85% of anesthetists claimed that their advice to patients followed current society guidelines: 84.6% (571/675) in CAN, 88.4% (160/181) in ANZ,

and 82.1% (87/106) in EUR (Table 3). However, preoperative fluids after midnight were encouraged by only 45.5% (300/659) CAN anesthetists, 64.1% (116/181) ANZ anesthetists, and 50.0% (53/106) EUR anesthetists. The most common reasons reported for either enforcing fasting or failing to encourage the intake of clear fluids were because of the perceived problems with a variable OR schedule (CAN 194/359, 54%, ANZ 38/64, 58%, and EUR 23/52, 44%) and safety issues related to the implementation of clear fluid drinking (182/476, 38.2%) of anesthetists across all regions). Overall, 22.9% (211/922) of anesthetists specified a maximum volume of clear fluids to patients, and 20.5% (192/935) reported encouraging a specific preoperative fluid (complex carbohydrate or electrolyte; Table 3).

Patients in ANZ and EUR are routinely allowed to take some solid food on the day of surgery, with 89.5% (162/181) of ANZ and 61.3% (65/106) of EUR patients being allowed to eat a light breakfast 6 to 8 hours before induction of anesthesia compared with only 22.5% (149/662) of CAN patients (Table 3). Only 10% to 14% of anesthetists allowed milk in tea or coffee, and a small proportion prescribed a carbohydrate or an electrolyte drink (20% to 25%) in all regions. The routine use of H₂-receptor antagonists or proton pump inhibitors in elective nonobstetric patients was low, with the highest use (10/99, 10%) in EUR (Table 3).

Operations being moved earlier than the planned time was reported to happen *frequently* by 17.4% (162/930) of anesthetists, *occasionally* by 60.7% (565/930), and *rarely* by 21.8% (203/930) overall (Table 4). These changes in schedule were deemed to cause problems *frequently* by only 5.0% (44/884) of anesthetists, *occasionally* by 41.0% (363/884) of anesthetists, and *rarely* by 54.0% (477/884) of anesthetists overall (Table 4). Overall, 31.0% (274/886) of respondents across all regions indicated that patients frequently comment on being allowed to drink preoperatively (Table 3; though the question did not specifically quantify whether these were comments on being allowed to, or being restricted from, drinking).



 Table 2. Origin of respondents.

Country or region	Respondents, n
Canada	713
Australia and New Zealand	191
United Kingdom	16
Germany	13
Italy and Spain	8 each
Belgium and Sweden	6 each
Czech Republic, France, Greece, Netherlands, Poland, Portugal, and Switzerland	5 each
Other	33

Table 3. Survey responses by region.

Survey questions	Canada	Australia and New Zealand	Europe	Total	
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	
Do your fasting instructions encourage drinking clear fluid	until 2 or 3 hours	before scheduled time of surge	ry?		
Yes	300/659 (45.5)	116/181 (64.1)	53/105 (50.5)	469/945 (49.6)	
No	359/659 (54.5)	65/181 (35.9)	52/105 (49.5)	476/945 (50.4)	
As we don't agree with the guidelines	1/359 (0.3)	1/65 (2.0)	2/52 (4.0)	4/476 (0.8)	
As too many of our patients are at high risk	24/359 (6.7)	4/65 (4.0)	0/52 (0.0)	28/424 (6.6)	
As we cannot establish a system to implement this safely	135/359 (37.6)	26/65 (40.0)	21/52 (40.0)	182/476 (38.2)	
As the operating room schedule is too variable	194/359 (54.0)	38/65 (58.0)	23/52 (44.0)	255/476 (53.6)	
Other reasons	106/359 (29.5)	22/65 (34.0)	6/52 (12.0)	134/476 (28.1)	
Do your fasting instructions routinely allow some solid food	l on the day of sur	gery?			
No solid food or milk (except breast milk) after midnight on the night before surgery	503/662 (76.0)	15/181 (8.3)	38/106 (35.8)	556/949 (58.6)	
Solid food/ <i>light breakfast</i> allowed until 8 (or 6) hours before surgery	149/662 (22.5)	162/181 (89.5)	65/106 (61.3)	376/949 (39.6)	
Other, please specify	10/662 (1.5)	18/181 (9.9)	2/106 (1.9)	30/949 (3.2)	
Do you encourage a specific preoperative fluid (complex car	rbohydrate or elec	ctrolyte) as part of your fasting/	drinking policie	s?	
Yes	131/656 (20.0)	36/180 (20.0)	25/99 (25)	192/935 (20.5)	
No	525/656 (80.0)	144/180 (80.0)	74/99 (75)	743/935 (79.5)	
Do members of your department prescribe preoperative H_2 elective surgery (not obstetric patients)?	-receptor antagoi	nists or proton pump inhibitors	in healthy patie	nts undergoing	
Routinely	21/645 (3.3)	4/174 (2.3)	10/99 (10)	35/918 (3.8)	
Only when clinically indicated	624/645 (96.7)	170/174 (97.7)	89/99 (90)	883/918 (96.2)	
Do patients comment on being allowed to drink on day of s	urgery?				
Frequently	181/624 (29.0)	56/171 (32.7)	39/91 (43)	276/886 (31.1)	
Rarely	382/624 (61.2)	102/171 (59.6)	42/91 (46)	526/886 (59.4)	
Never	61/624 (9.8)	13/171 (7.6)	10/91 (11)	84/886 (9.5)	



Table 4. Scheduling issues

Rate of event	Canada, n (%)	Australia and New Zealand, n (%)	Europe, n (%)	Total, n (%)
Occasionally operati	ons are moved earlier f	rom their slated time. In your hospital is this.	•	
Frequent	115 (18)	26 (15)	21 (21)	162 (17)
Occasional	414 (63)	107 (60)	107 (44)	565 (61)
Rare	124 (19)	45 (25)	34 (34)	203 (22)
Have such changes in	n operative time been o	bserved to cause problems?		
Frequently	27 (4)	11 (6)	11 (12)	44 (5)
Occasionally	254 (41)	47 (48)	31 (33)	363 (41)
Rarely	347 (56)	47 (46)	53 (56)	477 (54)

Discussion

Principal Findings

Our study is the largest published survey of practicing anesthetists in multiple regions and societies. In this survey of preoperative fasting practices, we established that a substantial proportion of anesthetists responding to our survey across all 3 regions impose strict fasting requirements for both solids and fluids after midnight before surgery. Problems with a variable OR schedule and safety issues related to the implementation of clear fluid drinking guidelines were the most common reasons cited for maintaining these outdated practices.

Starving from midnight seems hardly apt any more given the clear evidence supporting the consumption of clear fluids up until 2 hours before surgery [4,5] for patients not otherwise at risk of delayed gastric emptying. The current fasting guidelines [7-9] have increasingly promoted more liberal advice to the consumption of fluids before surgery. Despite this, it seems that clinical practice in large part lags behind the evidence and society guidelines. Although 85% of anesthetists indicated that they follow the current fasting guidelines, only 54% of anesthetists in CAN and EUR reported allowing the consumption of clear fluids 2 to 3 hours before the surgery.

With regard to solid foods, a greater proportion of ANZ anesthetists allowed some solid food on the day of surgery compared with anesthetists from EUR and especially CAN. Most clinicians in ANZ and EUR allow a light breakfast on the morning of the surgery. This may be because of the difference in the manner of OR scheduling. Many European and Australian OR suites have fixed morning and afternoon lists which are usually not changed and which allow a clear period of fasting after consumption of a meal (in comparison with CAN where OR procedure schedules are typically booked for a whole day). Despite this, the practice of allowing fluids until 2 to 3 hours before surgery is similar among regions at only approximately 50%.

Although the most commonly cited reason for not adhering strictly to the society guidelines was the variability in the OR schedule; 83% of respondents stated that such changes happened only occasionally or rarely. The second most common reason quoted, by 36% of respondents, was that "we cannot establish a system to implement this safely." Changes to the OR schedule were reported to cause a problem *frequently* in less than 5% of

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cases, which is somewhat inconsistent with the safety concern. It is certainly the case in the Royal Columbian Hospital in CAN that cases are rarely pushed up so far as to cause a problem with fasting for fluids (RN Merchant, unpublished data).

The risk to which these responses refer is presumably vomiting and pulmonary aspiration of gastric contents, to which John Snow referred in 1858, as quoted by Maltby [6]:

In his 1858 book on chloroform, he again commented on the unpleasantness of vomiting, but not on its danger: 'chloroform is very apt to cause vomiting, if inhaled while there is a quantity of food in the stomach. The sickness is not attended with any danger but it constitutes an unpleasantness and inconvenience which it is desirable to avoid.'

However, the risk of aspiration is being reexamined by many authorities, particularly in pediatric anesthesia. Beach et al, representing the Pediatric Sedation Research Consortium (PSRC), analyzed the PSRC database and reported an aspiration rate of 8 cases among 82,546 patients who fasted and 2 cases among 25,401 patients who did not fast [14]. Brady et al, in a Cochrane review of 22 studies, found that different fasting regimens were not associated with differences in complications and patients who had consumed fluids preoperatively had the same or smaller residual gastric volume and there was no difference in complications but greater patient satisfaction [15].

Adopting more liberal fasting guidelines will not necessarily translate to equivalent reductions in actual fasting times. Implementation issues include poor quality of available information, especially from internet-based resources [16]; misunderstanding of guidance by the patients (a concern among some of the respondents in our survey); and patients' own (mis)perceptions that fasting is better. In Brazil, de Aguilar-Nascimento et al in the aptly named BIGFAST study reported that the actual median preoperative fasting time was 12 hours [17]. The fasting time was longer in hospitals using an older fasting protocol than in those that had adopted new guidelines, but 80% of the patients were operated on after 8 or more hours of fasting and 46% after more than 12 hours. Similarly, in South Africa, Lamacraft et al found that the median duration of fasting was 14 hours for solids and over 13 hours for oral fluids, despite fasting guidelines similar to those quoted for our regions [18].

Results such as these are not limited to the developed world. Njoroge et al reported the results of a survey of patients and providers in Kenya that showed that most patients believed they should fast, although only 25% of the providers prescribed a 2-hour fast for fluids [19]. Similarly, Gebremedhn et al reported that although Association of Anesthetists of Great Britain and Ireland guidelines were in place in their Ethiopian hospital, 95% of the patients fasted for fluids for longer, with a mean of 19 hours [20].

Our review did not determine the actual fasting times in our countries, but it is clear that the effort must go beyond promoting guidelines. The adoption of quality improvement methods may provide a useful strategy for changing practice as demonstrated in a recent initiative in a pediatric setting [21]. Indeed, fasting protocols and practices have become a priority debate in the pediatric anesthesia literature [22,23], and it seems likely that more liberal fasting practices may have particular benefit in children [24,25]. One novel approach may be to provide patients with fluids after they are admitted to hospital. Allowing patients to drink until they were transferred to the OR appeared to reduce postoperative nausea and vomiting without apparent evidence of harm [26] and provided further evidence that even a 2-hour fluid fast may be excessively conservative.

Limitations

There are several limitations to the study. First, our results are based on a self-reporting group of anesthetists and represent a small proportion of the total number of practicing physicians from each region. This relatively small sample size limits our ability to make accurate comments on the differences among regions; however, it still allows us to analyze how a group of anesthetists across the Western world view how they are practicing in the modern era. We sent only 1 invitation to the survey and did not track the respondents or those who failed to respond.

Second, the surveys were distributed at different times because of constraints in the survey distribution. This could have changed how physicians responded because of new literature being presented or the greater adoption of guidelines. However, the society guidelines in each region did not change during our survey distribution, so it is unlikely that these would cause large swings in the anesthesia practice.

Finally, the perception of anesthesiologists may not be the actual advice given to patients as a significant proportion report that the clinic paramedical staff and surgeons give advice. We did not review the advice given by those sources. We have not posted our data on a Web resource.

Conclusions

Preoperative fasting as a protective maneuver from pulmonary aspiration of gastric contents has been discussed since 1848, but the guidelines developed in the 1950s swayed for many years and, in large part, continue to do so despite the evidence-based research and updated guidelines presented over the last 30 years. A substantial and clinically important number of anesthesiologists from our sample of practitioners from CAN, ANZ, and EUR continue to follow practices that have been replaced by guidelines and standards based on research from the 1980s and 1990s. Many believe that these practices are unpleasant and potentially harmful to patients [10]. The current interest in liberalizing fluid administration even further will require a further change in the culture of anesthesia practice on an ongoing basis.

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Conflicts of Interest

OL has consulted with Nutricia, Abbot, and Advanced Medical Nutrition and has received travel and speaking honoraria from Fresenius-Kabi, Merck, Medtronic, B Braun, and Nutricia.

Multimedia Appendix 1

Survey questions of preoperative fasting practices across 3 anesthesia societies. [DOCX File, 22 KB - periop_v3i1e15905_app1.docx]

Multimedia Appendix 2

Presentation of our work at the IARS Annual Meeting in 2015 in Honolulu Hawaii. [PPT File (Microsoft PowerPoint Presentation), 1809 KB - periop v3i1e15905 app2.ppt]

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Abbreviations

ANZ: Australia and New Zealand CAN: Canada EUR: Europe NPO: nil per os OR: operating room PSRC: Pediatric Sedation Research Consortium

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Economic Advantages of Telehealth and Virtual Health Practitioners: Return on Investment Analysis

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Abstract

Background: Telehealth is a disruptive modality that challenges the traditional model of having a clinician or patient physically present for an appointment. The benefit is that it offers the opportunity to redesign the way services are offered. For instance, a virtual health practitioner can provide videoconference consultations while being located anywhere in the world that has internet. A virtual health practitioner also obviates the issues of attracting a specialist medical workforce to rural areas, and allows the rural health service to control the specialist services that they offer.

Objective: The aim of this research was to evaluate the economic effects of 3 different models of care on rural and metropolitan hospital sites. The models of care examined were patient travel, telehealth using videoconferencing, and employment of a virtual health practitioner by a rural site.

Methods: Using retrospective activity data for 3 years, a return on investment (ROI) analysis was undertaken from the perspective of a rural site and metropolitan partner site using a telehealth orthopedic fracture clinic as an example. Further analysis was conducted to calculate the number of patients that would be required to attend the clinic in each model of care for the sites to break even.

Results: The only service model that resulted in a positive ROI for the rural site over the 3-year period was the virtual health practitioner model. The breakeven analysis demonstrated that the rural site required the lowest number of patients to recoup costs in the virtual health practitioner model of care. The rural site was unable to recoup its costs within the travel model due to the lack of opportunity for reimbursement for services and the requirement to cover the cost of travel for patients.

Conclusions: Our model demonstrated that rural health care providers can increase their ROI by employing a virtual health practitioner.

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KEYWORDS

clinical services; e-health; health economics; health funding and financing; rural and remote health; workforce

Introduction

Telehealth is a disruptive modality that challenges the traditional model which requires the clinician and patient to be physically present for an appointment. It is widely accepted that telehealth increases patient access, increases productivity potential for clinicians, and potentially reduces costs for service providers

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[1-4]. Although it is disruptive, telehealth often seeks to emulate traditional service models. For example, when a rural and remote service cannot provide specialist care, the patient is traditionally transported to a metropolitan partner facility; with telehealth, patients can access specialist care from the same metropolitan partner facility without having to travel.

Telehealth represents a valuable opportunity to redesign health service models in Australia. In one potential redesign, rural and remote health services can employ virtual health practitioners. A virtual health practitioner is an employee who works remotely but is otherwise considered to be a regular employee of the organization [5]. The standard telehealth model often functions by connecting two sites: one site employs a specialist health practitioner, and the other site requires a consultation from that specialist. The virtual health practitioner model enables the site that requires a specialist health practitioner to employ that staff resource directly. Use of telehealth by virtual health practitioners to provide specialist services has been previously reported; however, the economic advantages of telehealth for these sites have not been investigated [6].

Assuming regulatory requirements are met, a virtual health practitioner can be located at any site that has internet access, including metropolitan and rural areas. A virtual health practitioner can reduce patient travel and associated costs, which is of particular interest when travel is subsidized by the health care provider. Furthermore, employing virtual health practitioners can obviate the difficulty of attracting medical specialists to rural areas and can allow the health service employing the specialists to control their specialist workforce and the services they offer [7].

Using an orthopedic fracture clinic as an example, this research explores the economic impacts of 3 different models of care: telehealth using videoconferencing (rural site to metropolitan partner), patient travel (rural site to metropolitan partner), and employing a virtual health practitioner at a rural site. The aim of this study was to evaluate the costs and ROI for rural and metropolitan sites for each of the 3 models of care.

Methods

An analysis of return on investment (ROI) was undertaken from the perspectives of a rural site and a metropolitan partner site. Ethics approval was obtained from the Metro South Human Research Ethics Committee, HREC/17/QPAH/438.

Setting

The state health department in the Australian state of Queensland is divided into 16 hospital and health services (HHSs). Some of these HHSs are located in metropolitan areas and provide a wide range of specialist services. In addition, some HHSs are located in rural and remote areas, where recruitment and retention of health care professionals can be difficult [2]. Patients are transferred to a metropolitan HHS when the rural HHS cannot provide specialty care.

This example is based on a consultant-led fracture clinic using real-time video consultations between a tertiary facility, Princess Alexandra Hospital, which is located in metropolitan Brisbane (the capital city of Queensland), and Mount Isa Hospital, which is located in remote Queensland. A pilot study examining the cost-effectiveness of this clinic demonstrated substantial cost savings for the remote HHS [8,9]. Prior to the introduction of telehealth, fracture clinic patients were required to drive or be transported to Townsville Hospital (approximately 900 kilometers from Mount Isa Hospital).

Mount Isa Hospital is part of the North West HHS, which spent approximately A\$16.6 million on patient transport in the 2016-2017 financial year, accounting for 9.4% of their spending [10]. Since only a small proportion of patients (17% in the 2016-2017 financial year) received a subsidy for their travel, these costs do not represent the full societal burden of patient travel for health care services. The Queensland Health Travel Subsidy Scheme eligibility criteria now state that individuals are only eligible for subsidized travel if they are "unable to use telehealth to access the required eligible specialist medical service" [11].

Data Collection

Retrospective data for the Metro South HHS telehealth orthopedic fracture clinic for the financial years of 2014-2015, 2015-2016, and 2016-2017 were accessed from the hospital data repository (Table 1).

Table 1. Telehealth activity reported for the orthopedic clinic during the 2014-2015, 2015-2016, and 2016-2017 financial years.

Financial year	Total patients, n	Clinics, n	New patient bookings, n (%)	Review patient bookings, n (%)	Adult patient bookings, n (%)	Pediatric patient bookings, n (%)	Failed to attend, n (%)
2014-2015	321	31	175 (55)	146 (45)	279 (87)	42 (13)	53 (17)
2015-2016	1235	82	686 (56)	549 (44)	776 (63)	459 (37)	321 (26)
2016-2017	1136	82	612 (54)	524 (46)	915 (81)	221 (19)	318 (28)

Clinic attendance information was used to calculate the costs and ROIs of three different care models: a videoconference telehealth model (the patient at Mount Isa Hospital contacts a specialist at Princess Alexandra Hospital), a travel model (the patient travels to Townsville Hospital for a telehealth consultation), and a virtual health practitioner model (the patient at Mount Isa Hospital contacts a remote virtual practitioner employed by Mount Isa Hospital). The involved hospitals, descriptions of the service models, costs, and income for each care model are outlined in Table 2.



Table 2. Details of the three examined models of care.

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Characteristic	Telehealth clinic	Patient travel	Virtual health practitioner
Involved hospitals	Mount Isa Hospital (small remote hospi- tal) and Princess Alexandra Hospital (tertiary metropolitan hospital)	Townsville Hospital (large regional hospital)	Mount Isa Hospital (small remote hospital)
Service model description	A videoconference is held between the patient at Mount Isa Hospital and a spe- cialist at Princess Alexandra Hospital. The specialist is employed by Princess Alexandra Hospital.	Patients travel from their home to receive in-person care at Townsville Hospital, which is the nearest hospi- tal that provides orthopedic services.	Mount Isa Hospital directly employs a specialist to conduct videoconference consultations with patients located at Mount Isa Hospital. The specialist is located in a different geographical loca- tion from Mount Isa.
Cost allocation	Mount Isa Hospital pays for local staff (eg, nurse, resident medical officer) and also pays Princess Alexandra Hospital for the specialist and administration staff time. Princess Alexandra Hospital pays for the clinical assistant for the specialist and for the remaining administration time.	Townsville Hospital pays for local staff as normal. Mount Isa Hospital pays to subsidize patient travel for individuals who claim from the Queensland Health Patient Travel Subsidy Scheme.	Mount Isa Hospital pays for all costs.
Income	Princess Alexandra Hospital claims ac- tivity-based funding reimbursement as the telehealth provider. Mount Isa Hospi- tal claims activity-based funding reim- bursement as the telehealth recipient.	Townsville Hospital claims activity- based funding reimbursement for the appointment as the consultation provider.	Mount Isa Hospital claims activity- based funding reimbursement for the appointment as the telehealth provider.

Cost Analysis

In ROI analysis, the cost-to-benefit ratio is calculated by dividing the total net benefit by the total cost, allowing outcomes to be expressed in terms of percentage of gain relative to cost [12]. To calculate the ROI in this study, the total cost was based on the costs of human resources and patient-subsidized travel, and the net benefit was determined from the activity-based funding each site received for each nonadmitted outpatient event.

All human resource costs were calculated using published wages for the 2016-2017 financial year [13], and on-costs were added according to the workplace agreements (23% extra for medical officers and 29% extra for all other staff). To calculate wages for previous years, a discount rate of 2.5% per year was used in accordance with Queensland Health workplace agreements. Income for each site was calculated by assuming that 100% of patients who attended appointments received the applicable activity-based funding. Activity-based funding rebates were based on the appropriate National Weighted Activity Unit (NWAU) code for the respective years, taking into account whether the event was a new or review case [14]. NWAU 20.29 was claimed by the provider site where the consultant was located, while NWAU 40.16 was claimed by the provider site where the patient and support clinical staff were present. NWAU funding rates do not discriminate between new and review appointments, unlike the Queensland Weighted Activity Unit (QWAU) values, which were unavailable [15]. Failure to attend (FTA) rates were assumed to be the same across the 3 models. All prices are reported in Australian dollars (US \$0.62) and have not been converted to 2018 prices, as they represent the cumulative economic implications for a 3-year period.

Travel subsidy costs were calculated assuming that 17% of the non-FTA population for each financial year received subsidized

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travel. Although the majority of patients are eligible to claim the travel subsidy, very few take advantage of the subsidy. The selection of 17% was based on the 2016-2017 annual report from the North West HHS, in which Mount Isa Hospital is situated [16]. An average travel cost of A\$1447 per individual receiving the subsidy was assumed based on the 2016-2017 annual report, which stated that A\$14.48 million was provided in patient travel subsidies to support 8623 patients. The travel amount was discounted by 2.5% per year for the two prior financial years, in accordance with local policies [16].

Breakeven Point

Using the calculations of cost per clinic, it is possible to calculate the breakeven point (ie, the minimum number of patients required per clinic to cover the cost of the service provision for that site). The breakeven point is the point at which the cost of running the outpateint clinic is negated by the income received from the appointments conducted. As FTA appointments do not yield income, they do not count toward the number of appointments required to break even.

Sensitivity Analysis

To investigate the uncertainty, we performed a sensitivity analysis. The income for each site was recalculated assuming 10% and 35% FTA rates. To investigate the effects of travel reimbursement, the population with subsidized travel was increased from 17% to a hypothetical 25%. Additionally, using the base case figures, we calculated the number of appointments required for each clinic to break even and cover its costs.

Results

Cost Analysis

Given the costs for providing each model of service, a cumulative 3-year net benefit was calculated for each site (Table

3). The analysis demonstrated that the only service model that resulted in a positive ROI for the rural site was the virtual health practitioner model of care.

The highest net benefit for the rural Mount Isa site was demonstrated for the virtual health practitioner model, followed

by the telehealth model (Table 4). The benefits were higher compared to the patient travel model, where the site bears all the costs and does not generate any income. If patient travel reimbursement is increased from the assumed 17% of travel costs to 25%, the travel costs for this single outpatient clinic are approximately A\$1 million.

 Table 3. Human resource costs associated with the 3 models of care at each clinic.

Site and staff role	Hourly rate, A\$	On-cost	Hours required per clinic	Cost, A\$
Felehealth clinic				
Princess Alexandra Hospital				
Radiographer	50.61	0.29	4	261.13
Administration (organization and clinic)	34.88	0.29	2	89.99
Total				351.12
Mount Isa Hospital				
Orthopedic specialist	134.57	0.23	4	662.08
RMO ^a	59.35	0.23	4	292.00
Nurse	39.20	0.29	4	202.25
Administration (organization and clinic) + 2 hours paid to Princess Alexandra Hospital	34.88	0.29	10	449.96
Plaster technician	28.73	0.29	4	148.23
Total				1754.52
Patient travel				
Townsville Hospital				
Orthopedic specialist	134.57	0.23	4	662.08
Radiographer	50.61	0.29	4	261.13
Administration (organization and clinic)	34.88	0.29	6	269.98
Plaster technician	28.73	0.29	4	148.23
Total				1341.42
Mount Isa Hospital				
Travel subsidy for patients	N/A ^b	N/A	Varied	Varied
/irtual health practitioner				
Mount Isa Hospital				
Orthopedic specialist (off site)	134.57	0.23	4	662.08
RMO	59.35	0.23	4	292.00
Radiographer	50.61	0.29	4	261.13
Nurse	39.20	0.29	4	202.25
Administration (organization and clinic)	34.88	0.29	8	359.97
Plaster technician	28.73	0.29	4	148.23
Total				1925.66

^aRMO: resident medical officer.

^bNot applicable.

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Table 4. Three-year ROI analysis for the three service models. All values are given in Australian dollars.

Clinic service model and site	2014-15		2015-16		2016-17		Three-year total		Three-year
	Cost	Income (FTA ^a 10%-35%)	Cost	Income (FTA 10%- 35%)	Cost	Income (FTA 10%- 35%)	Cost	Income (FTA 10%- 35%)	net benefit (profit)
Telehealth clinic	•					•			
Mount Isa Hospital referral site	50,507	17,847 (13,989- 19,369)	140,361	153,693 (134,986- 186,904)	143,870	121,244 (109,446- 151,540)	334,738	292,785 (258,421- 357,813)	-41,954
Princess Alexandra 10,108 Hospital provider site	10,108	67,547	28,090	234,199	28,792	184,082	66,990	485,828	418,839
	(52,589- 72,815)		(205,693- 284,806)		(166,169- 230,080)		(424,450- 587,701)		
Patient travel									
Mount Isa Hospital referral site ^b	-75,158 (-110,526)	N/A ^c	-296,388 (-425,234)	N/A	-279,445 (-391,146)	N/A	-650,991 (-926,906)	N/A	–650,991 (–926,906)
Townsville Hospital provider site	39,580	61,488 (52,589- 72,815)	107,314	240,503 (205,693- 284,806)	109,996	194,289 (166,169- 230,080)	256,890	496,281 (424,450- 587,701)	239,390
Virtual health practitione	er								
Mount Isa Hospital referral site	(52,589	67,547		234,199	157,904	184,082	367,390	485,828	118,439
		(52,589- 72,815)		(205,693- 284,806)		(166,169- 230,080)		(424,450- 587,701)	

^aFTA: failure to attend.

^bCosts for patient travel for this site are represented as cost (25% patient travel paid).

^cNot applicable.

The analysis demonstrated that the only service model that resulted in a positive ROI for the rural site over the 3-year period was the virtual health practitioner model. The ROI for the rural site was -100% for the patient travel model, from which they derived no income, -12.5% for the telehealth model, and 32% for the virtual health practitioner model. Moreover, the ROIs for the metropolitan site were 93% for patient travel and 625% for telehealth; because the virtual health practitioner model is not applicable to the metropolitan site, it incurred neither cost nor income.

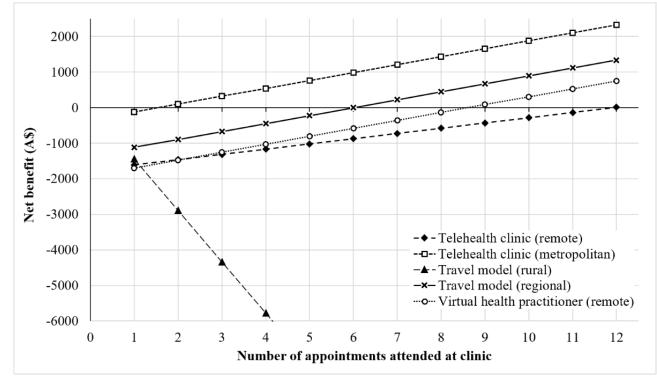
Breakeven Point for Each Model of Care

The breakeven analysis demonstrated the number of appointments that each site needs to conduct in order to cover

the costs of providing the clinic service (Figure 1). For the travel model of care, the provider site must complete a minimum of 6 appointments to cover their costs; however, the rural site is unable to recoup their costs within this model due to the cost of travel and lack of income opportunity. Alternately, in the telehealth model of care, the provider site can break even by providing a minimum of 2 appointments, while the rural site must provide a minimum of 12 appointments. This disparity between the number of patients required to break even is due in part to the cost sharing arrangements for the service being modelled, where the rural site covers some human resource costs for the provider site (health practitioner and administration).



Figure 1. The breakeven point for each model of care.



Discussion

Principal Findings

Our model demonstrated that rural health care providers can increase their ROI if they employ a virtual health practitioner as an alternative to subsidized patient travel or if they refer patients to telehealth clinics provided by a tertiary center. This largely results from savings from patient travel subsidies and generation of activity-based funding under the virtual health practitioner model. Increasing this to include all eligible patients (100%) would increase the volume of negative ROI for the model (Figure 1) but would not change the results. Further, our modelling showed that the rural site could break even when 3 patients attended, rather than 12. Additionally, we demonstrated that rural sites receive greater net benefits from using a virtual health practitioner than from the other models of care. The greater the economic benefit that is achieved by the rural sites, the greater the benefit to the community in which they are located.

Previous studies have shown that in the context of the Australian health care system, rural sites and metropolitan sites can gain economic benefit from implementing a telehealth service model [2-4]. International studies have also demonstrated cost mimimization potential for videoconferencing in orthopedic applications [17,18] and high acceptance from rural health care practitioners and patients when specialists provide services using videoconferencing [19,20]. Our study adds to the body of knowledge on telehealth economics by modelling the use of virtual health practitioners; to the best of our knowledge, this has not been done previously.

In addition to economic advantages, the virtual health practitioner model may provide other benefits. Often, it is

difficult to entice specialist clinicians to move to rural and remote areas to provide services [2,6]. The virtual health practitioner model provides an alternative by which rural and remote hospitals can gain specialty services for positions for which they are unable to recruit or retain staff or for positions that only require a small fraction of a full-time equivalent. One additional benefit is that patients can be referred back to primary care sooner, if appropriate, which will support the local rural health workforce.

Implications for Practice

While the economic focus in this paper is the optimization of outpatient clinics, the aim is not to advocate for a purely virtual care model for Australian patients. Instead, as models of care change to integrate telehealth and other virtual care provision modalities, we propose that alternate funding and employment models to those used in traditional in-person models of care (and telehealth emulations of these models) should be possible. Patients will still be required to travel for procedures, diagnostics, and outpatient appointments where a telehealth consultation is not appropriate.

Additional alternative models of care may present economic advantages; for example, a store-and-forward consultation with feedback to the general practitioner may be sufficient to diagnose and treat a simple fracture [21]. As telehealth services mature, patient cases can ideally be triaged to the most appropriate service model for their condition.

Strengths and Limitations

A strength of this study is the use of activity data from an existing telehealth service. By basing our analysis calculations on actual activity, we were able to present realistic economic examples for the 3 service models.

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A limitation of this study is that the economic analysis is based on a specific orthopedic clinic example; therefore, the findings lack generalizability. The ROI was estimated within the public funding models for the Australian state of Queensland (activity-based funding and travel subsidy scheme) and was based on local transportation costs. The model would require adaptation if it were transferred to alternate contexts.

The economic analysis presented here was for a service which experiences high and regular activity; the ROI estimates would need to be recalculated if the analysis were adapted for a service with low activity. As demonstrated by the example of this orthopedic fracture clinic, the virtual health practitioner model has a lower patient attendance rate requirement to break even on clinic costs. Additionally, the proportion of the population who claim the travel subsidy for this analysis was assumed to be 17%. If this percentage was increased to reflect the near-100% eligibility of the population, it would only serve to reduce the already negative ROI for the small rural site; for this reason, a pragmatic assumption was made to reflect the real-world scenario.

The substitution rate of telehealth for in-person encounters is an additional variable that influences the ROI. The teleorthopedic service for the fracture clinic described in this paper is highly amenable to telehealth because physical examination of the patient is largely mitigated by the supplementary information provided by x-rays. When a physical examination is required, it can be performed by a junior doctor at the rural site. For other services, such as a general orthopedic clinic, it may not be possible to provide consultations by telehealth; as a result, the substitution rates will be lower. Different medical specialities have different telehealth substitution rates [22]. Hence, the economic findings of this study cannot be extended to all specialities. Economic modelling of blended models involving care delivered by a combination of telehealth, virtual health practitioners, outreach, and patient travel is an area for future research.

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Conflicts of Interest

None declared.

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Abbreviations

FTA: failure to attend **NWAU:** National Weighted Activity Unit **RMO:** resident medical officer **ROI:** return on investment

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Original Paper

A Real-Time Mobile Intervention to Reduce Sedentary Behavior Before and After Cancer Surgery: Usability and Feasibility Study

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Abstract

Background: Sedentary behavior (SB) is common after cancer surgery and may negatively affect recovery and quality of life, but postoperative symptoms such as pain can be a significant barrier to patients achieving recommended physical activity levels. We conducted a single-arm pilot trial evaluating the usability and acceptability of a real-time mobile intervention that detects prolonged SB in the perioperative period and delivers prompts to walk that are tailored to daily self-reported symptom burden.

Objective: The aim of this study is to develop and test a mobile technology-supported intervention to reduce SB before and after cancer surgery, and to evaluate the usability and feasibility of the intervention.

Methods: A total of 15 patients scheduled for abdominal cancer surgery consented to the study, which involved using a Fitbit smartwatch with a companion smartphone app across the perioperative period (from a minimum of 2 weeks before surgery to 30 days postdischarge). Participants received prompts to walk after any SB that exceeded a prespecified threshold, which varied from day to day based on patient-reported symptom severity. Participants also completed weekly semistructured interviews to collect information on usability, acceptability, and experience using the app and smartphone; in addition, smartwatch logs were examined to assess participant study compliance.

Results: Of eligible patients approached, 79% (15/19) agreed to participate. Attrition was low (1/15, 7%) and due to poor health and prolonged hospitalization. Participants rated (0-100) the smartphone and smartwatch apps as very easy (mean 92.3 and 93.2, respectively) and pleasant to use (mean 93.0 and 93.2, respectively). Overall satisfaction with the whole system was 89.9, and the mean System Usability Scale score was 83.8 out of 100. Overall compliance with symptom reporting was 51% (469/927 days), decreasing significantly from before surgery (264/364, 73%) to inpatient recovery (32/143, 22%) and postdischarge (173/420, 41%). Overall Fibit compliance was 70% (653/927 days) but also declined from before surgery (330/364, 91%) to inpatient (51/143, 36%) and postdischarge (272/420, 65%).

Conclusions: Perioperative patients with cancer were willing to use a smartwatch- and smartphone-based real-time intervention to reduce SB, and they rated the apps as very easy and pleasant to use. Compliance with the intervention declined significantly after surgery. The effects of the intervention on postoperative activity patterns, recovery, and quality of life will be evaluated in an ongoing randomized trial.

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KEYWORDS

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sedentary behavior; mobile health; smartphone; mobile phone; wearable device; surgical oncology; physical activity

Introduction

Surgery is the first step of curative treatment for most cancers, but despite advances in surgical techniques and perioperative care, postoperative morbidity and complication rates remain high. Risks are particularly high after advanced abdominal cancer resection and include 30%-40% major complication rates, 15%-40% readmission rates, 40% reduction in functional capacity, and significant persistent symptoms [1-3]. Supportive behavioral interventions to enhance postoperative functioning and reduce risks of complication and readmission are needed.

Perioperative physical activity is a promising target for behavioral intervention given evidence that higher step counts after cancer resection are associated with lower readmission risk [4]. In the context of major abdominal cancer surgery, breaking up prolonged sedentary behavior (SB) bouts with brief walking breaks may be more attainable than increasing moderate physical activity (PA) or aiming for a specific step count goal. SB, defined as low energy expenditure activity in a seated or reclined position during waking hours, shows a sustained and marked increase after gastrointestinal cancer surgery, with patients spending more than 95% of their time sitting or lying in the week after surgery [5]. Prolonged SB after surgery could lead to physical deconditioning and reduced functional capacity that increases short- and long-term risks [6]. Independent of the health protective effects of moderate-to-vigorous PA, excessive SB has also been associated with lower quality of life and increased mortality in cancer survivors [7-9].

The growing ubiquity of smartphones and wearable activity monitors offers an unprecedented opportunity to harness real-time SB data and to deliver behavioral interventions before surgery, during inpatient recovery, and after hospital discharge as patients recover at home. Mobile technology is increasingly being utilized to deliver PA interventions, with emerging data suggesting that mobile health interventions can effectively increase PA [10,11] and are acceptable for patients with cancer and survivors [12,13]. Given evidence that physical symptoms are the primary barrier to breaking up SB in patients with cancer and survivors [14,15], mobile technology can also be used to collect patient-reported symptom data that can be leveraged to tailor recommendations to be responsive to fluctuations in health. The goal of this pilot study was to develop and test a mobile technology-supported intervention to reduce SB before and after cancer surgery. We conducted a single-arm pilot trial evaluating the usability and acceptability of a real-time mobile intervention that detects prolonged SB in the perioperative period and delivers prompts to walk that are tailored to daily self-reported symptom burden.

Methods

Participants

Participants were recruited between June and September 2018 at their preoperative clinic visit. Potential research participants were identified by their surgical oncology care team, who confirmed eligibility. If patients expressed interest in learning more about the study, they were approached by the research team after consenting to and scheduling surgical treatment of metastatic colorectal or peritoneal cancer. The study was open to English-speaking adults able to stand and walk unassisted. Patients who were less than 2 weeks from their scheduled surgery date were excluded, which ensured that participants had adequate time to become familiar with the study's technology and activity prompts prior to surgery.

Study Procedures

After providing written informed consent, participants completed a questionnaire to collect information about demographic variables, health behaviors, and experience with mobile technology. They were provided with a Fitbit Versa smartwatch paired with a Google Pixel 2 smartphone on which the Detecting Activity to Support Healing (DASH) study app as well as the Fitbit app had been installed. From the time of consent to 30 days after hospital discharge following their surgery, participants were asked to keep the devices charged, to wear the smartwatch as much as possible, to rate their daily experience of symptom severity once each morning, and to respond to activity prompts. Participants were called once per week, when feasible, to complete semi-structured interviews about their experiences with the intervention. A questionnaire about the usability of the apps was administered at the end of the study. All procedures were approved by the University of Pittsburgh Institutional Review Board.

The DASH Study App and Intervention

The DASH Study Android smartphone app, created by members of the research team, sent a notification to participants each morning (at a time that was set and could be adjusted by participants) reminding them to rate the severity of 10 symptoms (pain, fatigue/tiredness, sleep disturbance, trouble concentrating/ remembering things, feeling sad or down, feeling anxious or worried, shortness of breath, numbness or tingling, nausea, and diarrhea or constipation) they had experienced in the last 24 hours using a scale from 0 (symptom not present) to 10 (symptom as bad as you can imagine; Figure 1).



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Figure 1. Daily symptom severity rating on smartphone app. DASH: Detecting Activity to Support Healing.

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Please rate how sever symptoms have been from 0 (symptom not p was as bad as you car Pain	in the last present) to	24 ho 10 (s	sympto	m ?	Shortness of breath	1
Fatigue / tiredness				?	Numbness or tingling	1.
Sleep disturbance				?	Nausea	1
Trouble concentrating	/ rememb	ering	things	?	Diarrhea or constipation	1
Feeling sad or down				?	Other •	1
Feeling anxious or wor	rried			?	SAVE ANSWERS	

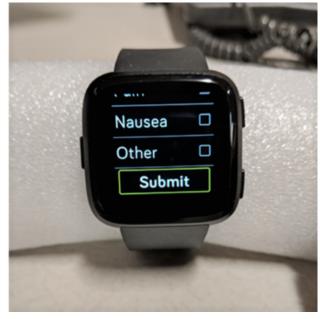
The DASH Study Fitbit OS smartwatch app used this information to set a threshold for SB bouts and used real-time step count data to trigger activity prompt notifications when that threshold was exceeded. If a morning symptom rating was not completed, the most recent symptom rating was carried forward to select that day's SB threshold. Activity prompts were sent when: (1) SB (defined for the purposes of this study as fewer than 50 cumulative steps since the most recent activity prompt) exceeded 60 consecutive minutes, and at the most recently completed symptom rating, all symptoms were rated less than 7 out of 10 or (2) SB exceeded 120 consecutive minutes and any symptom was rated 7 or higher. When SB thresholds were exceeded, an activity prompt notification ("Ready for a short walk?") was sent to both the smartphone and the smartwatch (Figure 2). Participants could respond on either the watch or the phone with the response options Yes, No, or Snooze. If Snooze was selected, an activity prompt was sent again 15 minutes later. If No was selected, participants were asked to indicate their reason(s) for not walking (Busy, Pain, Nausea, or Other; Figure 3). Regardless of response, participants received a positive feedback message ("Great job being active!") if 30 or more steps were logged within 15 minutes of an activity prompt. Daily step counts as well as sleep data were also available to view in the Fitbit app as desired.

Figure 2. Activity prompt on Fitbit Versa smartwatch app.



Figure 3. If responding "No", provide reason(s) you are unable to walk. DASH: Detecting Activity to Support Healing.





Measures

Usability was assessed in two ways: (1) via weekly ratings on a scale of 0 to 100 on how easy it was to use the smartphone and smartwatch apps; how pleasant the interface of each app was in terms of appearance, design, and usability; and how satisfied the participant was overall with the DASH intervention and (2) via the System Usability Scale, a widely used ten-item questionnaire used to evaluate technological systems that was administered at the end of the intervention [16]. Notes from the semi-structured interviews were also reviewed by the research team and organized into identified themes related to issues encountered, suggestions for improvement, and other feedback.

Feasibility was assessed via accrual and retention rates as well as compliance with reporting symptoms. Objective activity and heart rate data indicated compliance with wearing the smartwatch as well as walking in response to activity prompts. Daily compliance with wearing the watch was defined as logging at least some activity (more than 0 steps) or heart rate data (more than 0 beats per minute).

Results

Participant Characteristics

Table 1 shows that the sample was primarily female, white, well-educated, and familiar with technology. Participants started using the mobile health intervention an average of 26 days (range 11-40) prior to surgery, throughout their inpatient stay (mean 10.4 days, range 6-15 days), and for 30 days postdischarge, for an average of 66 total days (range 47-81) using the intervention.



Table 1. Participant characteristics (N=15).

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Characteristics	Value
Age (years), mean (range)	49.7 (25-65)
Sex, n (%)	
Female	12 (80)
Male	3 (20)
Race, n (%)	
White	13 (87)
Black	2 (13)
Marital status, n (%)	
Married	9 (60)
Divorced/separated/widowed	4 (27)
Never married	2 (13)
Employment status, n (%)	
Working full-time	6 (40)
Working part-time	2 (13)
Retired/not working	7 (47)
Education, n (%)	
High school diploma or equivalent	4 (27)
Some college	5 (33)
Bachelor's degree or higher	6 (40)
Body mass index, mean (SD)	27.2 (6.4)
Smoking history, n (%)	
Current smoker	2 (13)
Former smoker	8 (53)
Never smoker	5 (33)
Exercise frequency, n (%)	
Seldom or never	5 (33)
1-2 times per week	4 (27)
3-4 times per week	3 (20)
5 or more times per week	3 (20)
Has Wi-Fi at home, n (%)	14 (93)
Owns a computer, n (%)	13 (87)
Owns a tablet, n (%)	10 (67)
Owns a smartphone, n (%)	14 (93)
Owns an activity tracker, n (%)	1 (7)
Uses social media, n (%)	12 (80)

Usability

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On a scale from 0 to 100, participants rated the smartphone and smartwatch apps as very easy (mean 92.3 and 93.2, respectively) and pleasant to use (mean 93.0 and 93.2, respectively). Overall participant satisfaction with the whole system was 89.9, and the mean System Usability Scale score at the end of the study was 83.8 (maximum possible score of 100).

Overall, participants reported that the activity prompts were mostly sent at an appropriate frequency and that they liked the simple wording of the prompts. Some participants found the Fitbit Versa to be bulky and unattractive, reported that the smartwatch did not seem to accurately record all steps (especially when walking slowly or with assistance), and reported occasional syncing or connectivity issues between the watch and the phone. The primary complaint about the

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smartphone app was that the slider used to adjust the symptom rating did not always work smoothly. Participants were generally satisfied with the "No" response options but wished they could elaborate on the "Busy" or "Other" responses on the watch. Participants also reported that it was especially difficult to walk in the hospital immediately after surgery when they were too weak to walk unassisted, were in the middle of tests or other care procedures, or were on medications that made it difficult to get up and walk. One participant (a 40-year-old white woman with a preoperative exercise frequency of 1-2 times per week) said, "During the hospital was the toughest part; you don't even want to talk to anybody or even think about technology...devices were the last thing (I) wanted to worry about."

At the end of the study, multiple participants reported that the system was motivating. One participant (a 55-year-old white man with a preoperative exercise frequency of 1-2 times per week) said, "It's cool to track how many steps I have and see what days were good days and what days were bad. It helps motivate (me) to walk." Another participant (a 51-year-old white female with a preoperative exercise frequency of 3-4 times per week) said that the smartwatch "made (me) more conscious of the need to move, before and after surgery." One participant (a

25-year-old black woman with a preoperative exercise frequency of 3-4 times per week) commented that she wished the system had been more personalized, because it was so simple and "felt generic."

Feasibility

Of the 19 eligible patients approached, 15 agreed to participate (79% accrual rate). Reasons for not participating were "too busy/overwhelmed" (n=2) and "not good with technology" (n=2). The retention rate for the study was 93% (14/15), and the 1 patient who did not complete the study withdrew due to poor health and prolonged hospitalization.

Over the course of the study, daily symptom ratings were completed 51% (469/927) of the days, with compliance rates decreasing significantly from before surgery to inpatient recovery and postdischarge (Table 2). Across all days that symptoms were rated, 37% (172/469) were classified as a high symptom day and were accompanied by a higher SB threshold, and the most common symptoms rated as severe (\geq 7 out of 10) were fatigue and pain. The frequency of severe symptom days increased slightly from the presurgery waiting period to postoperative inpatient recovery.

Table 2. Trends in compliance, symptoms, and activity over the perioperative course.

Variable	Preoperative	Inpatient recovery	Postdischarge
Symptom reporting compliance, % (n/N)	73 (264/364)	29 (42/143)	41 (173/420)
Severe symptom days, % (n/N)	34 (90/264)	47 (15/32)	39 (67/173)
Smartwatch wearing compliance, % (n/N)	91 (330/364)	36 (51/143)	65 (272/420)
Daily step count, mean (SD, range)	5865 (3113, 637-21,115)	1594 (1567, 0-6100)	2054 (1753, 42-9645)
Average sedentary behavior bout duration (minutes), mean (SD, range)	23 (12, 7-94)	177 (201, 32-720)	72 (72, 17-720)

Step count data were collected on 70% (653/927) of the days, but compliance with wearing the smartwatch also declined from before surgery to inpatient and postdischarge. On average, participants logged 3944 steps per day (SD 3185, range 0-21,115) with an average SB bout duration of 55 minutes (range 7-720, SD 83). As expected, step counts decreased significantly and average SB bout durations increased significantly from before surgery to during inpatient recovery (Table 2), but an important limitation is that these mean step counts and SB bout values are based on the subset of participants who were compliant with wearing the smartwatch.

Unfortunately, due to data syncing issues, timestamped logs of all activity prompts and participant responses were not available for all participants during this pilot deployment. Activity prompts and participant responses were completely or partially logged for 8 participants. For these participants, an average of 133 activity prompts were sent during the deployment for an average of 4.18 prompts per day when activity prompts were logged. Overall participants walked and received positive feedback messages after 27% (288/1064) of the prompts, although walking was detected after only 14% (45/311) of the prompts sent during inpatient recovery.

Participant age and gender were not significantly related to pleasantness or ease of use ratings, System Usability Scores, or

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smartwatch wearing compliance. Older age was significantly correlated with higher symptom rating compliance (r_{14} =.61, P=.02).

Discussion

Principal Findings

This study describes the successful development and preliminary testing of a mobile technology-based intervention to reduce SB before after abdominal cancer surgery, and with recommendations tailored to patient-reported symptom severity. Perioperative patients with cancer were willing to use a smartwatch- and smartphone-based intervention to reduce SB in real time, and they rated the apps as very easy and pleasant to use. Participants generally reported that they liked the simplicity of the intervention and found the prompts to be motivating. However, overall compliance with completing daily symptom ratings, wearing the smartwatch, and walking after receiving an activity prompt declined significantly from before to after surgery, and compliance with symptom reporting did not significantly improve even after patients were discharged from the hospital. This significant drop in engagement with the intervention after surgery may limit the effects of this behavioral intervention on postoperative outcomes.

The high usability ratings and low postoperative compliance rates observed in our study are consistent with previous work testing mobile health apps in gastrointestinal surgery patients. In one study testing a symptom, wound, and temperature tracker after colorectal surgery, participants rated the app as highly usable, but 30% of participants never used the app and 10% used the app only once [17]. In a study testing a similar symptom-monitoring app along with Fitbit monitoring and hydration reminders, 89% of patients described the app as easy to use, with Fitbit data collected on 85% of days, but only 68% completed symptom ratings and 51% uploaded photos of their wounds [18]. These studies were not attempting to modify patient activity behavior, but the barriers to daily use of the mobile apps after surgery reported in those studies (eg, postoperative pain and fatigue or trouble remembering to use the app if it was not part of a typical routine) are likely to be similar to those in our study and should be carefully considered when designing mobile apps for perioperative patients with cancer.

The declining compliance in Fitbit wear time is also consistent with studies in healthy adults, which showed that 40% of volunteers abandoned the Fitbit within six months [19]. Of note, there was significant variability in postoperative compliance, with some participants maintaining high levels of engagement before and after surgery and others disengaging completely after surgery. Decreases in compliance were particularly marked in the 43% (6/14) of patients who were readmitted within 30 days. Finding ways to maintain patient engagement during inpatient recovery and beyond is an important future goal for this research. These strategies may include contacting patients more frequently or involving caregivers in the intervention to emphasize feelings of being cared for and monitored [20]. Given that very few activity prompts (45/311, 14%) delivered to patients while in the hospital were followed by walking breaks, the frequency of notifications may have been too often or the definition of a walking break (30 steps in 15 minutes) not attainable during this time of acute illness; therefore, increasing the threshold of SB permitted during hospitalization could also be useful.

The intervention was designed to be responsive to daily patient-reported symptom burden based on the hypothesis that increasing the threshold for SB on days with even 1 severe symptom may make the intervention more attainable for patients, resulting in better self-efficacy. However, low compliance with symptom reporting after surgery limited the ability of the intervention algorithm to reduce the frequency of activity prompts on such days. Only 47% of days (15/32) with symptom data available during inpatient recovery were classified as including one or more severe symptoms, possibly because

participants were more likely to be compliant with symptom reporting on days when they were feeling better and less symptomatic. Estimation of high symptom burden based on passive sensors within the smartphone and smartwatch, which could be done with minimal burden to patients, is another important direction for future research [21].

To our knowledge, this is the first study to use both patient-reported symptoms and real-time activity monitoring data to deliver a SB intervention and the first study to explicitly target SB before and after cancer surgery. Strengths of the study included the use of real-time step count data to trigger activity prompts that were tailored to patient-reported symptom ratings and the use of ubiquitous commercial devices to deliver the intervention.

Limitations

This study also had several limitations. The sample size for this feasibility study was small and was biased toward well-educated younger female patients, who may have been more willing to participate in a technology-supported behavior change intervention. All patients were scheduled for surgery for metastatic peritoneal cancer, and results may not generalize to other surgical oncology or surgery populations. Complete data about activity prompts delivered and participant responses to prompts were not available, limiting our ability to examine participant adherence to recommended walking breaks. The intervention used a study-provided Android smartphone, although 14 of 15 participants already owned a smartphone. The need to carry and charge a second device across perioperative transitions of care may have contributed to poor compliance to symptom reporting as well as syncing issues. Future studies should consider installing study apps on participants' personal devices to minimize participant burden and increase the likelihood of participant engagement and compliance.

Conclusions

In conclusion, mobile technology-based interventions have the potential to improve postoperative outcomes after cancer surgery by targeting modifiable behaviors in real-time. Results from this pilot study demonstrate moderate feasibility and acceptability and good usability of a real-time mobile technology–based SB intervention for perioperative patients with abdominal cancer. Future research involving perioperative mobile health interventions should consider ways to enhance postoperative compliance, including engaging caregivers or providing additional personalization of behavioral interventions. A randomized controlled trial testing preliminary effects of the intervention on postoperative activity patterns, recovery, and quality of life is currently underway.

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Conflicts of Interest

JJ has a conflict of interest with the Scientific Advisory Board for WW (formerly Weight Watchers International, Inc). The remaining authors declare no conflicts of interest.

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Abbreviations

DASH: Detecting Activity to Support Healing **PA:** physical activity **SB:** sedentary behavior

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Original Paper

An Automated Text Messaging System (Tonsil-Text-To-Me) to Improve Tonsillectomy Perioperative Experience: Exploratory Qualitative Usability and Feasibility Study

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Abstract

Background: Inexperience and forgetting perioperative care instruction are significant drivers of parental stress during pediatric tonsillectomy care. With the widespread use of mobile technology, parents now desire a system that provides them with information that is timely, accessible, and comprehensive. Tonsil-Text-To-Me (TTTM) is a text messaging system that sends out automated and timed texts to parents of children who are undergoing tonsillectomy.

Objective: The objective of this study was to pilot-test TTTM to assess for feasibility and usability and collect suggestions for system improvements desired by parents from a pediatric otolaryngology text message service.

Methods: Parents of pediatric patients who were being scheduled for tonsillectomy with or without adenoidectomy were prospectively enrolled. An exploratory qualitative study using a semistructured interview guide was performed after parents received the automated texts 2 weeks before and 1 week after their child's surgery.

Results: A total of 7 parents were interviewed (data saturation was reached). Participants were all of maternal relation to the patient. Overall, all parents felt that the TTTM service was an improvement to the current standard model of information delivery. Parents also reported that the text messages reduced their anxiety and improved their performance when caring for their children during the perioperative period. No parents expressed privacy concerns about receiving texts and regarding the information included in the messages. Service suggestions showed that parents were eager for more information and had a high threshold for message reception regarding their child's surgical care.

Conclusions: All parents expressed enthusiasm for a text message service during their child's tonsillectomy perioperative period. The care instructions and reminders provided to parents via automated and timed text messages may be a strategy to improve information delivery in a simple and accessible format that could empower families in their own health care.

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KEYWORDS

short message service; tonsillectomy; pediatric otolaryngology; perioperative care



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Introduction

Perioperative tonsillectomy care can be stressful for families. Parents often report that they would benefit from more information and direction. A family-centered approach requires the integration of high-quality resources to assist parents and improve adherence to posttonsillectomy protocols [1,2]. Traditionally, this has been accomplished with verbal, written, or printed discharge notes. However, as our society becomes increasingly media-driven, there is a need for technically focused medical resources that provide comprehensive information in a faster and more accessible format. With widespread use of mobile technology, most people now have access to a network-supported mobile device that provides short message service (SMS, also known as text messaging) [2]. These services provide a timely, effective, and financially viable platform that can facilitate convenient and comprehensive communication between health care services and patients [2].

Our team recently developed an automated text messaging service, Tonsil-Text-To-Me (TTTM), to expand our current perioperative consultation practices and assist parents in caring for their children. Prior to this study, our team completed a review of online recommendations for pediatric perioperative care following tonsillectomy and conducted a Delphi study with medical experts to develop an evidence-based list of recommendations for parents of children undergoing tonsillectomies [1,3]. The resulting data was used to generate our perioperative care–related text-messaging content for parents. We also completed the software development required to automatically and securely deliver SMS reminders to parents.

The purpose of this study was to pilot-test the implementation of TTTM into clinical practice and review feedback from parents using our service for the first time. The goal of the pilot test was to (1) obtain the opinions and suggestions of parents regarding their experience with the TTTM service and (2) confirm the software is functional and ensure an error-free SMS workflow for future clinic-wide implementation. Ultimately, field testing our SMS system will allow our team to assess its suitability and potential scalability into real-world clinical practice.

Methods

Study Design

Testing the usability and feasibility of interventions prior to full-scale testing and implementation can help to identify problems with acceptability and compliance and inform a full implementation strategy [4]. This exploratory usability and feasibility study used a qualitative semistructured interview guide to elicit the experience of parents who first used the TTTM SMS service. The qualitative methodology provided meaningful, in-depth feedback from relevant stakeholders and was informed by key usability and feasibility constructs explored in related research (eg, ease of use, satisfaction, learnability, safety, errors) [5]. Thematic analysis was performed on interview data and guided revisions to the format and content of TTTM.

Text messages were sent using email-to-text functionality from a designated institutional email so that it could be easily recognized by the participants. This setup also allowed for an audit trail through our email server. The SMS portal was built by our research team using Drupal, an institutionally approved software platform.

Ethical approval was obtained from the Izaak Walton Killam (IWK) Health Centre research ethics board (No 1021582).

Recruitment and Eligibility Screening

Participants were parents of typically developing children (aged 3-14 years) who underwent tonsillectomy with or without adenoidectomy at the IWK Health Centre (a pediatric tertiary care hospital in eastern Canada). Inclusion criteria included parents' age 18 years or older, fluent in English, have a cell phone, able to read text messages, and willing to receive 13 text messages over a 3-week period (2 weeks presurgery to 1 week postsurgery). Parents were excluded from the study if their child had complex medical needs beyond what is routinely accommodated for in tonsillectomy surgery such as previous history of peritonsillar abscess, complex chronic conditions, craniofacial abnormalities, diabetes, or a disorder in hemostasis.

Sample Size

Previous studies investigating mobile health technology showed that preliminary usability issues can be detected with a sample size of 5 to 10 participants [6-8]. Thus, we aimed to recruit a minimum of 5 and continued recruitment until theoretical data saturation was reached [9,10]. After 7 interviews, no additional new insights were identified and therefore recruitment was stopped.

Procedure

All eligible parents were offered service enrollment, in addition to conventional supports, during their child's preoperative consultation. Information regarding our service was also advertised via posters displayed in the pediatric otolaryngology clinic and through otolaryngology clinic nurses. Recruitment began in January 2018 and ended in May 2018. Two months before their child's surgery date, interested parents were contacted by a research team member, who further explained the study and obtained informed consent. Parents were offered a Can \$20 (US \$15) gift certificate (applicable to various retailers) as compensation for their involvement in our study. A nominated mobile number for contact during the study and the scheduled surgery date was recorded at the time of consent. Text messages delivered to parents during the study are presented in Table 1. Parents were contacted within 2 weeks of their last expected text message for their interview. Interviews were semistructured, audio recorded, and approximately 30 minutes in duration. All interviews were conducted by one researcher (NF) who did not have any previous relationship with the families. None of the families enrolled in our study were lost to follow-up.



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Table 1. Tonsil-Text-To-Me text messages automatically delivered to parents during the perioperative period.

Perioperative period and text delivery day relative to surgery day	Text message			
Before surgery				
14 days before (morning)	Thanks for signing up for Tonsil-Text-To-Me! Your child's surgery is coming up—time to get ready. Starting today stop giving your child aspirin.			
3 days before (evening)	You can help your child get ready for surgery. Be honest and up front about what will happen. Wa the day-surgery tour (URL).			
1 day before (evening)	Tomorrow is surgery day. Please stop giving solid foods 8 hours before, breast milk 4 hours before, a clear fluids 3 hours before surgery time. Learn more about how to manage pain after surgery (URL).			
Day of surgery				
Day of (morning)	It's surgery day. We can do this! Bring a favorite toy to help your child feel more calm. Do you have everything you need? Day surgery checklist (URL).			
Day of (evening)	Surgery is over! You made it. Comforting your child will help them relax and relieve pain. Tips on h to comfort and distract them from pain (URL).			
After surgery				
1 day after (morning)	Check on your child after surgery for pain and breathing changes. Learn how to ask your child about pain (URL).			
1 day after (evening)	Eating soft foods and drinking clear fluids as soon as possible can help soothe your child's throat. It's okay for them to shower or bathe and brush their teeth as usual. Need soft food and clear fluid ideas (URL)?			
2 days after (morning)	Reasons to call your doctor:			
	 Bleeding in the nose or mouth Trouble breathing Your child seems dehydrated (should pee minimum 2x/day) or is refusing to drink fluids Pain that won't go away, is getting worse, or isn't helped with medication Fever greater than 39.0°C (102.2°F) 			
2 days after (evening)	Remember, it is normal for a white coating to form on the tonsils as they are healing.			
3 days after (morning)	Have your child take it easy for the first 10 to 14 days after surgery (no sports, gym class, or roughhous- ing). No travel for 14 days.			
5 days after (morning)	It is normal for pain to peak around 5 to 7 days after surgery. Continue to give medication as directed to help your child get through this time.			
5 days after (evening)	 Most children return to school after 7 days. When can they go back? Are they eating normally? Sleeping through the night? No longer need pain medication? 			
	If yes to all three, then school is okay.			
7 days after (morning)	Thanks for using Tonsil-Text-To-Me to help care for your child. This is your last message :)			

Data Analysis

Data analysis was initiated after the first interview. Interviews were transcribed verbatim and analyzed using thematic content analysis [11]. Participant responses were reviewed by the primary coder (NF) to identify an initial set of inductive codes. Themes and potential subthemes were noted. To minimize researcher bias, several meetings between the authors were held to review and refine coding scheme and approach to thematic analysis. In addition, a second researcher (LW) was appointed to review the transcripts using the refined codes to ensure emergent themes accurately represented the transcript data. The second researcher, who has experience in usability and feasibility research, found that the codes had content validity. All authors agreed that the themes were representative of the parent's experiences with and feedback about the TTTM system.

RenderX

Simple frequency analysis was conducted on quantified code data related to direct text recall from parents and text improvement suggestions. Frequency analysis was conducted using Excel (Microsoft Corp) and SPSS Statistics (IBM Corp).

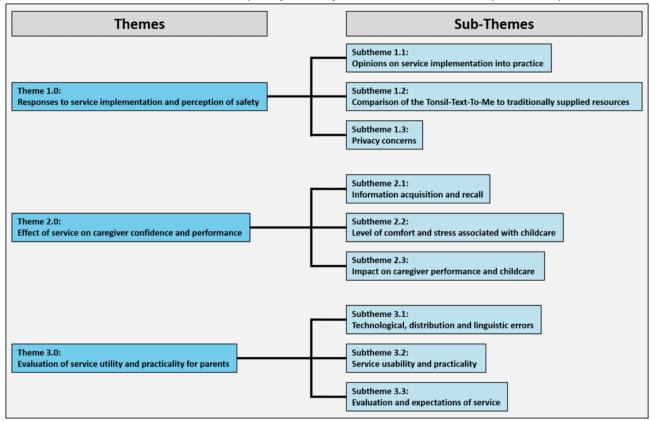
Results

Participants

After 7 interviews, there were no new insights obtained to inform design changes to the TTTM system and therefore recruitment was stopped. Participants were all of maternal relation to the patient. Three major themes were identified from parent interviews. These themes and their subthemes are shown in Figure 1 and described in detail below.

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Figure 1. Themes and subthemes identified from the analysis of parental responses and feedback on the usability and feasibility of Tonsil-Text-To-Me.



Theme 1.0: Responses to Service Implementation and Perception of Safety

Subtheme 1.1: Opinions on Service Implementation Into Practice

Throughout the interviews, the response to TTTM was overwhelmingly positive. All families expressed encouraging remarks regarding TTTM service being implemented into practice.

Subtheme 1.2: Comparison of the Tonsil-Text-To-Me to Traditionally Supplied Resources

Parents commonly described having grievances with the current model of information delivery from health care providers. Mostly, parents reported forgetting, losing, or not having time to comprehensively review hard copy resources such as pamphlets or brochures.

I was frantically racing around the house the night before, trying to find the paper to figure out when she could eat last. [Participant 5]

I know that's all given in the active care pamphlet though, but if somebody lost that, maybe if it's in the text they might not lose it. [Participant 4]

It was a lot to take in, even though you had pamphlets and stuff. [Participant 2]

The preoperative consult was another aspect of information delivery that was perceived as suboptimal. The combined effect of a large information load during consultation and lengthy gap between consultation and surgery date were cited as factors that disrupt information reception and overwhelmed parents.

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During the consultation, which was months previous, a lot of the information was given to us by the nurses, and when you walk away you're just like, oh, that's a lot. But to have a text, it was almost more reassuring, and more of a comfort thing, if anything because it's now closer to the time and you now can follow protocol, and not trying to remember everything from five months previous. [Participant 2]

Of the three parents who had previous pediatric surgical experiences with their child, none reported being offered a service similar to TTTM. Two parents elaborated further to express that they felt TTTM implementation would be an improvement for parents compared to previous experiences. They appreciated how it was a useful tool that helped ease stress and enhance knowledge, especially for parents with no prior pediatric surgical experience.

Comparing it, I did really enjoy having this type of service...it's comforting. [Participant 5]

This was my child's second surgery, so you know, I had different information going into this one than somebody who would be in the situation where it would be their child's first surgery. So, I think it is definitely useful. [Participant 1]

Although not explicitly asked, two parents self-reported that they found the URL links to additional information useful and time saving, as previously they would have to look for this information on their own. Overall, the ubiquitous enthusiasm for service implementation was in response to their desire for improved informative delivery in a simple and accessible format.

That I didn't have to take my time to go online and research it. I could just actually look at the text and read the attachment and go, okay, oatmeal is good, because I actually was wondering that at one point. [Participant 2]

I don't think it gets much simpler than texting. [Participant 3]

Subtheme 1.3: Privacy Concerns

When explicitly asked about comfort level and privacy concerns over receiving perioperative tips and reminders over SMS, none of the parents reported any such concerns. One parent commented that in terms of privacy, the content was perceived as a low-yield security risk, however acknowledging that others may feel differently.

Yes, I was comfortable getting them, and I was never concerned about privacy. [Participant 2]

Yeah, I was comfortable and no, I'm not concerned about any of the privacy. It really doesn't matter to me who knew that my child was getting surgery. But you know, other people may have those concerns. [Participant 1]

In relation to the pediatric patients, all parents enrolled in the study were mothers, six of whom reported sharing the roll of perioperative care with other guardians (mainly fathers). Views over sending concurrent messages to other caregivers were mixed. Three parents expressed an interest in concurrently sent messages, while the other four parents were content receiving the messages themselves and relaying them to other guardians.

Yeah, I guess it could have gone to my husband as well. We share parental duties, I don't think that it going to multiple numbers in the same household would be an annoyance. [Participant 1]

Theme 2.0: Effect of Service on Caregiver Confidence and Performance

Subtheme 2.1: Information Acquisition and Recall

The most commonly cited concern by parents was their propensity to forget or overlook care instructions.

I thought it was a good idea because parents are busy, and it's easy to forget things. A simple text as a reminder of what needs to be done and when was nice. [Participant 4]

I thought it was great, even though I knew it was coming up, I forgot kind of the different steps, like not giving her different medicines.... So, it was nice to have that reminder. [Participant 3]

Parents reported that the service reminders facilitated an improvement in knowledge and helped them prepare for upcoming benchmarks in their child's care.

One thing actually that did help me was a reminder to have pain medication, and the text was what prompted me to go buy that. [Participant 6] In the sense that if your child is being particularly distraught and upset, it's nice to see a little message saying that it will end. [Participant 3]

I found it helpful, and it definitely relieved stress in the fact that I knew that I was going to get messages, rather than having to rely on my memory of what was coming next. [Participant 4]

Subtheme 2.2: Level of Comfort and Stress Associated With Childcare

Parents reported that preparing for surgery and caring for their children after surgery were stressful experiences. However, with SMS reminders, parents reported that they felt more informed, were reassured about their child's condition, and felt better equipped to care for their child.

...when I read that I was like, oh, okay, now it makes me more aware of what he may be going through. Whereas before, if I didn't get it I might be like, oh my god, what's going on? [Participant 2]

I think it would be a really good benefit, especially knowing just that you're on the right track with it or just reminders to kind of keep you calm. Seeing your child go through a procedure is never easy, so it's kind of just the peace of mind thing, as well as a nice reminder to make sure you're still on the right track... [Participant 5]

I mean, that was definitely a good reminder so that I could really lessen the feeling of his symptoms to what was supposed to be happening, so I didn't panic and think that something was wrong when those symptoms occurred. [Participant 4]

Also, despite knowing that the messages were being sent via an automated system, parents expressed feeling reinforced sense of support from their health care team.

It's nerve racking leading up, and I'm stressed out leading up, so just kind of having that touch base check in type thing, even though I'm not actually speaking to anybody, it's comforting. [Participant 5]

If I had any stress, it would have taken it all away because it was like you had someone virtually guiding you through text about what to expect when you bring your child home after surgery. [Participant 2]

Overall, parents reported that SMS reminders increased feelings of security and calm, prevented panic, and reduced stress when caring for their child.

I found it helpful, and it definitely relieved stress...through keeping the parent calm, and allowing the parent just to focus on one thing at a time, as opposed to stressing about everything all at once. [Participant 4]

It was just that added security with regards to recovery, and all that stuff. [Participant 1]

It was super helpful, instead of worrying and wondering; knowing that there's going to be a text.... Yeah, it eased my mind a little bit, for sure. [Participant 7]

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Conversely, during prolonged intervals between subsequent SMS distributions, some parents reported increased stress levels, transiently. These feelings generally occurred during the preoperative period and were associated with ideas of abandonment by the service and not having accessible information to refer to.

At the ending, I felt it was really good, but in the beginning I was just waiting for another coming. [Interviewer: Did the beginning increase stress?] Yeah, I was expecting more information, for sure. I honestly felt like maybe you guys had forgotten about me. [Participant 7]

And like I said, if the texts came once a day, it makes a parent feel like they have that support on a daily basis. [Participant 1]

Subtheme 2.3: Impact on Caregiver Performance and Childcare

All parents reported the service was helpful in assisting with their child's care, and 5 parents believed it improved their child's care. Ambiguity in how parents perceived the phrase "improvement in your child's care" was observed.

I thought it was very helpful...I don't think it affected his care. [Participant 2]

I think that it definitely is, I don't know if it really benefits the children. It does I guess, through keeping the parent calm, and allowing the parent just to focus on one thing at a time, as opposed to stressing about everything all at once. So, I guess it helps the child, but it's more of a parent thing. [Participant 4]

I don't think you can improve on how a parent's care—because when you talk about caring, you're talking about how they love their child, because care comes with that. So, parents tend to go by instinct...I think it better informs them in how to appropriately care for their child during this time. [Participant 1]

All but one parent believed that the service would be a helpful tool to improve how parents prepare their child for surgery. All parents believed that the service would improve how parents care for their child postoperatively.

So, I wouldn't say it's anything to prepare them for the surgery. I think that was limited, but it was very good for the guidelines after the fact. [Participant 2]

I think it does assist them in preparing, like I got the text about stop giving, I believe it was aspirin or something like that. I believe it was a week or two before the surgery, so things like that, that parents may not even think about are beneficial. I think that it made me better able to deal with the situation and the care after, well during and after. [Participant 1]

It was super helpful because I found afterwards they were bang on, when we would be having those sorts of questions. So, I thought it was super beneficial. [Participant 7]

Theme 3.0: Evaluation of Service Utility and Practicality for Parents

Subtheme 3.1: Technological, Distribution, and Linguistic Errors

No technical issues interfering with text reception such as a lost or stolen mobile phone, change in surgery date, or phone malfunction were reported. However, two parents reported that they received the final closing text message three consecutive times.

They were all fine. The only thing is, I think I got that last one about three times, so it might have been a little glitch. [Participant 6]

The only thing I noticed was that the very last text saying that this would be the last one, I got three different times on three different days. [Participant 3]

No grammatical or spelling errors were reported. The reading level of the messages was determined to be appropriate as no literacy barriers were recognized by parents.

Subtheme 3.2: Service Usability and Practicality

Parents were prompted to comment on message quantity, length, and time of delivery. All parents were content with overall message lengths, stating that they provided a sufficient but manageable information load. Likewise, all parents were satisfied with the time of day that the messages were delivered.

I found everything straightforward. They came through at a reasonable time. It wasn't like too early in the morning or too late at night. And they were short and sweet and to the point. I didn't have to read paragraphs of information. It was very straightforward. [Participant 4]

While no parents reported experiencing superfluous text reception, all but one reported a desire for more messages, particularly in the preoperative period. Some parents proposed message delivery frequencies as high as one message every 1 to 2 days as being optimal.

I think you could do it daily for frequency, and that even wouldn't be a nuisance, just getting a text daily about things, changes, things like that is appropriate. [Participant 1]

If you were to add more, it would just be to reiterate the information people have. [Participant 6]

Subtheme 3.3: Evaluation and Expectations of Service

Parents were prompted to express their expectations and level of satisfaction with the service. Only two parents reported that the service completely satisfied expectations. Among parents who expressed the service fell short of their expectations, four reported that they expected more preoperative information and one anticipated receiving live message responses.

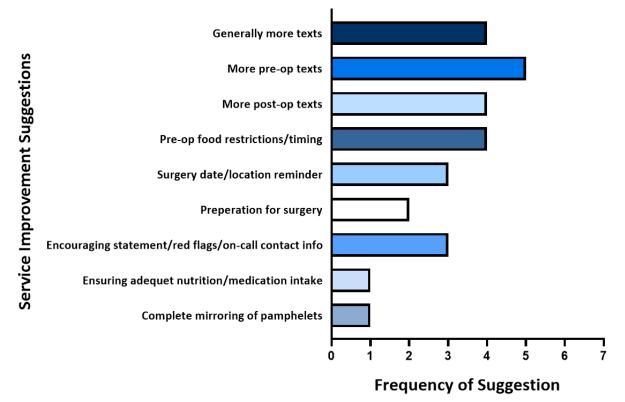
There was one text that I replied to, so I expected to get a reply back, so I guess that was my expectation—that if there were questions that I could ask them, and get an answer back, and that wasn't the case. [Participant 1]



I found the information before the surgery was minimal. And I guess I was thinking that more information would have been provided before the surgery. I find the information after was really, really good, and there was not an abundance of it. [Participant 2] *I think it's a super useful tool, just felt there could have been more information in the beginning.* [Participant 7]

The most frequent messages and information that parents recommended be incorporated into the TTTM service were recorded throughout the interview and quantified. They are summarized in Figure 2.





Discussion

Principal Findings

In this feasibility and usability study, parental response to SMS service implementation into our practice was strongly positive. Parents were particularly satisfied with the format of information delivery compared with traditional instructive practices such as verbal and written modalities. This supports data from Hofstetter et al [12], who studied vaccine reminder preferences and showed that parents much preferred SMS reminders over phone calls from clinic staff, written reminders, or automated phone reminders. Text messages are favored because they are timely, brief, and to the point. Additionally, they have the added advantage of integrated links to other forms of media, such as websites and videos, which helps personalize care to individual parental needs. All parents were comfortable receiving text messages on their phones and had a very low level of concern regarding the information they received via SMS. However, to safeguard patient confidentiality, TTTM reminders excluded patient names and any identifiable information. Thus, these safety findings may not be readily extrapolated to other platforms.

Parents who had previous surgical experiences with their child reported no similar mobile device reminder tools or accessible online services offered to them prior to TTTM. This highlights a major area of need for providers. In the absence of health care team-derived platforms to deliver tailored information, the internet has become the resource of choice for parents seeking more information about their child's condition [13,14]. Pehora et al [15] showed that following day surgery, 98% of parents used internet search engines to find information regarding their child's health, despite only 24% reporting that they regarded this information as reliable and safe. The high, yet reluctant, use of such poor resources illustrates the anxiety and helplessness that parents feel when having to self-sufficiently manage their child's perioperative care needs without adequate resources. The combination of a society that highly desires information in an online or mobile device format with the availability of misinformation online should warrant concern in health care. Thus we believe that SMS is a reliable and inexpensive method to deliver clinician-reviewed instructions with links to trusted resources to parents.

Parent perception of benefit, convenience, and integration into daily life is essential for successful service implementation. In this study, incorrectly recalling perioperative care instructions comprised the bulk of parental anxiety when caring for their

child, results that corroborate with previously published reports [16-19]. Participants in our study felt that information sent via SMS was an ideal strategy to help remember important care instructions. Timely delivery of pertinent information helped parents prepare for important milestones in their child's care, such as organizing appropriate pain medication during the expected period of highest pain. While our study did not include objective measures of parental memory, a previous study by Yang et al [20] showed that mothers receiving reminder information via text messaging performed better on a knowledge assessment survey compared with mothers provided with the same information by conventional means (verbal and written form). This illustrates how SMS reminders can help parents be more informed, reassure them about their child's condition, and make them better equipped to care for their child.

While parents clearly perceive the service as helpful to them, we have yet to determine whether perioperative text-messaging reminders make a significant impact on preoperative errors (such as appropriate fasting and timely arrival for their procedure) and postoperative outcomes (postoperative recovery and subsequent health care use). Studies suggest that uncertainty in knowing how to respond to the tasks of their child's rehabilitation are associated with significant errors in care [16-19]. For instance, studies investigating postoperative pain management show that parents struggle to adequately assess their child's pain and often provide less than optimal analgesic medication [21-23]. Consequently, uncontrolled pain subjects children to increased nausea, vomiting, and dehydration, which accounts for one-third of all posttonsillectomy emergency department use [24]. Reminders and information sent via SMS have the potential to improve child care perioperatively, reducing unnecessary health care use such as emergency department visits and clinic calls. The best evidence so far comes from a quality improvement study and pilot study, both by Newton and Sulman [25,26], who show that in a group of 85 parents receiving perioperative reminder text messages at their institution, none of them required procedure cancellation or postoperative emergency department visits. They also report reduced postoperative phone calls from parents (25%) compared with previous studies conducted without text-messaging reminders (29% to 40%) [25,26]. However, it is worth noting that these studies lacked control groups and thus no significance can be drawn from these results. A comparative trial of TTTM service is underway and will help illuminate these potential impacts.

In general, parents were not concerned with high text volumes and in fact most indicated that they anticipated more frequent messages, with some suggesting that daily texts would be acceptable. Sharifi et al [27] has reported similar results, showing that after receiving informative SMS messages on behavioral modification for pediatric obesity, parents sought more frequent text reception and even valued a mixture of instructive and reassuring content sent to them. Interestingly, despite knowing messages were sent via an automated system, parents reported that receiving regular texts made them feel continuously supported by their health care team. The parental perception of continuous support by the health care team is a novel insight into the value of perioperative SMS reminders to parents and is a functional outcome worth investigating for future studies.

Limitations

Several limitations to our findings should be considered. Our study had a small sample size and other than relationship to the patient, parental demographic information was not collected. Thus, our results may not be representative of the entire eligible population, and we can not extrapolate these results to any general population other than those who are serviced by our institution. As well, the low number of participants may have limited the power of our study to reached thematic saturation for all possible factors associated with our SMS reminder system.

Our participants were all parents of children who received care at our institution. It is possible that existing client-provider relationships or experiences outside of this study could have biased interview responses. However, efforts were made to minimize potential impact. Participation was voluntary and parents could withdraw at any time; parents were explicitly made aware that participating in our study would have no impact in the care that they or their child received at our institution and that clinicians were blinded to identifying information of participants involved in the study. However, this study succeeded in providing real-world feasibility testing and collecting valuable feedback to improve the usability of our system. As a result, progress has been made on updating SMS reminder content, frequency, and regularity. Field testing our system also helped to identify a software malfunction associated with replicate messages that was subsequently investigated and mended. Currently, further testing is underway to gain insight into how large-scale rollout of our system will influence postoperative health care use and functional outcomes following pediatric tonsillectomy.

Conclusion

This study specifically focused on the stakeholder perspectives to optimize adoption by parents and adequately address their needs with technological health information and resources. In doing so, we identified novel insights into parental preferences regarding text message reminders to support their child's perioperative care and developed themes that can be used to guide future interventions. The key strategy for successful implementation was delivering comprehensive and relevant information at appropriate and regular intervals. Providing efficient and adaptable information to parents translated into confidence when caring for their children. Parental support for perioperative care instructions provided via SMS was strong and may be a cost-effective strategy to overcome recall errors, lessen parental anxiety, and empower families in their own health care.



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Conflicts of Interest

None declared.

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Abbreviations

IWK Health Centre: Izaak Walton Killam Health Centre **SMS:** short message service **TTTM:** Tonsil-Text-To-Me

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Original Paper

Potential Benefits and Drawbacks of Virtual Clinics in General Surgery: Pilot Cross-Sectional Questionnaire Study

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Abstract

Background: Escalating demand for specialist health care puts considerable demand on hospital services. Technology offers a means by which health care providers may increase the efficiency of health care delivery.

Objective: The aim of this study was to conduct a pilot study of the feasibility, benefits, and drawbacks of a virtual clinic (VC) in the general surgical service of a busy tertiary center.

Methods: Patient satisfaction with current care and attitudes to VC were surveyed prospectively in the general surgical outpatient department (OPD; n=223). A subset of patients who had undergone endoscopy and day surgery were recruited to follow-up in a VC and subsequently surveyed with regard to their satisfaction (20/243). Other outcomes measured included a comparison of consultation times in traditional and virtual outpatient settings and financial cost to both patients and the institution.

Results: Almost half of the patients reported barriers to prospective use of VCs. However, within the cohort who had been followed-up in the VC, satisfaction was higher than the traditional OPD (100% as compared with 187/223, 83.9%). Significant savings in both time (P=.003) and financial costs to patients and the institution were found.

Conclusions: For an appropriately selected group of patients, VCs offer a viable alternative to traditional OPD. This alternative can improve both patient satisfaction and efficiency of patient care.

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KEYWORDS

telemedicine; surgery; outpatient care; remote consultation; delivery of health care

Introduction

Background

As the global population continues to grow, pressure on health care systems is increasingly evident. This is apparent in developed countries, where an increasing proportion of gross domestic product is spent on health care costs [1], and also in the developing world as noncommunicable disease costs escalate [2]. Just as financial costs associated with health care provision

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are on the rise, so is the time commitment by physicians looking after increasingly complex patients with multiple comorbidities [3]. To address these issues, technological advances are one possible component of a solution to the challenges faced by health care systems worldwide. Although the use of technology is only one part of a larger policy response to ongoing health care provision issues, it represents an area in which significant improvement of services may be made. Virtual clinics (VCs) are at the forefront of this technological health care innovation.



Virtual consultation is a broad term that describes a form of nonphysical contact (eg, over the telephone, a video link, or other Web-based platform) between a patient and their health care provider(s), or between 2 or more health care providers, to encourage collaborative efforts between physicians to ensure the best possible outcome for the patient. There are different types of virtual consultations, examples of which may include the following: (1) Patient-general practitioner (GP), in which the patient calls the GP on telephone or video call as opposed to physically going to the clinic [4]; (2) GP-consultant, in which the GP contacts a specialist doctor regarding the joint management of a patient between the community and a specialist center [5]; (3) GP-multidisciplinary team (MDT), whereby GPs call into MDT meetings to learn from experts and acquire clinical skills [6] as well as to receive assistance with the management of less severe cases, thereby allowing health care resources to be reallocated to patients with more serious or complex cases [7]; and (4) Patient-specialist, in which the patient contacts a specialist doctor to receive care for a specific condition [8].

The potential advantages of VCs are evident and include reduced waiting times [9], decreased travel times to and from health centers [10,11], increased utilization of specialist knowledge [12], and increased efficiency of appointments and streamlining of referrals [13]. However, valid concerns exist regarding the safety of patient data, acceptability of this model to patients and clinicians, and feasibility of implementation [14]. Although a compelling argument for increased efficiency and cost-saving measures does exist, this must be balanced against patient safety and acceptability and developed with due regard to integration into current services.

Overall, the advantages of VCs may include higher patient satisfaction [5], more time-efficient appointments, reduced travel costs [10] and waiting times in outpatient department (OPD), and increased efficiency in the use of health care resources [15]. However, on the other hand, it has brought about reasonable concerns with regard to practicality [16], data breaches, patient privacy, and confidentiality [17], technical challenges, as well as some apprehension regarding the lack of face-to-face interaction and physical examination [18]. Other disadvantages such as limited capability, differing internet access, and concerns among both patients and the medical community remain. It is clear that blanket application of one size fits all VCs is inappropriate and that any integration into current systems must follow a structured and evidence-based approach [19]. It is also clear that there are issues and attitudes that still must be addressed before VCs can become a part of worldwide health care. For a comprehensive overview of the development of the field, including a conceptual overview and discussion of barriers to use, the reader is directed to reviews by international groups [16,20,21]. However, as technology develops and specific populations are considered, ongoing appraisal of the role of technology in health care is crucial. Thus, an investigation into the suitability of VCs in specific clinical areas is an important area of study.

Objectives

In 2016, Beaumont Hospital Dublin launched a pilot VC project in partnership with an Irish telemedicine provider, VideoDoc [22]. This platform was initially conceived as a substitute for primary care, in which a video link between a patient and GP could be used to conduct a consultation. Additional facilities for prescribing and documentation were included in the technology. An expansion of this platform into the hospital system, therefore, trialed video consultation instead of OPD follow-up for selected general surgical patients. Inclusion criteria included follow-up for operations such as laparoscopic cholecystectomy, hernia repair, or appendectomy as well as the ability to use the necessary technology. Similarly, patients with benign biopsy results (breast and thyroid) and endoscopy (+/needing additional surveillance) were consulted over the telephone, instead of traveling to the tertiary center and waiting for a long time in the OPD to receive benign results. The aim of the pilot project was to assess the feasibility of the use of VCs in the surgical service. Outcomes such as time efficiency of VCs as compared with standard outpatients; economic considerations; and patient attitudes, both prospectively and retrospectively, were also examined.

Methods

The objective of this pilot study was to assess the potential benefits and drawbacks of a VC system embedded within a larger general surgical population. Metrics included the following: (1) prospective patient attitudes to the concept of a VC; (2) retrospective attitudes in a smaller cohort; (3) a description of efficiency of standard outpatient care as compared with VCs in terms of waiting times and consultation times; and (4) a preliminary estimation of economic benefit of VCs to patients and the institution, without formal in-depth analysis of the economic impact of policy.

To assess the attitude of patients toward VCs, a survey was drafted with 17 questions (Multimedia Appendix 1). Questions 1 to 13 related to the current outpatients setting, asking for details regarding travel (1-7) and patient satisfaction (8-13). Patient satisfaction was assessed with the use of ordinal questions, ie, answers were given on a Likert scale from 1 (strongly disagree) to 7 (strongly agree). Questions 15 to 17 related to the views of patients in relation to the concept of VCs. Answers were organized in a dichotomous format (though question 17 had a space for patients to give a reason if they would not want to attend a VC). Surveys were distributed twice a week in the outpatient clinic of 2 general surgical consultants with the clinicians' permission, under registered audit CA340 in Beaumont Hospital from January 2018 to April 2018. An announcement was made at the outpatient reception by a clinical staff member regarding the survey; thereafter, patients who wished to partake indicated their willingness to do so. Both a morning and afternoon clinic were utilized to generalize findings.

Patients who had used the VC during the pilot study were also presented with a modified version of the survey to assess their experience and identify any problems and make improvements where necessary (n=20). A total of 20 patients who had

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undergone care in the VC were selected at random. The 20 patients were "seen" in the VC for postprocedure follow-up, eg, instead of follow-up in the OPD. These patients had been recruited to the VC follow-up at the time of their discharge from hospital. A protocol was employed whereby patients were contacted at 3 separate time points only before cessation of contact attempts to minimize patient burden. Overall, between prospective and retrospective cohorts, 243 participants completed the surveys.

In addition to the analysis of patient attitudes and satisfaction, we sought to demonstrate the efficiency of a VC by comparing the time taken for a senior house officer to see 10 patients in the VC against the time taken to see the same number of patients in the OPD. Only OPD patients who fit the previously mentioned VC inclusion criteria had their consultation times recorded. The time taken for a patient to be seen in the VC was provided to us by the VideoDoc app itself. In addition to this information, we were also provided with patients' waiting times between logging on to the app and being seen by a doctor as well as their satisfaction with the VideoDoc experience.

A comparison of average costs between the VCs and traditional clinics was also compiled using information provided by the hospitals' department of finance. In this manner, both patient and provider costs were assessed.

Results

Travel and Waiting Times

The data collected during this project were obtained from the patients of 2 general surgical consultants at a busy tertiary center in Dublin, Ireland, over a period of 15 weeks, using a survey handed out to a total of 223 patients. Separately, a subset (n=20) of patients who had used the VC in Beaumont were surveyed after their appointment to ascertain patient satisfaction and evaluate the new virtual service.

The first component of the survey looked at the travel requirements for attending an outpatient appointment.

The average one-way travel time from the patients' respective homes to Beaumont Hospital for their appointment was found to be 43 min (range: 2-180 min; median: 30 min; SE 2.44; SD 35). The average time spent waiting to be seen by a clinician was 61 min (range: 3-240 min; median: 60 min; SE 3.16; SD 41), underlining the fact that the patients spend more time waiting to be seen than they do commuting to the hospital

The median cost incurred by the patients during their commute to the hospital was calculated at a value of $\in 10$ (range: \oplus -100; mean $\in 12.50$; SE 1.13). The average number of work days missed to attend the outpatient appointment was 0.85 days, with varying levels of lost earnings for this time

Patient Attitudes Toward the Virtual Clinic

Another survey component dealt with patients' opinion on the use and application of VCs and whether or not they would be open to this model of care. This showed that 52.0% (116/223) of patients believe that the physician can still provide care without being able to perform a physical examination at every appointment.

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Importantly, 88.8% (198/223) of patients are of the view that physical examination is an important part of a consultation. When asked whether they would attend a VC over an outpatient appointment, data showed that 48.9% (109/223) said no, with 43.0% (96/223) saying they would. If they did attend a VC, however, 57.8% (129/223) reported no issue with answering personal questions. When asked to take into account the time and cost it takes to come to an outpatient appointment and compare it with that of a VC, which would they prefer to attend, 55.2% (123/223) of patients prefer OPD despite the downsides, 30.9% (69/223) chose VC, and 4.0% (9/223) had no preference.

Patient Attitudes Toward the Current Model of Care

Finally, another section of the survey is the patient satisfaction component, as it relates to the current "traditional" OPD. A total of 83.0% (185/223) of patients strongly believed that taking an active role in their own health care is important. Moreover, 87.9% (196/223) of patients were pleased with the quality of the medical appointment. In addition, 74.0% (165/223) of patients agreed that their appointment was on time and efficient. Patients found the appointments to be conducted in a confidential manner, with 81.2% (181/223) strongly agreeing and 87.0% (194/223) in total agreeing to this point. Patients had no problems disclosing personal information, as 88.9% (198/223) of patients felt comfortable sharing personal information with their health care provider. Overall, 83.0% (185/223) of patients were satisfied with their appointments within the current framework.

Retrospective Patient Attitudes Toward the Virtual Clinic

A separate cohort of patients who had attended the VC were selected at random and surveyed with a modified version of the questionnaire to assess their satisfaction level and their opinion on the outcome of their health care (n=20). A total of 100% of the patients found the technical quality to be acceptable and the appointment to be very time- and cost-effective and conducted in a confidential manner. All of this cohort believed that the outcome of their care was exactly the same as if they were to attend an outpatient appointment and meet their doctor in person, and they were overall satisfied with the appointment.

Financial Impact of New Technologies on Hospital

The stated cost per patient was, on average, \bigcirc 58.92 per general surgery patient in the OPD, resulting in an annual cost of \bigcirc 553,995 (Beaumont Finance Department). When the salary of both administrative and clinical staff was taken into account, it costs the hospital an average of \bigcirc 14 to see a patient in the VC, as based on the average time of less than 10 min to see a patient and complete the associated documentation (n=10). However, this was predicated on free usage of the technological platform as sponsored by the private company.

The length of the average consultation in VideoDoc was 5 min and 19 seconds (range: 2-14 min; SD 4.1), with an average waiting time of 4 min and 40 seconds. This was skewed somewhat by 1 user who had some technical difficulties and needed assistance using the app. Overall, a representative sample of patients had a total waiting and consultation time of less than 10 min. The length of the average OPD consultation for similar

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matched patients was 14 min (range: 3-24; SD 6.7). An unpaired 2-tailed *t* test assuming unequal variances showed that these were statistically significantly different (P=.003).

Discussion

Principal Findings

The OPD sees more than 143,000 patients per year [7]. However, up to 15% of patients miss their appointments [23], and there are many patients who have to wait for an extended period for an appointment because of minimal availability. The Irish Times reported that there were 478,569 people waiting for OPD appointments as of May 2017 [24,25]. Our research has shown that it takes a patient approximately 43 min on average to travel to Beaumont Hospital, after which they are checked in at the reception and have to wait for an even longer period, estimated at 61 min, before they are called in by the doctor. Therefore, it takes patients a total of 104 min to attend an outpatient appointment, which includes both one-way travel time to the hospital and waiting time at the reception. This means that for every 1 patient waiting to be seen in the OPD, approximately 5 patients can be seen by VC, given that our data show that VC only takes 10 min, even allowing for note-taking and administrative tasks in between consultations.

Potential Financial Impacts

It is important to note that time off work has to be taken to attend these appointments; on average, patients had to take a full day off, with the majority of this leave of absence being unpaid. Some patients also had to be accompanied by a relative or friend. On the other hand, a VC appointment is not associated with any travel time and very little waiting time as the doctor and patient are both available at the scheduled time of appointment. The clinic in the pilot project ran outside typical work hours between 5 to 6 pm to allow patients to attend a full day of work and conveniently attend their appointment after working hours, without missing a day's pay.

Furthermore, in this pilot program, use of the VC was free of charge for the selected VC patients and, thus, was associated with no additional travel cost. Recalling that the average travel cost for an outpatient appointment was €10 on top of lost wages/ productivity, our data suggest from a patient perspective that VCs are certainly the more cost-effective option. Access to the requisite technology is an important consideration in an equitable health care system that incorporates a virtual aspect; however, 97% of the adult Irish population have access to a mobile phone [26]. Furthermore, internet access in urban areas in Ireland is generally of high quality, with a national plan in place to improve rural broadband coverage over the next 7 years [27].

In addition, the use of the VC saves the hospital and the health care system a considerable amount. It costs the hospital an average of 158.92 per general surgery patient in the OPD, resulting in an annual cost of 53,995 (Beaumont Finance Department). When the salary of both administrative and clinical staff was taken into account, it costs the hospital an average of 14 to see a patient in the VC.

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XSL•F() RenderX This leads us to conclude that if VC were to become the mainstay of follow-up care, there would be an increase in the total number of patients seen on a daily basis and a decrease in the number of missed appointments. Although VC is not suitable for everyone (as video clinic is clearly inappropriate for very elderly patients without access to the necessary technology; VCs are inappropriate forums for sensitive consultations in oncology, etc.), it indirectly benefits them because of the reduced waiting times for appointments and more frequent appointments if necessary.

VCs also have the potential to free up space on waiting lists, thereby reducing the time between appointments. It could also provide patients with easier and more frequent access to their health care providers. We speculate that this could have positive effects on compliance and communication and overall improve the doctor-patient relationship.

Patient satisfaction is a crucial part of making the VC a part of the future. The key aim of any innovation in health care technology must be to enhance ease of accessibility to the health care system and improve outcomes. Patient satisfaction is a strong predictor of improved outcomes, including compliance and treatment adherence [28,29]. To allow for a thorough assessment, a patient satisfaction component was added to the survey to provide some insight into how patients feel about different aspects of their health care.

We looked at how importantly patients rate their involvement in their health care as opposed to having their doctor assume control, and we found that patients consider it very important, with 82.2% (152/185) in strong agreement with the statement. Due to the arguably impersonal nature of the VC, there may be a reduced ability for the patient to be as involved as they would like to be. Conversely, there is a plausible case that taking control of appointment times/location can facilitate a greater sense of empowerment in health care decisions, as could be the case in VCs.

When asked how comfortable they were with sharing personal/sensitive information with their doctor, all patients agreed that they would be comfortable sharing personal/sensitive information, with 78.0% (174/223) strongly agreeing, 11.2% (25/223) moderately agreeing, and <1% disagreeing. The rest gave no answer. However, 35.0% (78/223) stated that they would be uncomfortable sharing personal information about their health in a virtual setting. Nevertheless, other authors have found that virtual settings encourage discussions about sensitive or potentially embarrassing information [30]. The identification of potential barriers to VC usage, including addressing patient fears regarding confidentiality, is key in the development of this service. Further research in this area is certainly warranted.

Another likely barrier to use is the central role of the physical examination in the doctor-patient relationship. This relationship is long recognized and well described in the literature [31]. Interestingly, in this cohort, it was found that 88.8% (198/223) of patients are indeed of the view that physical examination is important during a consultation, but 51.1% (114/223) believe that the doctor is able to perform their job even if they are not able to conduct a physical examination. Again, the concept of VCs must be applied to a carefully selected group of patients;

eg, new patients with red flag symptoms clearly warrant a physical examination.

Despite the benefits of VC to patients in terms of time and expense, the data showed that in the prospective cohort, 55.2% (123/223) of patients expressed a preference for the OPD as compared with 30.9% (69/223) preferring VC. This may be partially explained by the fact that the average age of the sample population was above 50 years. This age group may be less familiar with technology and smartphones; this may explain their reluctance to make the change from the more traditional setting. Retrospectively, the fact of being an older patient was not necessarily an impediment to successfully using the VC; however, we observed anecdotally that younger patients had greater facility with the technology, which may merit further investigation.

A separate cohort of patients who had attended the VC were surveyed with a modified version of the questionnaire used for the other patients to assess their satisfaction level and their opinion on the outcome of their health care. A total of 100% (20/20) of the patients found it to be very time- and cost-effective and believe that the outcome of their care will be exactly the same as if they were to attend an outpatient appointment and meet their doctor in person. Furthermore, those who were unable to operate the technology were often assisted by family member or friends. Therefore, as mentioned previously, older patients are not always ineligible to be a part of the VC system, though they may need additional considerations and resources.

When we compared the satisfaction ratings in traditional and virtual outpatient clinics, 83.9% (187/223) of outpatients overall were satisfied with their appointment, showing that the OPD has an overall good patient satisfaction rate, which is important as it is the current standard of care. It should be noted that the retrospective analysis of patient satisfaction in VC had a much smaller sample size, and we acknowledge the potential for bias in a telephone interview as compared with an anonymous survey. Nonetheless, our results are encouraging and suggest that in an appropriately selected cohort, VCs can offer a viable alternative to the traditional model in the outpatient setting.

Limitations

Before the findings of this study can be fully appreciated, its limitations must be acknowledged. First, the participants of this study cannot be said to be representative of all patient groups. Patients were recruited on a voluntary basis after an announcement at the outpatient reception; thus, it is not possible to quantify exactly how many patients were in the overall sample size. Patient groups excluded from completing surveys included children; patients with poor vision; and patients with limited hand mobility, literacy, etc. It is possible that if the authors had additional resources and permissions to facilitate including these patients that this may influence results (eg, if interpreters were on hand to include the viewpoints of those with poor vision or limited English language proficiency). Similarly, very few younger adults took part in the survey, given that the majority of participants in outpatients were older adults. It is plausible to speculate that this cohort may have been more receptive to the idea of VCs; this would represent a key area of future

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research. It should also be noted that the larger prospective cohort was heterogeneous in nature, with some patients having had inpatient stays, which may well color their attitude toward virtual care as compared with patients who had a straightforward day procedure without complication. Even within the total pool of patients available in the sample, our findings pertain only to the population in the general surgical outpatients, and we caution against generalizing these finding to other specialties without further research.

With regard to the survey itself, its structure could have been improved by predistribution validation for reliability and relevance by a panel of both patients and professionals. The "age" and "gender" questions were commonly overlooked, which compromised a key aspect of our demographic analysis. Furthermore, there were some gaps in data, which may reflect "participant fatigue" because of a lengthy survey.

In terms of the retrospective follow-up cohort who had previously attended the VC, the survey was significantly shortened to minimize additional burden to the patients, given the need to read it to participants over the phone. Initial concerns raised by stakeholders included the feasibility of the technical aspects of the software, and so, an additional question regarding the audiovisual quality of the consultation was included. Conversely, the survey did not include the section regarding travel times, time off work, etc as this was irrelevant to the cohort. The rest of the survey focused on general satisfaction and confidence regarding confidentiality. Thus, the detail of some specific questions was lost in the retrospective cohort, such as attitudes to necessity of physical examination. However, given that the patient satisfaction in general with the VC was 100%, it is reasonable to hope that the lack of physical examination did not represent an insurmountable hurdle to these patients.

In future work, we would consider a longer survey identical to that filled out in OPD, though this raises different issues regarding poor follow-up rates (postal surveys) and privacy concerns (email responses). Further work is needed to identify areas of patient concern and further refine the VC service.

Relevance of findings would have been improved had the clinical conditions of both prospective and retrospective respondents been recorded; however, these data were outside of the data protection scope permitted by this project. Patients were noted to fall within the eligibility criteria, but the individual procedures were not enumerated as the collection of patient-specific data (medical comorbidities, etc) was outside of the permissions granted for this pilot project; thus, regrettably, we were unable to include this information in this study. Again, future work should take this shortcoming into account.

In addition, costing analysis was based on salary provision of administrative and clinical staff only, with accurate information technology maintenance costs unavailable at the time of writing. As this project was a pilot of the concept of VCs within this setting, further detailed analysis of this component and others is certainly warranted. Future work in this field should follow the nonadoption, abandonment, scale-up, spread, and sustainability framework [19] to explore the challenges inherent in health care delivery change, and indeed, it is acknowledged

that this project would have been improved by use of the framework.

Another limitation that was evident was the lack of awareness about VCs among the general public and medical professionals. It is hoped that ongoing work in this area will lead to the improvement of the VC service and its expansion in the hospital service for appropriate patients.

Conclusions

In conclusion, VCs have the capacity to deliver on its expectations of reducing patient waiting times and improving patient care. However, it requires a meticulous integration into the existing system to convince patients of the advantages that it may offer. More research is required to assess which patient cohorts and departments it is most suitable for.

Acknowledgments

The technological platform in this study was provided free of charge by VideoDoc.

Conflicts of Interest

The technological platform in this study was provided free of charge by VideoDoc. A conference registration fee was paid by VideoDoc on behalf of the lead author (EJR). VideoDoc has no input in study design, manuscript compilation, or review.

Multimedia Appendix 1

Survey regarding patient logistics (travel time/waiting time/work missed), attitudes toward the current standard of care, and attitudes toward the virtual clinic.

[DOCX File, 20 KB - periop_v3i1e12491_app1.docx]

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Abbreviations

GP: general practitioner **MDT:** multidisciplinary team **OPD:** outpatient department **VC:** virtual clinic

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Review

Impact of Intensive Care Unit Readmissions on Patient Outcomes and the Evaluation of the National Early Warning Score to Prevent Readmissions: Literature Review

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Abstract

Background: Intensive care unit (ICU) readmissions have been shown to increase a patient's in-hospital mortality and length of stay (LOS). Despite this, no methods have been set in place to prevent readmissions from occurring.

Objective: The aim of this literature review was to evaluate the impact of ICU readmission on patient outcomes and to evaluate the effect of using a risk stratification tool, the National Early Warning Score (NEWS), on ICU readmissions.

Methods: A database search was performed on PubMed, Cumulative Index of Nursing and Allied Health Literature, Google Scholar, and ProQuest. In the initial search, 2028 articles were retrieved; after inclusion and exclusion criteria were applied, 12 articles were ultimately used in this literature review.

Results: This literature review found that patients readmitted to the ICU have an increased mortality rate and LOS at the hospital. The sample sizes in the reviewed studies ranged from 158 to 745,187 patients. Readmissions were most commonly associated with respiratory issues about 18% to 59% of the time. The NEWS has been shown to detect early clinical deterioration in a patient within 24 hours of transfer, with a 95% CI of 0.89 to 0.94 (P<.001), a sensitivity of 93.6%, and a specificity of 82.2%.

Conclusions: ICU readmissions are associated with worse patient outcomes, including hospital mortality and increased LOS. Without the use of an objective screening tool, the provider has been solely responsible for the decision of patient transfer. Assessment with the NEWS could be helpful in decreasing the frequency of inappropriate transfers and ultimately ICU readmission.

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KEYWORDS

patients; critical care; hospitalization; risk; news

Introduction

Background

There is a problem associated with patients being readmitted to the intensive care unit (ICU) following transfer from the ICU to the medical floor. Hospitals rely on quality metrics to address many aspects of patient care; one of those metrics is the unplanned ICU readmission within 72 hours of transfer [1]. ICU readmission or *bounce backs* are associated with worse outcomes for the patient and increased resource utilization [2]. The poor outcomes include increased hospital mortality [3];

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increased length of stay (LOS) [4], which ultimately effects the availability of ICU beds [2]; and increased hospital costs [5]. An increase in hospital cost not only affects the patient but also impacts the entire hospital system, as the ICU readmission rate is associated with the performance of the ICU and the hospital [6-8].

Unexpected readmission to the ICU is associated with significantly high hospital mortality compared with patients who are not readmitted: 21.3% to 40% compared with 3.6% to 8.4% [9-17]. The odds of death remain 6 to 7 times higher among readmitted patients, independent of other factors [11].

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Among the most common reasons for readmissions were pneumonia and respiratory failure [18,19]. Although primary reasons for readmission to the ICU have been established within the medical critical care population, the reasons have not clearly been delineated for the surgical population [1].

This problem has been identified at the national level [1,5] and at the local level as well. Surgical trauma ICU readmissions have been noted specifically at a local hospital in the southern Piedmont region of North Carolina. The major predictor of surgical trauma ICU readmissions within this organization is respiratory failure. A goal has been set within this organization to identify the patients at high risk for bouncing back to the surgical trauma ICU after transfer and to prevent these bounce backs from occurring. The use of a risk stratification tool, such as the National Early Warning Score (NEWS), could identify the patients at high risk for readmission to the surgical trauma ICU and, therefore, prevent their premature transfer to the progressive care or medical units [20].

Objective

The aim of this literature review was to evaluate the impact of ICU readmission on patient outcomes and to evaluate the effect of using a risk stratification tool, the NEWS, on ICU readmissions.

Methods

Search Strategy

In a review of the literature, focus was placed on ICU readmissions and assessment tools utilized for patient transfers. The literature was evaluated to answer the 2 proposed questions. The first question was as follows: Does ICU readmission increase mortality and LOS? If so, what are the readmission rate and risk factors for readmission? The second question was as follows: Is the NEWS an adequate tool for evaluating the patient's readiness for transfer out of the ICU to the medical floor? A search was conducted on the electronic databases PubMed, Cumulative Index of Nursing and Allied Health Literature, Google Scholar, and ProQuest. The search was limited to articles that were published within the last 10 years, ie, the publication date had to be 2008 onward. Key search terms were ICU, critical care, surgical, and assessment tool. Search terms were identified in the abstract of other articles, and these were used to expand the search. Additional key terms used included "characteristics," "readmission, risk," "trauma," and "National Early Warning Score" (NEWS). Medical Subject Headings terms included "(ICU readmission AND risk), ((ICU readmission AND risk) AND (assessment tool))", and "(ICU AND (bouncebacks OR bounce backs) AND trauma)."

Inclusion and Exclusion Criteria

In addition to searching key terms, the bibliographies of the articles reviewed were also searched, and key articles were identified that were useful in the evaluation of ICU readmissions and assessment tools. The articles were independently searched and evaluated for use within the review of the literature. Of the 519 articles identified, the top 200 articles were screened for review. The inclusion criteria for the search were studies of adults, readmissions to the ICU, and articles that focused on the

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NEWS as a screening tool. Of the 200 articles identified, the titles and abstracts were reviewed, and 13 articles were considered to have met the inclusion criteria. The exclusion criteria were studies that were not published in the English language, studies that were published before 2008, studies that did not include full-text articles, and studies that reviewed other risk assessment tools such as the Minimizing ICU Readmission score. Of note, one article was reviewed as it evaluated the Stability and Workload Index for Transfer score because it provided details on readmission and mortality rates in the surgical patient population [21]. A literature matrix has been provided to break down the articles that were reviewed. Of those articles, there were 2 systematic reviews, 5 retrospective chart reviews, 1 descriptive study, and 4 prospective studies.

Results

Evaluation

A thorough review of the literature was performed to identify the risk factors associated with ICU readmission and to examine if the NEWS is an adequate tool for evaluating the patient's readiness for transfer out of the ICU. After inclusion and exclusion criteria were applied, a total of 200 articles were reviewed, and 13 articles were utilized in this literature review. A literature matrix has been included within Multimedia Appendix 1, outlining the articles reviewed. The evidence level of all articles has been identified within the literature matrix. Additionally, the findings of each article can be referenced in Multimedia Appendix 2. Among the articles reviewed, the most popular research method was a prospective observational study. Of the 13 articles that were reviewed, it is important to note that 2 were systematic reviews and represented the highest level of evidence. The sample sizes within the studies ranged from 158 to 745,187 patients [5,22]. The definition of bounce back ranged in the studies from 72 hours to 7 days [2,9,21,23].

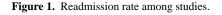
Readmission Rate

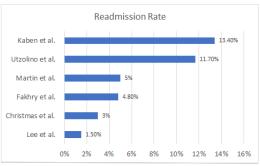
The readmission rate of patients transferred out of the ICU to the medical floor was reviewed in 13 articles. Within these articles, the readmission criteria varied; readmissions were considered between 72 hours [2,21,23] and up to 7 days [9]. The readmission rate varied among articles from as low as 1.5% (378/25,717 patients) [23] to as high as 13.4% (381/2852) patients) [9] (Figure 1). The variation in the rates is likely attributed to the difference in readmission time, with Kaben et al [9] allowing 7 days and Lee et al [23] only including readmissions within 3 days. Not only does the readmission time affect the patient's readmission rate, but other factors such as mental status, age, and sex also play a part in the readmission rate; these factors are discussed further later. It is interesting to note that 1828 out of 2852 (64.1%) patients discharged from the ICU in the study by Kaben et al [9] were men, which was later noted to be a risk factor for readmission. In addition, the patients within this study were strictly monitored for readmission to a surgical ICU setting, whereas the other studies looked at medical and surgical patients, which too could have affected the readmission rate. It is important to note that readmission to the ICU was significantly increased to 25.1% (110/439 patients) in patients with unplanned discharges, that is, those patients

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who were transferred because of a lack of availability of ICU beds [14]. It is clear from the readmission rates provided within the reviewed articles that allowing a longer period for ICU readmission will increase the readmission rate. It is not clear within the articles which timeframe is most appropriate to deem the patient's as a true readmission because of inappropriate ICU

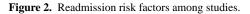
transfer. It is most likely that identifiable factors for readmission at the time of transfer would show themselves within the first 72 hours of transfer, resulting in readmission. It is not favorable to think that readmissions occurring after 7 days would have shown signs for potential readmission at the time of transfer from the ICU.

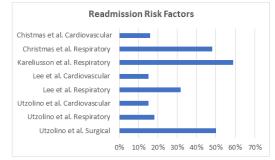




Readmission Risk Factors

Although many risk factors were associated with ICU readmission, the most common cause for ICU readmission was respiratory insufficiency or failure, accounting for 18% to 59% of all readmitted patients [14,21]. A total of 72 out of 148 patients were readmitted because of respiratory distress, with 31% requiring intubation [5]. In addition, it was shown that if mechanical ventilation was required on readmission to the ICU, an increased mortality was identified (P < .001) [23]. In the case of patients readmitted because of a respiratory failure, it would be important to identify their oxygen requirements before they were discharged from the ICU and if they were receiving any preventative respiratory therapies. The second most common cause of ICU readmission was cardiac etiology; this accounted for 15% to 30.2% of patients readmitted, with one study identifying 91 out of 378 patients readmitted because of cardiovascular issues [14,23]. Figure 2 breaks down the risk factors associated with readmission per study; the figure compares respiratory problems with cardiovascular problems. In additional, Utzolino et al [14] report surgical complications as an additional risk factor for readmission.





Mortality and Length of Stay

Although an increased LOS was reported among the studies, the increase was not always quantified; however, it did range from an increase of 11 to 40 days following ICU readmission [5,14,21]. Readmission to the ICU during the patient's hospitalization ultimately increases the patient's overall LOS

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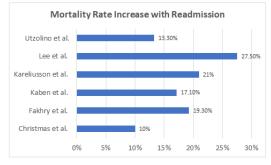
in the hospital. A prolonged ICU admission would ultimately result in a prolonged hospital stay, limiting the number of hospital beds available for new admissions. In addition, all studies noted an increase in mortality rate among patients readmitted to the ICU; mortality ranged from 10% to 27.5% [5,23]. Figure 3 shows the mortality rate in percentage per study.

that identified a patient to be at a higher risk for ICU readmission, namely, male sex, age greater than 54 years, surgical patient, decreased Glasgow Coma Scale (GCS) at the time of initial transfer from the ICU to the medical unit, and multiple comorbidities at the time of initial transfer [2,5-9,14,21,23,24]. A male patient had an odds ratio of 2.9, and patients with 3 or more comorbidities showed an odds ratio of 8.4, with P < .001 for readmission [2]. In addition, according to Christmas et al [5], patients with traumatic brain injury were more vulnerable to ICU readmission; this likely ties into the patient's GCS at the time of discharge from ICU, with additional research providing an odds ratio of 22.3 and P<.01 for the risk of readmission if the patient's GCS was less than 9 at the time of transfer [2]. There were tools available for screening patients with multiple comorbidities and the risk associated with these diagnoses. These tools were used in the evaluation of comorbidities throughout the literature that was reviewed; however, those tools were not evaluated within this literature review.

Among the studies reviewed, there were additional risk factors

The increase in mortality rate following ICU readmission is likely associated with the severity of the patient's illness prompting the return to the ICU. According to Utzolino et al [14], the mortality risk was increased if the ICU readmission was related to a respiratory cause; the study additionally showed that 33 out of 249 (13.2%) patients died following their readmission to the ICU. Those patients who were readmitted to the ICU and required mechanical ventilation at that time had an increase in mortality rate, with P < .001 [23]. On the basis of these data, those patients who are readmitted to the ICU because of a respiratory issue, especially those requiring mechanical ventilation, will have an increased LOS as well as an increase in their mortality; in addition, those with a cardiac event have the next highest mortality rate.

Figure 3. Increase in mortality rate with readmission.



Discussion

Principal Findings

A review of the literature showed that ICU readmission ranged from 1.5% to 13.4% [5,7]. The greatest risk factors identified for ICU readmission include increased age, the male sex, a decreased GCS (less than 9), and multiple comorbidities [2,9,14,21,23,24]. The most common reason for ICU readmission was respiratory distress or failure, with those patients who required mechanical ventilation at the time of readmission showing a greater mortality [23]. Overall, readmission to the ICU increased the patient's LOS and overall mortality rate from 10% to 27.5% [5,23]. The transition of patient care from the medical ICU to the medical unit is a routine process that exposes patients to preventable adverse events [22]. This transition is often challenging as the sickest patients within the hospital are transferred from a resource-intensive environment to a resource-limited environment [22]. Evidence suggests that readmissions to the ICU, no matter the type, leads to worse patient outcomes. The quality of evidence varied greatly from expert opinion to systematic reviews. Throughout the literature, the parameters quantifying ICU readmission varied from 72 hours to 7 days [2,9,21,23]. The readmission rate varied across the studies from 1.5% to 13.4% [9,23]. Although timing was a factor in the readmission rates, other risk factors for readmission were identified, such as mental status, sex, and age; the variation in patient's reason to transfer likely also contributed to the variation in readmission rate. An additional driving factor associated with patients being discharged too early from the surgical trauma or medical ICU is the demand for ICU beds [5,14,25]. The demand for ICU beds in the hospital setting is going to remain an issue; however, medical units need to be prepared to provide the level of care that is required by this patient population. Given this demand, ICU readmission rates are a quality metric for hospital care [1,24]. It should also be noted that ICU readmissions ultimately result in increased hospital costs [2].

Kaben et al [9] have shown that patients readmitted to the ICU have an increased incidence of inpatient morbidity and mortality.

The evidence of leading factors for ICU readmission varied across the studies reviewed and were contingent on the type of patient being evaluated. For example, it was most commonly noted that patients with respiratory failure [5,21,23]; vital sign instability [2]; and surgical complications, which included anastomotic leak, surgical site infection, and bleeding [14], were most commonly readmitted to the ICU. It has been noted that patients discharged from the ICU with residual organ dysfunction were more likely to be readmitted to the ICU than patients without residual organ dysfunction [23]. The mortality rate was not quantified in every study, but in those in which it was stated, the rate ranged from 10% to 17.1% [5,9]. Given this increased mortality rate associated with ICU readmissions, a risk stratification tool could provide clinicians with the information needed to make an informed decision related to patient transfers. An ideal tool for implementation will forecast patient outcomes and, therefore, facilitate the delivery for safe, effective, and efficient care [22]. Rapid deterioration in patients' status can occur during their hospitalization because of disease progression; evidence suggests that the signs of deterioration can be identified up to hours of being a serious clinical event [26]. It is, therefore, important for the clinician to make an informed decision about those patients who are appropriate for transfer from the ICU; the use of a risk stratification tool could be helpful in identifying patients at high risk for readmission to the ICU [22]. Screening tools can be effective in alerting clinicians in real time of those high-risk patients and can assist in individualized decision making for their patients [26]. The NEWS is a risk stratification tool and has been evaluated for many clinical outcomes including cardiac arrest, unanticipated ICU admission, or death within 24 hours of admission [20]. For the purpose of this literature review, the NEWS was the only screening tool evaluated. This is a simple tool and can easily be implemented for evaluation of patients before transferring them out of the ICU; it is an aggregated weighted score based on the measurement of 6 vital signs and the level of inspired oxygen [25]. This tool is favored as it has been shown to improve patient outcomes in a variety of settings. It was noted to have identified deterioration in nonelective surgical patients and medical patients [27]. When evaluating patients using

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NEWS, a higher score indicates a greater severity of illness and an increased risk of adverse events. When patients were evaluated with NEWS before ICU discharge, the scores were an independent predictor of the clinical deterioration of the patients within 24 hours of transfer, with P<.001 [25]. This study demonstrated significant sensitivity and specificity in the prediction of clinical deterioration within 24 hours of transfer. The evidence to support the implementation of NEWS was gathered from 3 systematic reviews and 1 prospective observational study. The implementation of the NEWS or any risk stratification tool relies heavily on the use of the tool by clinicians [22]. Therefore, it is important to identify a tool that is easy to use, does not increase the clinician's or nurse's workload, and identifies high-risk patients. The NEWS meets all these criteria [27].

Limitations

Limitations were noted in this review of the literature. The focus of this literature review was to identify the impact of ICU readmission on patient outcomes and to evaluate the NEWS as a tool for assessing patients before transferring them out of the ICU, which would be appropriate for application for surgical trauma critical care patients. Many of the studies identified were performed on medical ICU patients. In addition, the definition of ICU readmission varied among studies, making it difficult to compare the studies that were utilized in this review of the literature. Finally, the study was limited by the strength of the data identified; although 2 systematic reviews were utilized, the remaining studies were prospective and retrospective in nature.

Conclusions

The evidence reviewed supports the fact that premature transfer from the ICU to the medical floor is associated with adverse outcomes for the patient. Those adverse outcomes affect the patient's mortality, hospital cost, and the LOS at the hospital. It is important to note that the adverse outcomes are likely not solely because of premature transfer but could be the result of the patient's overall clinical picture and severity of illness. To this point, ICU transfer has solely been the clinical decision of the provider caring for the patient. This decision is often clouded by the constant need for ICU beds and the request for transfers in the middle of the night to make beds available. A risk stratification tool, such as the NEWS, supplies the provider with objective data to support the decision to transfer the patient and to identify the patients at high risk for readmission. Implementation of a risk stratification tool such as the NEWS would be beneficial in evaluating the patient's readiness to get transferred from the ICU, in addition to the clinician's judgment. However, further research needs to focus on the application of the NEWS on the surgical trauma critical care patient.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram. [DOCX File, 30 KB - periop v3i1e13782 app1.docx]

Multimedia Appendix 2 Article tables. [DOCX File, 36 KB - periop_v3i1e13782_app2.docx]

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Abbreviations

GCS: Glasgow Coma Scale ICU: intensive care unit LOS: length of stay NEWS: National Early Warning Score



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Original Paper

A Redesigned Order Entry System for Reducing Low-Value Preprocedural Cardiology Consultations: Quality-Improvement Cohort Study

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Abstract

Background: Preprocedural cardiac evaluation is a common reason for outpatient cardiology visits. Many patients who are referred to cardiology clinics for preprocedural evaluation are at low risk of perioperative events and do not require any further management. Our facility treats patients over a large geographic area; avoiding low-value consultations reduces time and travel burdens for patients.

Objective: Our study objective was to assess the impact of a novel algorithm in the electronic order entry system aimed to guide clinicians toward patients who may benefit from cardiovascular referral.

Methods: We retrospectively reviewed in-person consultations and electronic consultations (e-consults) to our cardiology service before and after implementation of the novel algorithm to assess changes in patterns of care. Data were stored in a custom electronic database on internal servers.

Results: We reviewed 603 consultations to our cardiology clinic and found that 89 (14.7%) were sent for preprocedural evaluation. Of these, 39 (43.8% of preprocedural consultations) were e-consults. After implementation, we reviewed 360 consultations. The proportion of consultations for preprocedural evaluation did not decrease (n=47, 13.0%; P=.39). We observed an absolute increase of 13.6% in the proportion of consultations ordered as e-consults (27/47, 57.4%). During the postintervention period, we received no remarks, concerns, or criticisms from ordering clinicians about the process change and no reports of adverse events.

Conclusions: Implementation of an ordering algorithm to reduce low-value preprocedural cardiology evaluations did not lead to a reduction in the number of overall preprocedural cardiology consultations. The number of patients seen electronically increased, potentially improving clinic access and reducing travel burden for patients.

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KEYWORDS

quality improvement; preoperative care; medical order entry systems

Introduction

Preprocedural evaluation is a common reason for outpatient cardiology clinic referrals in both community and academic settings. Such referrals are sometimes made for patients undergoing minimal risk procedures with no history of and few risk factors for heart disease. Despite clear appropriate use criteria and guideline recommendations, unnecessary preprocedural testing is often performed, and preprocedural assessments infrequently result in modification of care [1].

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For patients who plan to undergo elective procedures, the addition of a referral to a cardiologist for preprocedural cardiac evaluation may delay the procedure for days or weeks depending on clinic wait times. Due to regionalization of care within the US Veterans Health Administration (VHA) system, some patients are required to travel for hours each way to receive a specialty care referral.

In order to reduce low-yield preprocedural cardiac evaluation and minimize inconvenience to patients, we implemented an

referral and which do not. The algorithm consisted of five

questions assessing the patient's cardiac symptoms, need for

anticoagulation management, exercise capacity, procedural risk,

and testing options (Figure 1). The intervention was built into the workflow of ordering a cardiology consultation, so that it

could not be bypassed. All referring physicians were required to use the new algorithm, including those in surgery and

subspecialties, anesthesia, primary care, and other procedural

specialties. Prior to implementation, these clinicians were

notified and educated about the algorithm via email

correspondence.

ordering algorithm to be used by all clinicians requesting cardiology consultation for preprocedural patients. We hypothesized that the algorithm would reduce the number of in-person clinic visits for preprocedural cardiac evaluation.

Methods

We conducted a quality-improvement project wherein we implemented a novel order entry system in our electronic health records at a single academically affiliated Veterans Affairs (VA) medical center. We devised a simple, stepwise algorithm to guide ordering clinicians on which patients need cardiology

Figure 1. Flowchart of preprocedural consult guidance.

Defer pre-procedural evaluation Has the surgical team seen the patient and is surgery planned or anticipated? until the patient has been seen by No surgeon Yes **Cardiology Consultation** Yes No No further cardiac evaluation necessary and patient can Yes proceed to surgery No No further cardiac evaluation necessary and patient can Yes • Walking up a hill proceed to surgery Walking up a flight of stairs No Obtain exercise stress test. If normal, no further cardiac Yes evaluation needed No Obtain nuclear stress test. If normal, no further cardiac

Prior to our intervention, we analyzed the pattern of consultations received for the cardiology clinic over a 3-month period (June 1, 2015, to August 31, 2015). Variables evaluated

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included the proportion of cardiology consultations that were

ordered for preprocedural assessment, the proportion of

consultations ordered as e-consults versus in-person



consultations, and the proportion of consultations that were converted from one type to another. As a balancing measure, after the intervention, we requested feedback via email from process stakeholders, including cardiology, primary care, and surgery clinicians. The e-consults at our facility consist of written and verbal asynchronous communication between the referring and consulted clinicians without any direct involvement of the patient. For cardiology at our facility, the same physicians provide both outpatient clinic and e-consult services.

Applying this algorithm to our baseline sample, we estimated that 50% of patients would not need clinic referrals if the algorithm was followed. We estimated that a review of consult requests over 6 weeks (approximately 300) would provide 80% power to detect a 50% reduction in preprocedural referrals with α of .05. The numbers of referrals before and after the intervention were compared by Fisher's exact test using SPSS version 25 (IBM Corporation).

In accordance with VA Handbook 1058.05, this project was performed with the purpose of improving quality of care and was determined to not qualify as human subject research. This manuscript was developed in accordance with the CONSORT-EHEALTH checklist [2].

Results

A total of 963 consultations (603 before and 360 after the intervention) were evaluated. The overall proportions of cardiology referrals for preprocedural evaluation were similar in the before and after groups (n=89, 14.7% vs n=47, 13.0%; P=.39; odds ratio 0.87; 95% CI 0.59-1.27). Table 1 shows the changes in the distribution of how consultations were ordered and completed after the algorithm was introduced (2×4 Fisher exact test, P=.03). The proportion of consultations ordered as e-consults increased (n=39/89, 43.8% to n=27/47, 57.4%), while the proportion of patients seen in the clinic decreased (n=60/89, 67.4% to n=20/47, 42.6%). Feedback from cardiology and referring clinicians was positive. Cardiology clinicians reported that preprocedural referrals were often more complete (eg, patients were not referred without first seeing a surgeon or unless the consult included a specific question to address). The referring clinicians did not voice any concerns or criticisms about the new ordering algorithm.

Table 1. Distribution of preprocedural consultations before and after implementation of the order entry algorithm. The change in proportions was significant (P=.03).

Outcome	Before implementation	After implementation	
	(n=89), n (%)	(n=47), n (%)	
Clinical consultation ordered and patient seen in clinic	49 (55.1)	17 (36.2)	
Clinical consultation ordered and e-consult ^a performed	1 (1.1)	3 (6.4)	
E-consult ordered and patient seen in clinic	11 (12.4)	3 (6.4)	
E-consult ordered and performed	28 (31.5)	24 (51.1)	

^aE-consult: electronic consultation.

Discussion

Principal Findings

Implementing an algorithm to reduce referrals for low-value preprocedural cardiac evaluation did not decrease the volume of referrals but did shift the ordering pattern to more e-consults. Based on an average volume of 20 preprocedural clinic visits per month, we estimate that 5 fewer patients per month were seen in the clinic because of the process change. Additionally, the burden on patients is reduced by eliminating travel for low-value care and reducing barriers to elective procedures.

The reasons why patients are commonly referred to cardiologists for preprocedural assessment are complex. The current American College of Cardiology/American Heart Association guidelines provide ample direction on how to adequately assess cardiovascular risk and suggest when further cardiac testing is indicated [1]. However, the guidelines do not specify which patients are likely to benefit from cardiologist expertise and which can be managed by primary care or anesthesiology alone. In 2003, Park et al [3] published a suggested strategy to determine which patients warranted specialty evaluation; their strategy was similar to the one we adopted for this project. Primary care scholarly literature, continuing medical education, and informal writings are replete with reviews on the topic of preprocedural assessment, demonstrating that this skill set is well within their purview [4,5]. The Centers for Medicare & Medicaid Services bundles preprocedural assessment with surgical reimbursement. This may lead to cardiology referrals where billing for separate evaluation and management services can be justified; however, these rules do not apply within VHA medical centers.

The preprocedural evaluation itself is of questionable clinical relevance. Among referring clinicians, there is a lack of consensus on what constitutes an appropriate consultation [6]. Referring clinicians commonly do not state a clear reason for cardiac evaluation and will use vague terminology such as "clear for surgery" [7]. In a recent study [8] of 273 referrals to cardiology for preprocedural evaluation, only 2% led to invasive intervention; 37% resulted in a medication change and 61% resulted in no changes or interventions following cardiology consultation. Kleinman et al [7] reviewed 202 preprocedural consultations and found that 52 (25.7%) had a change in preprocedural therapy. Most of these changes were related to uncontrolled hypertension or angina, which are both conditions that can be readily managed in a primary care setting. If we accept that preprocedural evaluation has limited clinical value, e-consults unfortunately do not directly address the root

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problem. In this context, e-consults function as a stopgap measure to reduce the burden of low-value care on facilities and patients; however, the burden on clinicians may not be substantially different. Adequately addressing the low value of preprocedural assessments will require, at a minimum, multidisciplinary agreement on which patients would benefit from them. After that, changes in front-line practice would require substantial effort, which may not provide a worthwhile return on investment of time and resources.

Adoption of the preprocedural assessment algorithm in our study did not reduce the number of referrals; however, we did see secondary evidence of improved clinic efficiency. Cardiology clinicians reported that when they saw patients in the clinic, the consultation referral was more often complete and included a specific question to address. Despite no decrease in overall referrals, more patients were evaluated using e-consults. Since their implementation in 2011, e-consults have been shown to be successful in VHA medical centers; both patients and clinicians were satisfied with the improvement in communication and timeliness of care [9]. Each time a patient was seen electronically instead of in person, the burden on the patient was also reduced. Approximately 43% of all veterans who receive VA care reside in nonurban areas where the average straight-line distance to the nearest VA health care facility is 23 miles [10]. Our facility is part of a network of 14 clinics and medical centers, only 3 of which offer outpatient cardiology care and where veterans may be required to drive up to 170 miles one way for an office visit.

Veteran patients are not substantially different from other populations; therefore, we do not believe that our intervention has any patient-specific limits on generalizability. It would be beneficial to study this algorithm outside the VA in an academic or private setting where e-consults are not widely used. Although the VA is not highly concerned with reimbursement from third-party payers, poor or inconsistent reimbursement for e-consults may limit adoption of similar practices in other care settings. There is potential for a decrease in overall use of preprocedural consultations, with benefits of decreased wait time and cost for patients.

We should note some limitations of our intervention. Formal tracking of clinical outcomes and downstream testing were beyond the scope of our research. As this is a report of a quality-improvement project, we are unable to provide some data that would be of interest, such as demographic information and medical history of the patients being evaluated. The postintervention sample (n=360) was higher than our projection of 300 because the quality improvement team divided the work into weeks of consultations and then collated the results of their reviews.

Conclusions

Our intervention standardized the approach to ordering preprocedural cardiology referrals and enhanced the quality of communication in the referrals. Face-to-face consultations were reduced through use of e-consults, allowing veterans to avoid unnecessary and burdensome travel.

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Authors' Contributions

LC and DW contributed equally to the concept and implementation of the project, data interpretation, and drafting and critical revisions of the manuscript. Both gave approval to the final version, and both agree to be accountable for the content of the work. LC primarily gathered the data.

Conflicts of Interest

None declared.

Multimedia Appendix 1 CONSORT-eHEALTH checklist (V 1.6.1). [PDF File (Adobe PDF File), 1481 KB - periop_v3i1e17669_app1.pdf]

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Abbreviations

e-consult: electronic consultationVA: Veterans AffairsVHA: Veterans Health Administration

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