Original Paper

Using Artificial Intelligence With Natural Language Processing to Combine Electronic Health Record's Structured and Free Text Data to Identify Nonvalvular Atrial Fibrillation to Decrease Strokes and Death: Evaluation and Case-Control Study

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Abstract

Background: Nonvalvular atrial fibrillation (NVAF) affects almost 6 million Americans and is a major contributor to stroke but is significantly undiagnosed and undertreated despite explicit guidelines for oral anticoagulation.

Objective: The aim of this study is to investigate whether the use of semisupervised natural language processing (NLP) of electronic health record's (EHR) free-text information combined with structured EHR data improves NVAF discovery and treatment and perhaps offers a method to prevent thousands of deaths and save billions of dollars.

Methods: We abstracted 96,681 participants from the University of Buffalo faculty practice's EHR. NLP was used to index the notes and compare the ability to identify NVAF, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category (CHA_2DS_2-VASc), and Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile INR, Elderly, Drug/alcohol usage (HAS-BLED) scores using unstructured data (International Classification of Diseases codes) versus structured and unstructured data from clinical notes. In addition, we analyzed data from 63,296,120 participants in the Optum and Truven databases to determine the NVAF frequency, rates of CHA_2DS_2-VASc ≥2, and no contraindications to oral anticoagulants, rates of stroke and death in the untreated population, and first year's costs after stroke.

Results: The structured-plus-unstructured method would have identified 3,976,056 additional true NVAF cases (P<.001) and improved sensitivity for CHA_2DS_2-VASc and HAS-BLED scores compared with the structured data alone (P=.002 and P<.001, respectively), causing a 32.1% improvement. For the United States, this method would prevent an estimated 176,537 strokes, save 10,575 lives, and save >US $13.5 billion.

Conclusions: Artificial intelligence–informed bio-surveillance combining NLP of free-text information with structured EHR data improves data completeness, prevents thousands of strokes, and saves lives and funds. This method is applicable to many disorders with profound public health consequences.

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KEYWORDS

afib; atrial fibrillation; artificial intelligence; NVAF; natural language processing; stroke risk; bleed risk; CHA2DS2-VASc; HAS-BLED; bio-surveillance

Introduction

Background

Atrial fibrillation (AF), the most common type of arrhythmia [1,2], consists of nonvalvular AF (NVAF) and valvular AF (VAF) [1]. NVAF comprises approximately 70% of AF and currently affects approximately 5.8 million US patients and approximately 11 million in Europe on VAF results in a five times greater risk of stroke [3] and causes approximately 15% of all strokes [2,4]. Anticoagulation treatment dramatically reduces one's odds of a stroke to <0.5% on average.

The incidence of stroke with AF has prompted the development of scoring risk systems to guide anticoagulation treatment [5,6]. In 2014, the American Heart Association, American College of Cardiology, and Heart Rhythm Society advocated for AF practice guidelines via the use of congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category (CHA_2DS_2-VASc) scores that combine the $CHADS_2$ score with additional moderate risk factors [2,7]. Individuals' stroke risks should inform therapeutic options, which may include anticoagulants [7]. The Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile INR, Elderly, Drug/alcohol usage (HAS-BLED) score is a practical tool to assess individuals' risk of major bleeding and to guide anticoagulant therapy [8,9]. Researchers posit that the assessment of bleeding risk factors—age, uncontrolled hypertension, ischemic heart disease, and prior ischemic stroke—may improve individualized treatment for AF.

However, despite strong recommendations, oral anticoagulation (OAC) for NVAF patients remains low, with rates ranging from 39%-65% [10]. Disease surveillance and clinical decision support could help detect potential candidates who could benefit from this therapy. Automatic extraction from electronic health records (EHRs) has been shown to aid health care providers by making health care information easily accessible and helping with risk calculation [11,12]. Using these tools could reduce clinicians' computer time for data retrieval and data entry and could facilitate capturing all qualifying patients [13].

The Need for Natural Language Processing

Although EHRs contain an abundance of codified information, factors related to the assessment of NVAF are often poorly reflected in structured data [11]. Clinical text harboring rich contextual medical information is unstructured and in free-text form. Extracting information from a clinical text remains challenging because of context-specific abbreviations, refusal to adhere to typical language conventions, and because text often includes a broad range of specific medical terms. To retrieve information from a clinical text, multiple natural language processing (NLP) approaches have been developed, including those that extract clinical entities and map them to clinical terminologies such as SNOMED CT (Systematized Nomenclature of Medicine–Clinical Terms) [14].

To capture all potential patients with NVAF and of CHA_2DS_2-VASc >1 who would benefit from appropriate anticoagulation therapy, we developed a method to automate risk scoring systems using a combination of multiple EHR data sources for diagnostic information, namely the International Classification of Disease (ICD) codes and clinical notes and lists. As natural language processors are expensive to develop and require individual tuning for each task or disease area, we make use of a high definition-NLP (HD-NLP) method that uses semisupervised learning to surpass the classification performance that could be obtained either by discarding the unlabeled data and performing supervised learning or by discarding the labels and performing unsupervised learning [15]. We compare the advantages of using NLP tools for NVAF phenotyping and calculate the risk scores of using structured ICD data alone.

Methods

This study compares the effectiveness of identifying NVAF patients using three methods: (1) structured EHR data, (2) a combination of structured EHR data and NLP-analyzed existing free text (EHR notes, problem lists, and laboratories), and (3) clinicians' assessments of NVAF patients (*the gold standard*). We used NLP of the EHRs' free text to improve the identification of NVAF patients and to assess their stroke and bleeding risks more accurately. We verified the improvement in the identification of NVAF cases and in determining the CHA_2DS_2-VASc and HAS-BLED scores. We then examined the rates of NVAF and treatment in patients with a CHA_2DS_2-VASc of ≥2 and no contraindications to treatment to determine the results from our local population. Finally, we extrapolated our findings on NVAF numbers to the US population and disease costs.

Study Populations

We had two samples: a local Western New York population of 96,681 individuals and 63,296,120 participants from the Optum and Truven databases.

Sample 1: Local

To understand the effectiveness of the system in identifying NVAF patients who should be treated and are not currently on OAC therapy, we abstracted a set of 96,681 participants (aged 18-90 years) from the Allscripts outpatient electronic records at the University at Buffalo's (UBMD) faculty practice. The research was approved by the institutional review board of the University of Buffalo.

Patient data were abstracted from 2010 to September 21, 2015, before the switch to ICD-10, allowing consistent use of ICD-9 terminology and sufficient follow-up data for the study period. This yielded 212,343 patients. Of those 212,343 patients, 96,681 (45.53%) had notes and were seen for ≥1 outpatient visits (Multimedia Appendix 1, Figure S1). Outcomes from these data included rates of AF, NVAF, and VAF diagnosis, components of the CHA_2DS_2-VASc and HAS-BLED scores, relevant contraindications, OAC treatment, and demographic variables. We excluded patients if they were on oral antithrombotic therapy for indications other than NVAF, had a mechanical prosthetic valve, had a hemodynamically significant mitral stenosis or significant aortic stenosis, were pregnant, had a transient AF because of reversible conditions, or had active infective endocarditis (Multimedia Appendix 1, Figure S2). We developed the NVAF cohort using ICD-9 codes (structured data) and ICD-9 and NLP (structured-plus-unstructured) of EHR notes and patient problems. AF and atrial flutter were defined by ICD-9 codes 427.31 and 427.32 and by SNOMED CT codes 49436004 and 5370000 with all subtypes in the hierarchy.

The structured data–only method used ICD 9 codes from problem lists, medications, and demographics. The structured-plus-unstructured method added clinical notes, vital signs, laboratory findings, and text from the problem list using HD-NLP for codification [14,16-18]. Free text elements were coded using SNOMED CT, a general description logic–based nomenclature of clinical medicine. Specific code inclusions can be found in Multimedia Appendix 1, Figure S3.

We then compared the accuracy of structured data alone with the structured-plus-unstructured EHR data derived using the HD-NLP system, focusing on the two models' abilities to identify true cases of NVAF and to determine stroke and bleeding risks (CHA_2DS_2-VASc and HAS-BLED scores).

Subsample of the Local Data

For validation of the accuracy of NLP, we used a gold standard created by human review (BS, JZ, EA, and SS) from a random sample of 300 patients. To verify the NVAF identification and CHA_2DS_2-VASc and HAS-BLED scores, we used this 300-patient random sample from our NVAF patients, which were dual human reviewed. We also looked to determine how much better structured-plus-unstructured data were in the identification of NVAF cases and in the determination of the CHA_2DS_2-VASc and HAS-BLED scores.

The human review data set was independently examined by 4 clinicians, each performing 150 reviews on deidentified patient encounters from the EHR. Each clinician made a judgment as to whether the patients had sustained NVAF and whether the patient had each of the components of the CHA_2DS_2-VASc and HAS-BLED scores. If there were disagreements, a fifth clinician adjudicated.

Calculations determined that 300 patients were needed for 90% power to predict a 5% change in accuracy given a two-sided alpha of .05, assuming a standard accuracy of 73% based on ICD-9 codes [19]. Multimedia Appendix 1, Figure S1 presents the decision tree and sample numbers, and Multimedia Appendix 1, Figure S2 illustrates the randomization scheme.

Sample 2: National—Optum and Truven Databases

We analyzed the claims data from 63,296,120 participants in the Optum and Truven databases from October 2015 to September 2016 to determine the frequency of NVAF, rates of CHA_2DS_2-VASc ≥2, and no contraindications to OAC, rates of stroke and death in the untreated NVAF, strokes and death in the large claims database, and the first year's cost after stroke [20,21]. Cost differences were based on 1-year cost before and after the stroke, adjusted for inflation.

We then extrapolated our findings to the US population.

Findings for NLP

We made use of an HD-NLP to rapidly assign ontological terms to the text in patient records (Multimedia Appendix 1, Figure S5) [14,16,17]. HD-NLP is a full-function NLP processing pipeline that takes sentences, parses them by their parts of speech, and builds a full semantic parse in memory; then, an ontological coder works by matching words to ontology terms, with the longest match being preferred. We used basic formal ontology as an upper-level ontology to index the data from individual trials [18]. We also used the ontology of biomedical investigation and SNOMED CT as our main ontologies [22,23].

A level of syntactic processing was required to match text with ontological terms. The linguistic representation is specified in language models. Of primary concern here was an English language model to identify sentences, phrases, words, and parts of speech. Terms from the input ontologies were then assigned to spans of text. String matching techniques allowed for inexact matches influenced by the underlying language model. The structures of the free-text medical records were captured and stored.

To develop the NVAF model, we used a semisupervised learning algorithm training set with 36,268 patients from the Allscripts EHR UBMD faculty practice data from 2007 to 2008, with 1972 AF cases and 1795 NVAF cases to determine the best SNOMED CT codes to match the case definition. As most clinical texts are unlabeled, semisupervised learning leverages a small amount of labeled data with a large amount of unlabeled data. Researchers have shown that large amounts of unlabeled data, when used in conjunction with a limited amount of labeled data, can produce considerable improvement in learning accuracy, especially with assistance from subject matter expert's annotation of the training set's false positive and false negative results from each training iteration [14]. All cases were coded using HD-NLP with SNOMED CT codes (the unsupervised portion of the study). Where the SNOMED CT codes and ICD-9 codes agreed that the patient had NVAF, we called that a true positive case. The same logic was used to determine true negatives. Where either coding system disagreed, our clinician (PE) reviewed the case and decided. After reviewing the false positive and false negative cases from the training data set, we used additional synonymy to the terminology and selected a more appropriate set of codes for each rule in the definition. This process was iterated on the training set until we met our accuracy goals.

Statistical Analysis

Statistical analyses were conducted using R 3.3.2. A random gold standard sample of 300 patients was taken from the sample 1 AF cohort defined by both ICD and HD-NLP. Interrater agreement was assessed using the two-way random effects model for intraclass correlation coefficient, with two-sided 10,000 samples bootstrapped 95% CI, treating the risk scores as continuous. Cohen κ with two-sided 10,000 samples bootstrapped 95% CI assessed the interrater reliability of each individual component of the scores, NVAF and AF.

The accuracy of the structured data alone was compared with structured-plus-unstructured data for the outcomes of NVAF, CHA_2DS_2-VASc score, and HAS-BLED score in the random sample. Cohen κ with two-sided bootstrapped CIs was calculated as a measure of reliability between the gold standard and the structured and structured-plus-unstructured data. For sensitivity and specificity, a hypothesis test comparing structured with structured-plus-unstructured data was assessed using either the McNemar test for paired observations or the binomial exact test. For positive and negative predictive values, a generalized score statistic proposed by Leisenring et al [19] was used for comparison.

As the CHA_2DS_2-VASc and HAS-BLED scores are on ordinal scales from 0 to 9, we analyzed the area under the receiver operator characteristic curve (ROC) using the C-Index and Somer D, based on ordinal logistic regression, where probabilities were modelled as $P(Y \geq k|X)$, where k defines the cut-offs from 0 to 9 that the score can take. We hypothesized that the structured and NLP data were more concordant than the structured-only data compared with the gold standard between the ordinal gold standard score and the ordinal method score.

We contrasted our findings with the clinical judgments from the physician review of the 300 patients, categorized as contraindicated (Multimedia Appendix 1, Table S1) or not on OAC, would or would not benefit from OAC, and not on OAC. To determine the potential effects of adopting the NLP-enabled method with structured-plus-unstructured data, the accuracy data of the structured and NLP data method were used to extrapolate the findings for all untreated US patients in the Optum and Truven data sets with no contraindications to OACs. Then, the potential savings from reduced strokes were derived and compared with the prevailing structured-only method.

Results

NLP Results

From the Allscripts UBMD practice EHR data, we found 2722 potential patients with NVAF using the structured and NLP method and 1849 cases using only ICD-9 codes. The use of NLP by combining structured-plus-unstructured data improved sensitivity by 32.1%, that is, 873/2722 (P<.001) in determining the NVAF population. In the random sample, participants were on average 72 years old (mean 72.7, SD 13.6), 41.3% (125/300) were female, and 86.3% (259/300) were White. The true NVAF population within the random sample, as determined by clinician review, was 88% (264/300) of cases with an average age of 73 (mean 73.4, SD 13.0), of which 41.7% (110/264) were female, and 87.1% (230/264) were White. The assessment of agreement between clinicians and interrater reliability was high for the CHA_2DS_2-VASc score (odds ratio [OR] 0.796, 95% CI 0.725-0.853 and OR 0.878, 95% CI 0.838-0.909) and adequate for the HAS-BLED score (OR 0.609, 95% CI 0.51-0.692 and OR 0.675, 95% CI 0.544-0.77). Cohen κ, depending on whether an outcome was a rare event, ranged from –0.080 to 0.84.

When we tested this in the human review of the 300 cases, we found a 46% improvement in sensitivity (Table 1), which is greater than the 32.1% improvement seen with the automated method.

Table 1. Clinician review (gold standard): comparison of outcomes for structured and structured-plus-unstructured data against the gold standard for identifying a case as nonvalvular atrial fibrillation.

Outcome	Structured surveillance	Structured and NLP[a] surveillance	*P* value
Sensitivity, OR[b] (95% CI)	0.54 (0.48-0.60)	1 (0.979-1)	<.001
PPV[c], OR (95% CI)	0.95 (0.90-0.98)	0.93 (0.893-0.956)	.24
F[d] score	0.686	0.964	N/A[e]

[a]NLP: natural language processing.

[b]OR: odds ratio.

[c]PPV: positive predictive value.

[d]For case finding of nonvalvular atrial fibrillation.

[e]N/A: not applicable.

Thus, the structured-plus-unstructured surveillance showed that the sensitivity for CHA_2DS_2-VASc ≥2 and HAS-BLED≥3 scores was significantly better than that for structured data alone (P=.002 and P<.001, respectively). The specificities of the two methods were not statistically different for CHA_2DS_2-VASc and favored the structured method for HAS-BLED (Table 2). The positive predictive value (PPV; precision) also improved for the HAS-BLED score using the structured-plus-unstructured method (Table 2) but was not statistically different from the structured data for the CHA_2DS_2-VASc score. However, the negative predictive value improved for both scores using the structured-plus-unstructured method. No cases identified by the structured method were missed by the structured-plus-unstructured method.

Table 2. Comparison of outcomes for structured and structured-plus-unstructured surveillance against the clinician review (gold standard) for identifying Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile INR, Elderly, Drug/alcohol usage (HAS-BLED) and congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category (CHA2DS2-VASc) components.

Method	HAS-BLED					CHA_2DS_2-VASc				
	Structured surveillance	Structured and NLP[a] surveillance	Difference	*T* test	*P* value	Structured surveil-lance	Structured and NLP surveillance	Difference	Test statis-tic	*P* value
Sensitivity										
McNemar method	0.382	0.806	0.424	72	<.001	—[b]	—	—	—	—
Exact binomial method	—	—	—	—		0.942	0.983	0.0413	—	.002
Specificity										
McNemar method	0.947	0.777	–0.17	16	<.001					
Exact binomial method	—	—	—	—	—	0.955	0.909	–0.0455		>.99[c]
PPV[d]										
Generalized score method	0.929	0.867	.061	4.487	.03	0.996	0.992	0.004	0.915	.34
NPV[e]										
Generalized score method	0.459	0.689	0.23	47.757	<.001	0.6	0.833	0.233	11.662	<.001

[a]NLP: natural language processing.

[b]There is a small number of discordant cells, such that for the gold standard's CHA_2DS_2-VASc <2, there is 1 case that was identified as CHA_2DS_2-VASc ≥2 in the structured and NLP method but not in the structured method. The exact binomial *P* value is calculated as $2 \times \binom{1}{0} 0.5^0(1-0.5)^{1-0}$

[c]There is a small number of discordant cells, such that for the gold standard's CHA_2DS_2-VASc <2, there is 1 case that was identified as CHA_2DS_2-VASc >2 in the Structured and NLP method but not in the structured method. The exact binomial *P* value is calculated as $2 \times \binom{1}{0} 0.5^0(1-0.5)^{1-0}$

[d]PPV: positive predictive value.

[e]NPV: negative predictive value.

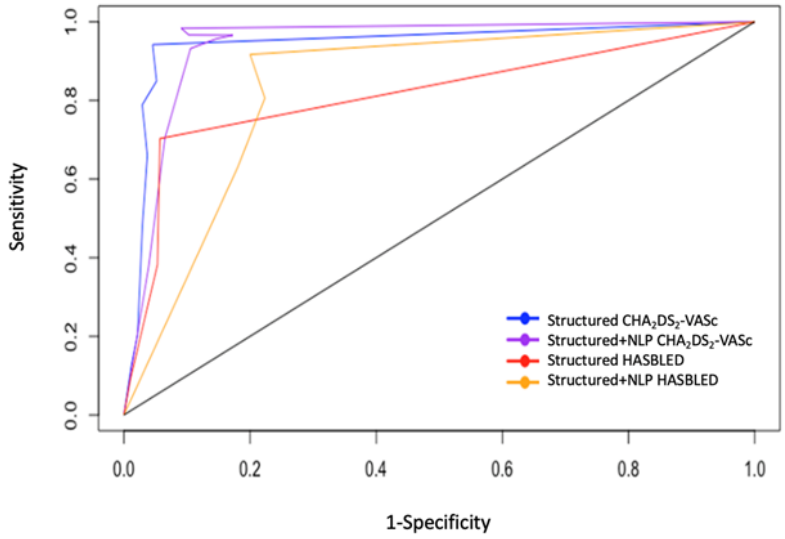
Multimedia Appendix 1, Figure S4 presents the conditional probability tree for the automated structured or structured-plus-NLP method, based on clinical guidelines.

In Figure 1, the area under the ROC for the CHA_2DS_2-VASc scores for the structured-plus-unstructured data compared with the gold standard score was 0.914 (95% CI 0.896-0.933) with a Somer D 0.829 (SD 0.0185), and for the structured data alone compared with the gold standard score, was 0.863 (CI 0.838-0.887), with a Somer D 0.726 (SD 0.0249). For CHA_2DS_2-VASc scores, structured-plus-unstructured data were more concordant than structured data alone when compared with the gold standard score (Z=19.77; *P*<.001). For the ROC curves of the HAS-BLED scores with the gold standard score as the outcome, the structured-plus-unstructured data was 0.816 (CI 0.783-0.849), with a Somer D 0.633 (SD 0.034), and the structured data alone was 0.797 (CI 0.761-0.833) with a Somer D 0.595 (SD 0.037). For HAS-BLED scores, structured-plus-unstructured data were not more concordant than structured data alone (Z=1.433; *P*=.149).

Figure 1 represents four areas under ROC curves, two for structured versus structured and NLP CHA_2DS_2-VASc score and two for structured versus structured and NLP HAS-BLED score. As these scores are ordinal (eg, ranging from 0-9) and not binary, as with typical ROC, we use the C-Index and Somer D based on ordinal logistic regression to model the probabilities, resulting in multiple y values for the same x.

We compared the findings of the gold standard with the NLP structured-plus-unstructured data (Multimedia Appendix 1, Table S1). Clinician reviewers found 31 untreated patients who should have been treated and 1 treated patient who, the clinicians felt, should not have been treated. This was the same total as that of the gold standard. After clinician review, there was a 32.1% improvement in PPV using the structured-plus-unstructured method when compared with the structured method alone.

Figure 1. Four receiver operator characteristic curves for cumulative congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category (CHA2DS2-VASc), and Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile INR, Elderly, Drug/alcohol usage (HAS-BLED) risk scores. NLP: natural language processing.



Extrapolating Findings to the US Population for Prevalence and Cost

Extrapolation to the US population of the Truman and Optum data results can be found in Table 3.

To determine the national cost savings from the NLP-assisted bio-surveillance of the structured-plus-unstructured data, we used Truven data and contrasted the mean monthly costs per patient after a stroke (US $11,538) with the monthly costs before a stroke (US $2,763.33), which yielded a mean savings of US $8,776.02. This was adjusted to US $2019 as the data were from 2010 to 2015. This revealed savings of US $8,556.66 per month or yearly savings of US $102,680.

The structured data method identified 1.5% (967,801/63,296,120) of the population as having NVAF. Of those cases, 84.3% (816,240/967,801) had a CHA_2DS_2-VASc score of ≥2. These data indicate that 60.7% (495,749/816,240) of these patients were not treated despite the current clinical guidelines. Untreated NVAF patients had a 4.4% (22,021/495,749) annual ischemic stroke risk, and the stroke patients had a 6.0% (1320/22,021) risk of death.

Table 3. Optum and Truven stroke data for 1 year after atrial fibrillation (AF) diagnosis.

Population for rates	Truven, n (%)	Optum, n (%)	Total, n (%)	Event rates (%)
All patients	32,046,193 (50.63)	31,249,927 (49.37)	63,296,120 (100)	—[a]
Patients aged ≥18 years in 2016 with any diagnosis of AF during October 2015-September 2016	422,092 (32.79)	865,072 (67.21)	1,287,164 (100)	—
Patients aged ≥18 years in 2016 with any diagnosis of AF during October 2015-September 2016 and without a VHD[b] diagnosis during 1-year preindex	355,811 (36.76)	611,990 (63.24)	967,801 (100)	1.5
Patients aged ≥18 years in 2016 with any diagnosis of AF during October 2015-September 2016 and without VHD diagnosis during 1-year preindex and with CHA_2DS_2-VASc[c] ≥2 and no contraindications to OAC[d]	276,465 (33.87)	539,775 (66.13)	816,240 (100)	84.3
Patients aged ≥18 years in 2016 with any diagnosis of AF during October 2015-September 2016 and without VHD diagnosis during 1-year preindex and with CHA_2DS_2-VASc ≥2 and no contraindications to OAC and were untreated	179,441 (36.20)	316,308 (63.80)	495,749 (100)	60.7
Stroke rate	11,530 (52.36)	10491 (47.64)	22,021 (100)	4.4
Death rate	727 (55.1)	593 (44.9)	1,320 (100)	5.99

[a]The values are not events.

[b]VHD: valvular hear disease.

[c]CHA_2DS_2-VASc: congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category.

[d]OAC: oral anticoagulation.

Estimates of Morbidity, Mortality, and Cost

After extrapolating our results combining the Optum and Truven data with our method of bio-surveillance, we estimated outcomes of implementing the NLP-assisted analyses of structured-plus-unstructured data nationally; that is, if implemented nationally (among a population of 316,005,000), this system could potentially prevent 176,537 strokes and 10,575 deaths in the first year of implementation, with stroke-associated savings >US $18.126 billion (Table 4).

Table 4. Untreated strokes and their costs for first year after the event.

Extrapolated results	Structured surveillance	Structured and NLP[a] surveillance	Difference between the two methods
NVAF[b] population	4,955,284	6,545,930	1590,646
NVAF population with no contraindications and CHA_2DS_2VASc[c] ≥2	4,543,995	6,002,707	1,458,712
NVAF population needing treatment	3,009,840	3,976,057	966,217
Strokes prevented	133,637	176,537	42,900
Deaths prevented	8,005	10,575	2,570
Cost savings[d] (US $)	13,721,820,000	18,126,800,000	4,404,981,210

[a]NLP: natural language processing.

[b]NVAF: nonvalvular atrial fibrillation.

[c]CHA_2DS_2-VASc: congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category.

[d]Cost basis is US $102,680 per untreated ischemic stroke patient's excess cost for the first year after event; cost is 1.9% inflation adjusted.

Discussion

Principal Findings

Compared with structured EHR data alone, we found that NLP-assisted structured-plus-unstructured EHR data identified previously unknown and untreated patients with NVAF and their stroke and bleed risks with greater accuracy. Adding the unstructured data significantly improved the sensitivity and negative predictive value across all measures, whereas the results for NVAF specificity and PPV were strong but mixed. Future applications of this artificial intelligence (AI) bio-surveillance method may involve identifying other underdiagnosed populations.

We estimated NVAF rates in large national database populations, the percentage of people who should be treated with OAC and are not currently treated, and yearly risks of stroke expressed as a percentage of these untreated patients [24,25]. We also estimated the average incremental 1-year cost for a stroke event and identified stroke-related average death rates in the first year after event.

Verhoef et al [26,27] showed that bleeding rates with warfarin were, on average, 0.34% risk per year. Given additional treatment for 3,976,057 new patients, we would expect 13,824 new patient bleeds. McWilliam [28] showed that the average cost of a major bleed was US $19,000 in 2008 (inflation adjusted to US $23,777.67). For the population, this equals US $328,702,452. Gilligan et al [29] showed that the average total cost for warfarin therapy was US $76.19 per member per month, which translates to a total national cost of US $3,750,758,790 per year. Potential net financial treatment benefits from using the NLP-assisted structured-plus-unstructured method equates to US $14.4 billion (US $18.13 billion to US $3.75 billion).

On the basis of the accuracy of the AI-derived bio-surveillance method, we show potential societal benefits of implementing this technology. Nationally, this method could identify approximately 4 million patients requiring treatment, potentially preventing >176,000 strokes in the first year, and >10,500 deaths, translating to national savings of >US $14 billion. Including the estimated costs of excess bleeding from the treatment and from our estimate, the national implementation costs would be no greater than US $300,000,000. This type of AI-driven clinical decision support bio-surveillance has the potential to significantly improve patient care and clinicians' treatment decisions.

NVAF is but one important condition among many. Future applications of this AI bio-surveillance method may identify other underdiagnosed populations. Once deployed, the infrastructure could be used for other disorders and could be implemented at a low incremental cost.

Limitations

This analysis and data extrapolation were based on previous 2014 American Heart Association, American College of Cardiology, and Heart Rhythm Society recommendations for OAC therapy in patients with NVAF and a CHA_2DS_2-VASc score of ≥2. The 2019 focused updates on AF now recommend that men with a CHA_2DS_2-VASc score of ≥2 and women with a CHA_2DS_2-VASc score of ≥3 should be treated with an OAC. As such, the numbers in this analysis may include women who, under the updated guidance, may not be recommended for treatment with an OAC. In addition, not all patients for whom therapy is indicated may agree to accept anticoagulation therapy.

The Optum and Truven databases, although found to be effectively nonoverlapping, are, on average, considered to be

for younger and healthier private payer populations; therefore, we may underestimate both protective effects and cost savings [30]. If this method were extended to other diseases, models must be built and distributed uniformly across the country and perhaps internationally.

The AI model processes the free text of the notes and reports, and as it can accept and process data from Cerner, Epic, and other EHRs, there should be no difference in outcome; however, this model has not been specifically tested with data from other EHRs.

ICD-9 codes were used in this study because of the desire to have a consistently coded data set. ICD-10 codes were not included. Future research should investigate this method using later ICD codes.

This informatics method promises many benefits. Of course, additional research is needed to determine its applicability to other diseases.

Conclusions

Although a common disorder (N=6 million Americans), NVAF is often underprophylaxed for thromboembolic events that may lead to strokes. Critical evidence may be found in patients' EHRs to aid in anticoagulation decision-making. Stroke rates of untreated patients with a CHA_2DS_2-VASc of ≥2 in our study were 4.44%, and of these, approximately 6% will die within 1 year. Treatment dramatically reduces one's odds of a stroke to <0.5% on average.

Our structured-plus-unstructured (NLP) method identified 36.3% additional true NVAF cases (P<.001) compared with the structured data alone. Extrapolating to the US population using the 63 million people in the Optum and Truven populations allowed us to predict that in just the first-year implementation of this system, it could prevent 176,537 strokes and 10,575 deaths and save the nation >US $13.5 billion dollars.

Moreover, this bio-surveillance method and preparedness, in general, may be useful for the discovery and treatment of many other disorders, and require further research with different diseases. Automated tools in partnership with clinicians have the potential to significantly improve adherence to established clinical guidelines and to precision medicine.

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Conflicts of Interest

GB, MW, JM, JT, and KM are employed at Pfizer.

Multimedia Appendix 1

Study recruitment diagram and additional analyses.
[DOCX File , 6156 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Financial and nonfinancial support.
[DOCX File , 14 KB-Multimedia Appendix 2]

References

1. Camm AJ, Lip GY, De Caterina R, Savelieva I, Atar D, Hohnloser SH, ESC Committee for Practice Guidelines (CPG). 2012 focused update of the esc guidelines for the management of atrial fibrillation: an update of the 2010 esc guidelines for the management of atrial fibrillation. Developed with the special contribution of the european heart rhythm association. Eur Heart J 2012 Nov;33(21):2719-2747. [doi: 10.1093/eurheartj/ehs253] [Medline: 22922413]
2. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC, American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the american college of cardiology/american heart association task force on practice guidelines and the heart rhythm society. J Am Coll Cardiol 2014 Dec 02;64(21):1-76 [FREE Full text] [doi: 10.1016/j.jacc.2014.03.022] [Medline: 24685669]
3. Roger VL, Go AS, Lloyd-Jones DM, Benjamin EJ, Berry JD, Borden WB, American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics--2012 update: a report from the American Heart

Association. Circulation 2012 Jan 3;125(1):2-220 [FREE Full text] [doi: 10.1161/CIR.0b013e31823ac046] [Medline: 22179539]
4. Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the framingham study. Stroke 1991 Aug;22(8):983-988. [doi: 10.1161/01.str.22.8.983] [Medline: 1866765]
5. Gage BF, Waterman AD, Shannon W, Boechler M, Rich MW, Radford MJ. Validation of clinical classification schemes for predicting stroke: results from the national registry of atrial fibrillation. J Am Med Assoc 2001 Jun 13;285(22):2864-2870. [doi: 10.1001/jama.285.22.2864] [Medline: 11401607]
6. Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: The Euro Heart Survey on atrial fibrillation. Chest 2010 Feb;137(2):263-272. [doi: 10.1378/chest.09-1584] [Medline: 19762550]
7. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the american college of cardiology/american heart association task force on clinical practice guidelines and the heart rhythm society in collaboration with the society of thoracic surgeons. Circulation 2019 Jul 09;140(2):125-151. [doi: 10.1161/CIR.0000000000000665] [Medline: 30686041]
8. Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY. A novel user-friendly score (has-bled) to assess 1-year risk of major bleeding in patients with atrial fibrillation: the euro heart survey. Chest 2010 Nov;138(5):1093-1100. [doi: 10.1378/chest.10-0134] [Medline: 20299623]
9. Lip GY, Frison L, Halperin JL, Lane DA. Comparative validation of a novel risk score for predicting bleeding risk in anticoagulated patients with atrial fibrillation: the has-bled (hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile inr, elderly, drugs/alcohol concomitantly) score. J Am Coll Cardiol 2011 Jan 11;57(2):173-180 [FREE Full text] [doi: 10.1016/j.jacc.2010.09.024] [Medline: 21111555]
10. Tiryaki F, Nutescu EA, Hennenfent JA, Karageanes AM, Koesterer LJ, Lambert BL, et al. Anticoagulation therapy for hospitalized patients: patterns of use, compliance with national guidelines, and performance on quality measures. Am J Health Syst Pharm 2011 Jul 01;68(13):1239-1244. [doi: 10.2146/ajhp100543] [Medline: 21690430]
11. Navar-Boggan AM, Rymer JA, Piccini JP, Shatila W, Ring L, Stafford JA, et al. Accuracy and validation of an automated electronic algorithm to identify patients with atrial fibrillation at risk for stroke. Am Heart J 2015 Jan;169(1):39-44. [doi: 10.1016/j.ahj.2014.09.014] [Medline: 25497246]
12. Demner-Fushman D, Chapman WW, McDonald CJ. What can natural language processing do for clinical decision support? J Biomed Inform 2009 Oct;42(5):760-772 [FREE Full text] [doi: 10.1016/j.jbi.2009.08.007] [Medline: 19683066]
13. Aakre C, Dziadzko M, Keegan MT, Herasevich V. Automating clinical score calculation within the electronic health record. A feasibility assessment. Appl Clin Inform 2017 Apr 12;8(2):369-380 [FREE Full text] [doi: 10.4338/ACI-2016-09-RA-0149] [Medline: 28401245]
14. Elkin PL, Froehling DA, Wahner-Roedler DL, Brown SH, Bailey KR. Comparison of natural language processing biosurveillance methods for identifying influenza from encounter notes. Ann Intern Med 2012 Jan 03;156(1 Pt 1):11-18. [doi: 10.7326/0003-4819-156-1-201201030-00003] [Medline: 22213490]
15. Yeung S, Downing NL, Fei-Fei L, Milstein A. Bedside computer vision - moving artificial intelligence from driver assistance to patient safety. N Engl J Med 2018 Apr 05;378(14):1271-1273. [doi: 10.1056/NEJMp1716891] [Medline: 29617592]
16. Murff HJ, FitzHenry F, Matheny ME, Gentry N, Kotter KL, Crimin K, et al. Automated identification of postoperative complications within an electronic medical record using natural language processing. J Am Med Assoc 2011 Aug 24;306(8):848-855. [doi: 10.1001/jama.2011.1204] [Medline: 21862746]
17. Schlegel DR, Crowner C, Lehoullier F, Elkin PL. HTP-NLP: A new NLP system for high throughput phenotyping. Stud Health Technol Inform 2017;235:276-280 [FREE Full text] [Medline: 28423797]
18. Birman-Deych E, Waterman AD, Yan Y, Nilasena DS, Radford MJ, Gage BF. Accuracy of ICD-9-CM codes for identifying cardiovascular and stroke risk factors. Med Care 2005 May;43(5):480-485. [doi: 10.1097/01.mlr.0000160417.39497.a9] [Medline: 15838413]
19. Leisenring W, Alonzo T, Pepe MS. Comparisons of predictive values of binary medical diagnostic tests for paired designs. Biometrics 2000 Jun;56(2):345-351. [doi: 10.1111/j.0006-341x.2000.00345.x] [Medline: 10877288]
20. Optum. 2019. URL: https://www.optum.com/solutions/data-analytics/data.html [accessed 2019-02-02]
21. Truven Health Analytics. IBM. 2019. URL: https://truvenhealth.com/Portals/0/assets/ACRS_11223_0912_MarketScanResearch_SS_Web.pdf [accessed 2919-02-02]
22. Wade G. Implementing snomed ct for quality reporting: avoiding pitfalls. Appl Clin Inform 2011;2(4):534-545 [FREE Full text] [doi: 10.4338/ACI-2011-10-RA-0056] [Medline: 23616894]
23. Bandrowski A, Brinkman R, Brochhausen M, Brush MH, Bug B, Chibucos MC, et al. The ontology for biomedical investigations. PLoS One 2016;11(4):e0154556 [FREE Full text] [doi: 10.1371/journal.pone.0154556] [Medline: 27128319]
24. Bray BD, Paley L, Hoffman A, James M, Gompertz P, Wolfe CD, et al. Socioeconomic disparities in first stroke incidence, quality of care, and survival: a nationwide registry-based cohort study of 44 million adults in england. Lancet Public Health 2018 Apr;3(4):185-193 [FREE Full text] [doi: 10.1016/S2468-2667(18)30030-6] [Medline: 29550372]

25. Freedman B, Potpara TS, Lip GY. Stroke prevention in atrial fibrillation. Lancet 2016 Aug 20;388(10046):806-817. [doi: 10.1016/S0140-6736(16)31257-0] [Medline: 27560276]
26. Verhoef TI, Redekop WK, Darba J, Geitona M, Hughes DA, Siebert U, EU-PACT Group. A systematic review of cost-effectiveness analyses of pharmacogenetic-guided dosing in treatment with coumarin derivatives. Pharmacogenomics 2010 Jul;11(7):989-1002. [doi: 10.2217/pgs.10.74] [Medline: 20602617]
27. Yao X, Abraham NS, Sangaralingham LR, Bellolio MF, McBane RD, Shah ND, et al. Effectiveness and safety of dabigatran, rivaroxaban, and apixaban versus warfarin in nonvalvular atrial fibrillation. J Am Heart Assoc 2016 Jun 13;5(6):e003725 [FREE Full text] [doi: 10.1161/JAHA.116.003725] [Medline: 27412905]
28. Desai JR, Hyde CL, Kabadi S, St Louis M, Bonato V, Loomis AK, et al. Utilization of positive and negative controls to examine comorbid associations in observational database studies. Med Care 2017 Mar;55(3):244-251 [FREE Full text] [doi: 10.1097/MLR.0000000000000640] [Medline: 27787351]
29. McWilliam A, Lutter R, Nardinelli C. Healthcare impact of personalized medicine using genetic testing: an exploratory analysis for warfarin. Per Med 2008 May;5(3):279-284. [doi: 10.2217/17410541.5.3.279] [Medline: 29783488]
30. Gilligan AM, Gandhi P, Song X, Wang C, Henriques C, Sander S, et al. All-cause, stroke-, and bleed-specific healthcare costs: comparison among patients with Non-Valvular Atrial Fibrillation (NVAF)newly treated with dabigatran or warfarin. Am J Cardiovasc Drugs 2017 Dec;17(6):481-492 [FREE Full text] [doi: 10.1007/s40256-017-0244-1] [Medline: 28795348]

Abbreviations

AF: atrial fibrillation
AI: artificial intelligence
CHA2DS2-VASc: congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category
EHR: electronic health record
HAS-BLED: Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile INR, Elderly, Drug/alcohol usage
HD-NLP: high definition natural language processing
ICD: International Classification of Disease
NIH: National Institutes of Health
NLP: natural language processing
NVAF: nonvalvular atrial fibrillation
OAC: oral coagulation
OR: odds ratio
PPV: positive predictive value
ROC: receiver operator characteristic curve
SNOMED CT: Systematized Nomenclature of Medicine–Clinical Terms
VAF: valvular atrial fibrillation

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Review

Electronic Monitoring Systems for Hand Hygiene: Systematic Review of Technology

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Abstract

Background: Hand hygiene is one of the most effective ways of preventing health care–associated infections and reducing their transmission. Owing to recent advances in sensing technologies, electronic hand hygiene monitoring systems have been integrated into the daily routines of health care workers to measure their hand hygiene compliance and quality.

Objective: This review aims to summarize the latest technologies adopted in electronic hand hygiene monitoring systems and discuss the capabilities and limitations of these systems.

Methods: A systematic search of PubMed, ACM Digital Library, and IEEE Xplore Digital Library was performed following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Studies were initially screened and assessed independently by the 2 authors, and disagreements between them were further summarized and resolved by discussion with the senior author.

Results: In total, 1035 publications were retrieved by the search queries; of the 1035 papers, 89 (8.60%) fulfilled the eligibility criteria and were retained for review. In summary, 73 studies used electronic monitoring systems to monitor hand hygiene compliance, including application-assisted direct observation (5/73, 7%), camera-assisted observation (10/73, 14%), sensor-assisted observation (29/73, 40%), and real-time locating system (32/73, 44%). A total of 21 studies evaluated hand hygiene quality, consisting of compliance with the World Health Organization 6-step hand hygiene techniques (14/21, 67%) and surface coverage or illumination reduction of fluorescent substances (7/21, 33%).

Conclusions: Electronic hand hygiene monitoring systems face issues of accuracy, data integration, privacy and confidentiality, usability, associated costs, and infrastructure improvements. Moreover, this review found that standardized measurement tools to evaluate system performance are lacking; thus, future research is needed to establish standardized metrics to measure system performance differences among electronic hand hygiene monitoring systems. Furthermore, with sensing technologies and algorithms continually advancing, more research is needed on their implementation to improve system performance and address other hand hygiene–related issues.

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KEYWORDS

hand hygiene; hand hygiene compliance; hand hygiene quality; electronic monitoring systems; systematic review; mobile phone

Introduction

Background

Hand hygiene is one of the most effective ways of reducing the transmission of pathogens that cause health care–associated infections (HAIs) [1-3]. HAIs are infections that people acquire in health care settings [4] and are the most crucial challenge to patient safety in health care [5]. HAIs dramatically increase patients' length of stay, costs, mortality, and morbidity worldwide [6,7]. Moreover, HAIs also impose a heavy financial burden on health care systems. Solely in the United States, the estimated annual costs range from US $28 billion to US $45 billion [8]. The hands of health care workers (HCWs) represent the main pathway of pathogen transmission during health care [2], and Stone et al [9] estimated that at least one-third of HAIs can be prevented by achieving better hand hygiene in health care settings.

In 2009, the World Health Organization (WHO) issued the first *WHO guidelines on hand hygiene in health care* to provide a thorough review of evidence on hand hygiene in health care and specific recommendations to improve practices in health care settings [2]. In the guidelines, the WHO summarizes the five key moments when HCWs should ensure hand hygiene [2], as shown in Figure 1. The guidelines also recommend two standard hand hygiene techniques, *handwash with soap and water* for visibly soiled hands and *hand rub with alcohol-based formulation* for routine decontamination of hands [2], as shown in Figure 2.

Figure 1. The key moments when health care workers should perform hand hygiene. Source: World Health Organization: "My 5 Moments for Hand Hygiene" (with permission) [2].

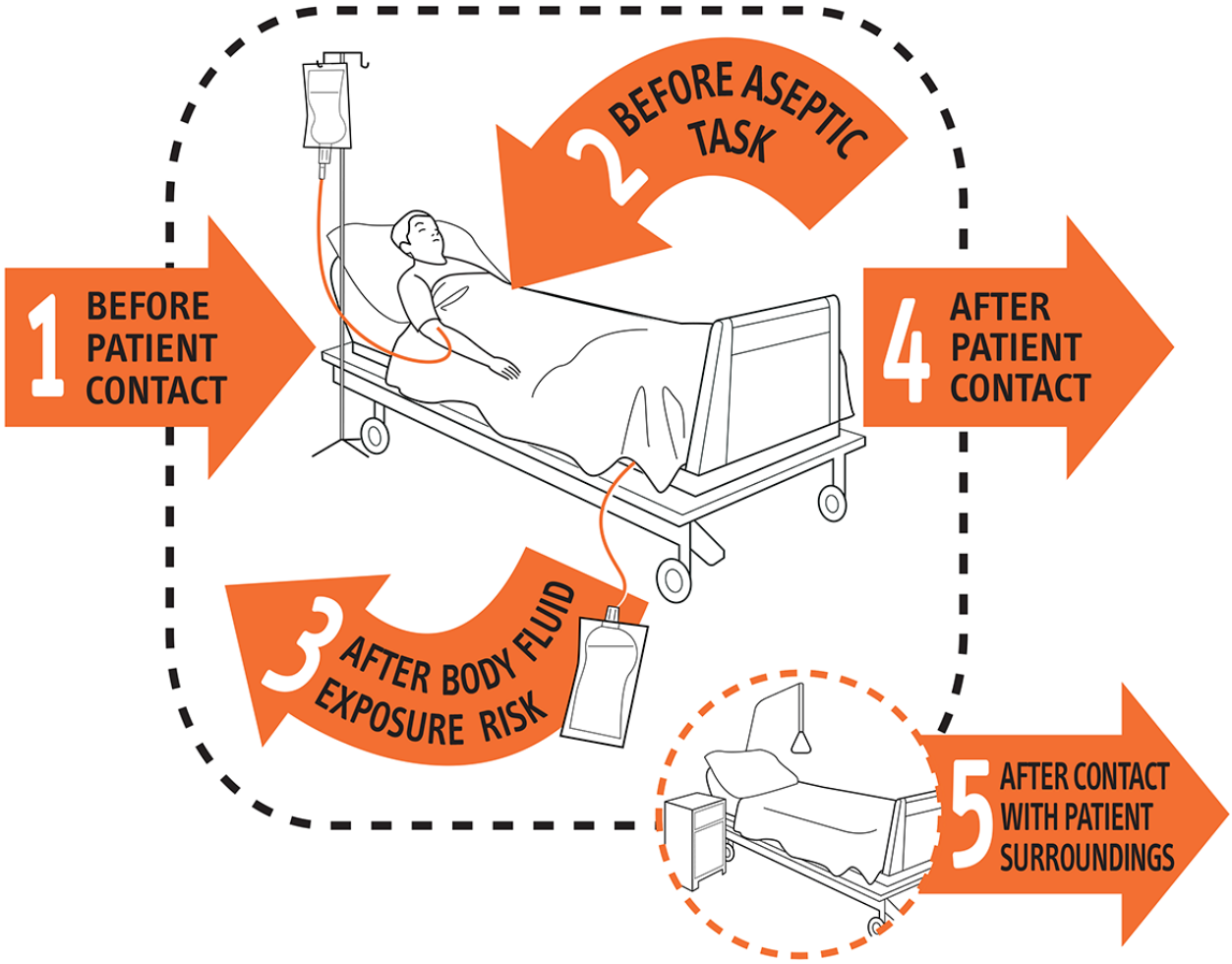


Figure 2. Standard World Health Organization procedures of alcohol-based hand rub and handwash with soap and water. Source: World Health Organization. How to Hand rub?/How to Handwash? (with permission) [10].

However, research has found that hand hygiene compliance is often poor [11,12]. By summarizing 96 empirical studies, Erasmus et al [12] reported that the median compliance rate was only 40% among HCWs. Meanwhile, research also found that hand hygiene quality was unsatisfactory [13-15]. Szilágyi et al [15] reported that only 72% of HCWs could adequately clean all hand surfaces immediately after hand hygiene training. Owing to the importance of hand hygiene, these findings suggest that monitoring hand hygiene practices and providing HCWs with feedback regarding their performance are essential to promote hand hygiene compliance and quality in health care settings [16].

Direct observation by trained auditors is considered the gold standard for monitoring hand hygiene compliance in health care settings [2,17]. Self-reporting by HCWs and the measurement of hand hygiene product consumption are also widely used to monitor hand hygiene compliance [18]. However, Boyce et al [18,19] argued that the disadvantages of direct observation include time and resource consumption, insufficient sample size, lack of standardized observational practices, and the Hawthorne effect. Furthermore, self-reporting is not recommended by experts, as HCWs tend to overestimate their level of compliance, and the measurement of hand hygiene consumption cannot assess the appropriateness of HCWs' hand hygiene timing and quality [18].

To assess hand hygiene quality, previous studies have used direct observation by trained auditors to observe HCWs' compliance with the WHO 6-step hand hygiene technique

[13,14,20]. Another common technique is using UV fluorescent substances to detect the surface coverage of hand hygiene products after hand hygiene [21,22]. Moreover, microbiological tests measure bacteria reduction count to evaluate hand hygiene quality [21,23,24]. However, using direct observation to monitor hand hygiene quality suffers from the same disadvantages as using direct observation to monitor hand hygiene compliance. Visual inspection of fluorescence is restricted to small sample sizes and a lack of standardized observational practices [25]. Furthermore, microbiological tests require time-consuming procedures and often overestimate the reduction of bacteria [21].

Given the above trade-offs, there has been increased interest in developing electronic monitoring systems to serve as an alternative or supplemental monitoring approach [19]. These electronic hand hygiene monitoring systems can be further categorized into electronic hand hygiene compliance monitoring systems and electronic hand hygiene quality monitoring systems.

Although previous reviews have described electronic hand hygiene compliance monitoring systems in detail, this is not the case for electronic hand hygiene quality monitoring systems [19,26,27]. Recent advances in sensor technologies and algorithms have also contributed to the development of new electronic hand hygiene monitoring systems. Furthermore, electronic hand hygiene monitoring systems have limitations that need to be identified and highlighted.

Objectives

This paper aims to (1) review the literature regarding the latest technological developments in electronic hand hygiene systems for monitoring compliance and quality and (2) summarize the limitations and challenges when developing and deploying such systems in health care settings.

Methods

Search Strategy and Selection Criteria

We conducted a bibliographic search of the following web-based databases: PubMed, ACM Digital Library, and IEEE Xplore Digital Library. This systematic review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [28] guidelines to reduce the risk of bias and increase its transparency and replicability. This systematic review is not registered on the network, and its review protocol is described below.

We derived the search query using a combination of key terms from previously published literature and expert advice. For the health-related database (PubMed), we specified search terms regarding hand hygiene, technological innovation, and observation to target electronic hand hygiene monitoring systems. For the technological databases (ACM Digital Library and IEEE Xplore Digital Library), we specified terms related to hand hygiene to include relevant technical innovations. The search queries for each database are given in Multimedia Appendix 1. Papers published between January 1, 2000, and June 30, 2020, were included in this study. As older literature is less relevant to today's electronic hand hygiene monitoring systems, we decided to exclude it.

Studies were included if they (1) developed an electronic method or system to monitor hand hygiene compliance or hand hygiene quality, (2) used an existing electronic device or application to support hand hygiene monitoring, or (3) adopted an existing electronic hand hygiene monitoring system and provided sufficient technical details. Meanwhile, studies were excluded if they (1) did not explicitly target electronic hand hygiene monitoring, (2) did not provide adequate technical details (eg, communication protocol and sensor specification), (3) were not published in English, or (4) were not original research papers (eg, abstracts, review papers, and editorials).

To identify the relevant studies, we first imported the search results into a spreadsheet for duplicate removal. Then, the titles were screened based on the selection criteria. If a publication passed the title screening, its abstract was assessed. Finally, the decision for inclusion was made according to the full text of the study. A total of 2 authors, CW and WJ, independently performed the study selection procedure for the retrieved publications. Disagreements between the 2 authors were further summarized and resolved by discussion with the senior author, VK, whenever necessary.

Data Extraction and Data Analysis

To collect information from the included studies in a consistent manner, we created a data extraction table (Multimedia Appendix 2). A total of 2 authors, CW and WJ, independently performed the data extraction procedure, whereas disagreements were resolved by discussion with the senior author, VK.

As we aimed to summarize the different technologies used in electronic hand hygiene monitoring systems, we adopted a narrative approach to synthesize the extracted data. All studies were first grouped by their study aims (monitoring either hand hygiene compliance or quality). After that, the categorized studies were further divided into several categories according to their technical details. Specifically, electronic hand hygiene compliance monitoring systems include (1) application-assisted direct observation, (2) camera-assisted observation, (3) sensor-assisted observation, and (4) real-time locating systems (RTLSs). Meanwhile, electronic hand hygiene quality monitoring systems include (1) measure compliance with the WHO 6-step hand hygiene techniques and (2) detect surface coverage or illumination reduction of fluorescent substances.

Owing to the high level of heterogeneity of the included studies, this study could not provide meta-analyses of the system performance and relevant HCWs' behavior changes. The significant heterogeneity also resulted in missing standardized automation tools to evaluate the risk of bias and assess the certainty for each included study.

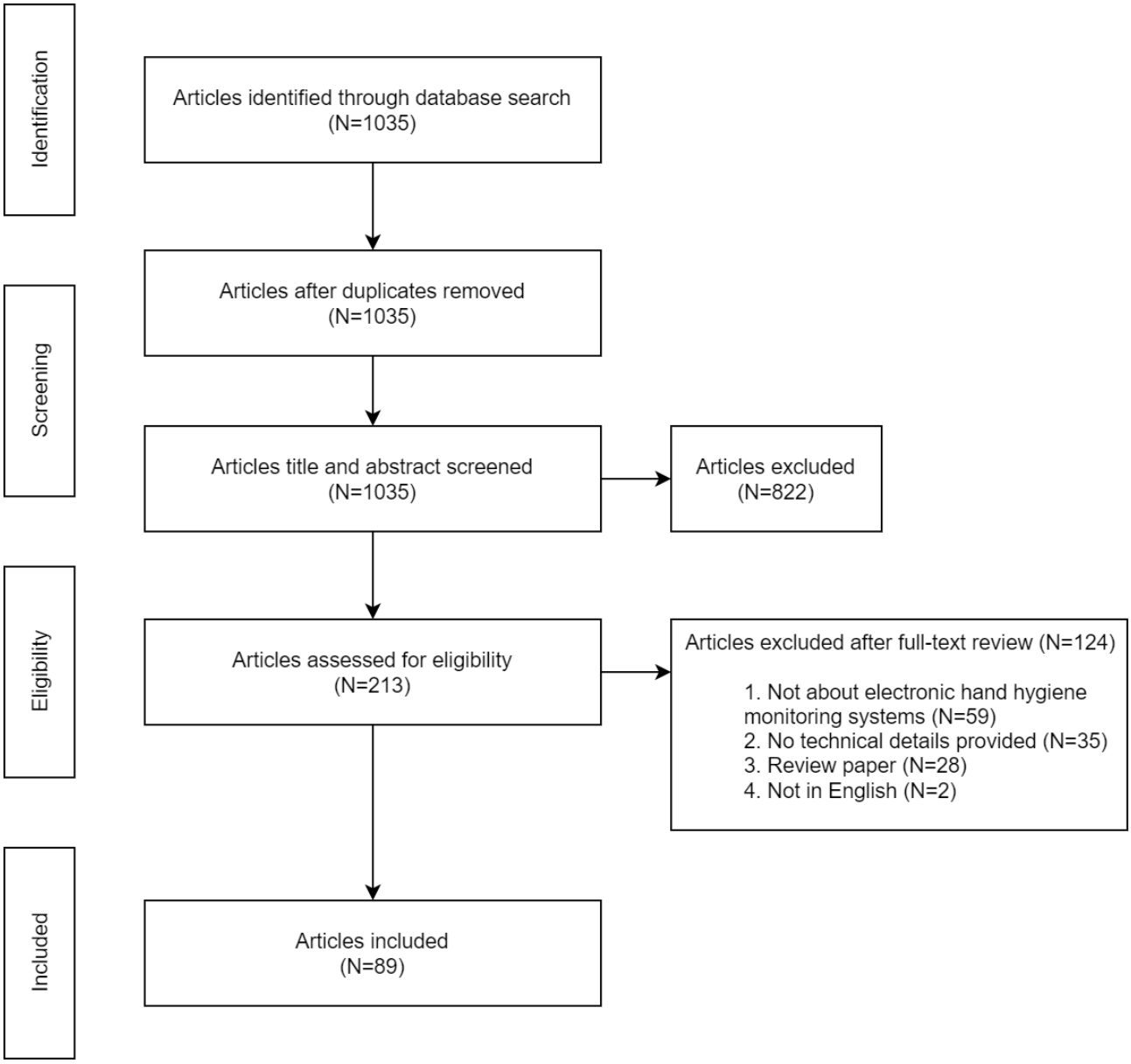
Results

Inclusion of Studies and Study Characteristics

In total, 1035 publications were retrieved by the initial search queries (777/1035, 75.07% from PubMed; 190/1035, 18.36% from the IEEE Xplore Digital Library, and; 68/1035, 6.57% from the ACM Digital Library). None of the retrieved studies were removed based on duplication. After screening the titles and abstracts, 79.42% (822/1035) of studies were excluded for

not meeting the eligibility criteria. Thus, 20.58% (213/1035) of studies were reviewed for the full text. Of these 213 studies, 124 (58.2%) studies were excluded. The main reasons for exclusion were the irrelevance of electronic hand hygiene monitoring systems (59/124, 47.6%) and insufficient technical details (35/124, 28.2%). No study was excluded if they met the inclusion criteria. Therefore, of the 213 studies, 89 (41.8%) fulfilled the eligibility criteria and were retained for review [25,29-116]. Figure 3 shows the process of searching for and selecting the studies included in the review.

Figure 3. Flowchart of the selection process for the systematic review.



All the 89 reviewed studies were published between 2009 and 2020, with 9 (10%) dated in or before 2010 [42,46,56,60,81,83,86,92,113], 38 (43%) dated between 2011 and 2015 [32,33,36,38,39,45,48,49,51,52,54,59,61,63-65,67,68,72,73,78-80,82,84,87-89,93-97,99-101,108,116], and 42 (47%) dated in or after 2016 [25,29-31,34,35,37,40,41,43,44,47,50,53,55,57,58,62,66,69-71,74-77,85,90,91,98,102-107,109-112,114,115]. Regarding the countries where the studies were conducted, 6 countries had ≥5 studies: United States (31/89, 35%) [25,30,31,36,38,39,41,46-48,51,52,59,61,63,68, 69,71,74,76,80-84,92,95,96,101,107,111], Canada (8/89, 9%) [42,72,86-89,98,100], Japan (7/89, 8%) [44,45,55,58,62,114,115], Brazil (6/89, 7%) [32,33,49,56,67,78], Germany (6/89, 7%) [37,40,50,66,108,109], and India (5/89, 6%) [64,65,94,99,102]. The demographic information of participants was provided in only 70% (62/89) of studies. Most studies (50/89, 56%) recruited HCWs from hospitals or clinics [29,30,32-40,44,46-57,59,61,66-68,73-75,77-80,82,84,86,87,89-91,95,96,98-100,103,106], and few (2/89, 2%) studies also involved patients from hospitals [66,94]. The remaining studies recruited the general public (7/89, 8%) [45,60,64,65,109-111] or students (4/89, 4%) [76,104,114,115] from communities or educational settings.

Compliance Monitoring Systems

We identified 73 studies that either implemented or adopted an electronic monitoring system for hand hygiene compliance and grouped them into 4 categories based on their enabling

technology [19,26]: application-assisted direct observation (5/73, 7%), camera-assisted observation (10/73, 14%), sensor-assisted observation (29/73, 40%), and RTLS (32/73, 44%).

Application-Assisted Direct Observation

Approximately 7% (5/73) of studies used applications to assist trained auditors in observing hand hygiene compliance (details are included in Table 1) [29-33]. With these applications, human observers could record their observations using smartphones or tablets. Unlike manual observation with paper forms, application-assisted observation avoids the need for transcription, which could cause delays in analysis, increase the associated cost, and introduce errors [117]. In addition, the prevalence of smartphones and tablets in health care settings makes data collection more unobtrusive and reduces the Hawthorne effect [26]. Both in-house and commercial applications have been used for application-assisted direct observations.

The monitored hand hygiene opportunities may vary in different studies. Most studies followed the instructions given by the WHO *5 moments for hand hygiene* [29,31-33]. Conversely, Sickbert-Bennett et al [30] simplified the observation process to *patient room entry or exit* events (as proxies for moments 1, 4, and 5).

Table 1. Description of application-assisted direct observation studies.

Paper and system description	Required device	System type	System metrics (hand hygiene opportunities)
Kariyawasam et al [29]			
Self-developed application	Android tablet	Research	WHO[a] 5 moments
Magnus et al [32] and Sodré da Costa et al [33]			
iScrub	iOS devices	Commercial	WHO 5 moments
Sickbert-Bennett et al [30]			
iScrub	iOS devices	Commercial	Patient room entry/exit events
SelectSurvey	Web browser	Commercial	Patient room entry/exit events
Wiemken et al [31]			
Google forms	Web browser	Commercial	WHO 5 moments

[a]WHO: World Health Organization.

Camera-Assisted Observation

In contrast with application-assisted direct observation, which solely relies on human auditors, studies with camera-assisted observation could rely on either human auditors [34-40] or algorithms [41-43] for analysis (details included in Table 2). Approximately 30% (3/10) of studies installed cameras inside and outside patient rooms to capture all five hand hygiene moments [34-36]. Researchers manually coded the streaming and recorded videos. Armellino et al [38,39] recruited a remote video auditing company (Arrowsight, Inc) to conduct compliance observations only when HCWs entered or exited the patient room (as proxies for moments 1, 4, and 5). Rather than installing cameras in the environment, Diefenbacher et al [37,40] proposed mounting a camera on the chest of HCWs that aimed at their hands, and researchers further analyzed these first-person view video recordings according to the WHO 5 moments for hand hygiene.

In terms of automated analyses, Zhong et al [41] attached a red green blue (RGB) camera to the chest of HCWs to collect egocentric videos. By feeding RGB images and optical flow images inside a two-stream convolutional neural network, they identified hand hygiene events in HCWs' daily routines [41]. Snoek et al [42] used an RGB camera with a microphone to observe handwash events in older adults with Alzheimer disease. Awwad et al [43] used an RGB-depth camera, Kinect (Microsoft Corporation), to achieve automatic detection of moment 1 (before touching a patient). Depth cameras generate pictures with stereo information, and these pictures have pixels with a value being the distance from the camera or *depth*. Hand hygiene compliance of moment 1 was then estimated by measuring the proximity between the subjects' hands and patient/bed with the presence of hand rub events [43].

Table 2. Description of camera-assisted observation studies.

Paper and system description	Device location	Video type	System type	System metrics (hand hygiene opportunities)
Auditor (human)				
Brotfain et al [34]				
RGB[a] camera	Patient room	Streaming	Research	WHO[b] 5 moments
Sánchez-Carrillo et al [35]				
RGB camera	Patient room	Recorded	Research	WHO 5 moments
Diller et al [36]				
RGB camera (with infrared lens)	Patient room	Recorded	Research	WHO 5 moments
Armellino et al [38,39]				
RGB camera	Sink and sanitizer dispenser	Recorded	Commercial (Arrowsight)	Patient room entry/exit events
Motion sensor	Patient room entrance	Recorded	Commercial (Arrowsight)	Patient room entry/exit events
Diefenbacher et al [37,40]				
RGB camera	HCWs[c] (chest)	Recorded	Research	WHO 5 moments
Auditor (algorithm)				
Zhong et al [41]				
RGB camera	HCWs (chest)	Recorded	Research	Hand hygiene events
Snoek et al [42]				
RGB camera	Sink	Recorded	Research	Hand hygiene events (5 states related to faucet interaction)
Microphone	Sink	Recorded	Research	Hand hygiene events (5 states related to faucet interaction)
Awwad et al [43]				
RGB depth camera	Patient bed	Recorded	Research	Moment 1 (before touching a patient)

[a]RGB: red green blue.

[b]WHO: World Health Organization.

[c]HCW: health care worker.

Sensor-Assisted Observation

Of the 73 studies, 29 (40%) observed hand hygiene compliance using sensors (details are included in Table 3) [32,33,44-70]. These studies were grouped into 3 categories on the basis of sensor type: electronic dispenser, electronic dispenser assisted by other sensors, and inertial measurement unit (IMU) and microphone.

Of these 29 studies, 15 (52%) used electronic dispensers to record the frequency of hand hygiene events and estimate the volume of hand hygiene products dispensed [32,33,44-50,54-57,59,67]. A range of sensors was used to trigger the electronic dispenser counter, including pressure resistors [45,53], magnetic sensors [66], and photosensors [58]. These records were then manually collected by researchers or wirelessly transmitted to the associated servers for further analysis. Compared with direct observation, electronic dispensers can capture hand hygiene events with substantially fewer personnel resources and are unaffected by the Hawthorne effect [19]. However, electronic dispensers cannot detect the hand hygiene opportunities specified by the WHO 5 moments for hand hygiene [19]. Thus, several studies supplemented hand hygiene events with further information to estimate hand hygiene compliance, including outpatient visit records, the expected number of hand hygiene events, ward-specific conversion factors, the number of patients in the unit, nurse visit records, and documented activities [44,48-50,55,57,59].

As electronic dispensers cannot detect hand hygiene opportunities according to the WHO guidelines, other sensors were used to capture these opportunities [51-53,61,62,66,68]. A common practice was to use motion sensors to record patient room entry or exit events (as proxies for moments 1, 4, and 5) [51,61,66]. Here, the dispensers and motion sensors uploaded the time stamp of dispense and room entry/exit events to a server. Once a motion sensor was activated, the server measured

the occurrence of a hand hygiene event within a predefined period and thus estimated the hand hygiene compliance rate. Conversely, Geilleit et al [53] placed a motion sensor around HCWs' working area and pressure plates on patient couches and chairs. Hand hygiene opportunities were defined as the movement of HCWs into a patient zone when the pressure plates were activated. Furthermore, studies used electronic dispensers with other sensors, including IMUs and microphones, to recognize different types of hand hygiene events from HCWs' daily routines [52,62,68].

Of the 29 studies, 7 (24%) used an IMU and microphone to distinguish hand hygiene events from daily activities [58,60,63-65,69,70]. An IMU is an electronic sensor that measures a body's specific force, angular rate, and orientation. Of the 7 studies, 2 (29%) attached an IMU wristband to users' wrists to collect physical signals and utilize these signals to recognize hand hygiene events [63,69]. By using acceleration, gyration, and audio signals from participants' wrists, Wijayasingha et al [70] applied the naive Bayes algorithm to identify both hand hygiene and oral hygiene events from people with developmental disabilities. Instead of placing sensors on users' wrists, 43% (3/7) of studies embedded IMU sensors with or without microphones inside soap bars [60,64,65]. These augmented soap bars were then distributed to low-income households to monitor their soap use associated with hand and body wash. Furthermore, Miyazaki et al [58] attached a microphone to a sink to distinguish hand hygiene events from other daily activities.

Table 3. Description of sensor-assisted observation studies.

Paper and system description	Device location	System type	System metrics (hand hygiene opportunities)
Electronic dispenser			
Arai et al [44]			
Dispenser	Outpatient area	Commercial (Compleo-IO)	Outpatient visit records
Asai et al [45]			
Dispenser	Hospital entrance	Research	Hand hygiene events
Boyce et al [46]			
Dispenser	Patient room and hallway	Commercial (iSIGNOL)	Hand hygiene events
Cohen et al [47]			
Dispenser	Throughout entire facility	Commercial (DebMed GMS)	Hand hygiene events
Conway et al [48]			
Dispenser	Throughout entire facility	N/A[a]	Expected hand hygiene events
Diefenbacher et al [50]			
Dispenser	Patient room	Commercial (Ingo-man We-co)	Hand hygiene events (conversion factor)
Helder et al [54]			
Dispenser	Patient room	Commercial (ComSens NewCompliance)	Hand hygiene events
Kato et al [55]			
Dispenser	Outpatient area	Commercial (CARECOM Co, Ltd)	Outpatient visit records
Morgan et al [59]			
Dispenser	Patient room	N/A	Patients number
De MacEdo et al [49]			
Dispenser	Patient room	Commercial (NXT 1-L model)	Nurse visits (nurse call system)
Marra et al [56,67], Magnus et al [32], and Sodré da Costa et al [33]			
Dispenser	Patient room	Commercial (NXT 1-L model)	Hand hygiene events
Scheithauer et al [57]			
Dispenser	Throughout entire facility	Commercial (Ingo-man We-co)	Documented activities
Electronic dispenser assisted by other sensors			
Ellison et al [51]			
Dispenser	Throughout intensive care units	N/A	Patient room entry/exit events
Motion sensor	Patient room entrance	N/A	Patient room entry/exit events
Sharma et al [61]			
Dispenser	Hallway	Research	Patient room entry/exit events
Motion sensor	Examination room entrance	Research	Patient room entry/exit events
Gaube et al [66]			

Paper and system description	Device location	System type	System metrics (hand hygiene opportunities)
Dispenser	Patient room and hallway	Research	Patient room entry/exit events
Motion sensor	Dispenser	Research	Patient room entry/exit events
Geilleit et al [53]			
Dispenser	Examination room	Research	Patient room entry/exit events
Motion sensor	HCWs'[b] work area	Research	Patient room entry/exit events
Pressure plate	Examination couch, Chair	Research	Patient room entry/exit events
Galluzzi et al [52,68]			
Dispenser	N/A	Research	Hand hygiene events
IMU[c]	HCWs (wristwatch)	Research	Hand hygiene events
Tobita et al [62]			
Dispenser	Sink	Research	Hand hygiene events
Microphone	Sink	Research	Hand hygiene events
IMU and microphone			
Uddin et al [63]			
IMU	HCWs (wristband)	Research	Hand hygiene events
Li et al [69]			
IMU	HCWs (wristband)	Research	Hand hygiene events
Ram et al [60]			
IMU	Soap bar	Research	Hand hygiene events
Wright et al [64] and Zillmer et al [65]			
IMU	Soap bar	Research	Hand hygiene events
Microphone	Soap bar	Research	Hand hygiene events
Wijayasingha et al [70]			
IMU	HCWs (wristwatch)	Research	Hand hygiene events
Microphone	HCWs (wristwatch)	Research	Hand hygiene events
Miyazaki et al [58]			
Microphone	Sink	Research	Hand hygiene events

[a]N/A: not applicable.

[b]HCW: health care worker.

[c]IMU: inertial measurement unit.

Real-time Locating Systems

Of the 73 studies, 32 (44%) studies deployed RTLSs to track hand hygiene compliance (details included in Table 4) [67,71-101]. The RTLS was originally used to identify and track the location of objects or people in real time within a specified area. By sensing dispenser actuation and HCWs' movements, servers from an RTLS can measure HCWs' hand hygiene compliance rates as the ratio of dispenser actuation to the patient room or area entry or exit events (as proxies for moments 1, 4, and 5) [19]. On the basis of the underlying technology, we divided these systems into 6 categories: radio-frequency identification (RFID), infrared, ultrasound, Bluetooth low energy (BLE), IEEE 802.15.4/ZigBee, and Wi-Fi.

Of the 32 studies, 10 (31%) developed or deployed an RFID-based RTLS [71,73,75,76,83,84,90,93,97,99]. RFID uses radio waves to identify and track tags attached to objects. RFID tags can come in a variety of shapes and can be embedded into HCWs' name tags, wristbands, bracelets, and even shoes. When HCWs with RFID tags pass RFID readers, the readers detect the HCWs' tags and then communicate the collected information to a central server. To record HCWs' hand hygiene events, 30% (3/10) of studies placed RFID readers either next to dispensers or embedded RFID readers into dispensers [71,76,93], and these RFID readers were activated by dispensing events. By installing RFID readers next to dispensers and at the entrance of patient rooms or around patient beds, RFID-based RTLS could recognize both hand hygiene events and the entry and exit of

individuals into a patient room or a patient area [73,75,83,84,90,99]. Furthermore, several other sensors were used to assist in the observation of RFID-based RTLS, including motion sensors (recording movements around patient beds), IMUs (recording duration of hand hygiene events), and ethanol sensors (recognizing alcohol-based hand rub events) [90,97,99].

Of the 32 studies, 8 (25%) studies adopted infrared-based RTLSs to monitor hand hygiene compliance [72,74,77,86-89,98]. An infrared transmitter uses infrared light pulses to transmit a unique infrared code to its receiver, and the receiver can then estimate their relative position inside a building. For all 8 studies, infrared transmitters were installed across health care settings and continuously emitted their relative location information (eg, patient room, patient bed, and hallway). In addition, the transmitters were embedded in dispensers and activated for a short period after dispenser actuation. The infrared receivers were carried by HCWs and continuously received location information from the transmitter and counted HCWs' hand hygiene events. In addition, 63% (5/8) of studies used a wearable dispenser to facilitate HCWs' hand hygiene practices. Furthermore, an ethanol sensor was deployed in an infrared-based RTLS to recognize hand rub events rather than relying on a wall-mount dispenser [77].

Of the 32 studies, 2 (6%) studies deployed ultrasound-based RTLSs [79,100]. Similar to other RTLS, ultrasound-based RTLSs comprise transmitters, receivers, and dispensers. Transmitters emit sound in the ultrasonic range, and receivers detect these sounds and thus locate the transmitters. Unlike infrared-based RTLSs, ultrasonic transmitters were typically either placed in health care settings or carried by HCWs, and thus the sound contained either location information or HCWs' identity. Through the collected signals, the receivers could locate the HCWs' real-time location and recognize patient room entry/exit events. When dispensers were used in ultrasound-based RTLSs, transmitters or receivers were also embedded in these dispensers and transmitted dispensing events to the receivers.

Table 4. Description of real-time locating system studies.

Paper and system description	Device location	System type	System metrics (hand hygiene opportunities)
Radio-frequency identification (RFID)			
Decker et al [76]			
RFID tag	HCWs[a] (tag)	Research	Class schedules
RFID reader	Dispenser	Research	Class schedules
Bal et al [71]			
RFID tag	HCWs (tag)	Research	Hand hygiene events
RFID reader	Dispenser and faucet	Research	Hand hygiene events
Dispenser/faucet	Patient room entrance and patient bed	Research	Hand hygiene events
Meydanci et al [93]			
RFID tag	HCWs (wristband)	Research	Hand hygiene events
RFID reader	Dispenser	Research	Hand hygiene events
Dispenser	Patient room and hallway	Research	Hand hygiene events
Boudjema et al [73] and Brouqui et al [75]			
RFID tag	HCWs (shoes)	Commercial (MediHandTrace)	Patient area entry/exit events
RFID reader	Floor (embedded under the dispenser, patient room, and area entrance)	Commercial (MediHandTrace)	Patient area entry/exit events
Dispenser	Patient room and hallway	Commercial (MediHandTrace)	Patient area entry/exit events
Jain et al [83]			
RFID tag	HCWs (tag)	Research	Patient room entry/exit events
RFID reader	Dispenser and patient room entrance	Research	Patient room entry/exit events
Dispenser	Patient room and hallway	Research	Patient room entry/exit events
Johnson et al [84]			
RFID tag	HCWs (tag)	Research	Patient room entry/exit events
RFID reader	Patient room entrance	Research	Patient room entry/exit events
Dispenser	Patient room entrance	Research	Patient room entry/exit events
Radhakrishna et al [99]			
RFID tag	HCWs (tag)	Research	Patient area entry/exit events
RFID reader	Patient trolley (around patient bed)	Research	Patient area entry/exit events
Dispenser	Patient trolley (around patient bed)	Research	Patient area entry/exit events
Motion sensor	Patient trolley (around patient bed)	Research	Patient area entry/exit events
Levin et al [90]			
RFID tag	HCWs (bracelet)	Research	Patient area entry/exit events
RFID reader	Patient bed, Dispenser	Research	Patient area entry/exit events
Dispenser	N/A[b]	Research	Patient area entry/exit events
IMU[c]	HCWs (bracelet)	Research	Patient area entry/exit events
Pleteršek et al [97]			
RFID tag	HCWs (tag)	Research	Hand hygiene events
Ethanol sensor	HCWs (tag), Patient room entrance	Research	Hand hygiene events
Infrared			
Baslyman et al [72]			

Paper and system description	Device location	System type	System metrics (hand hygiene opportunities)
Infrared transmitter	Patient bed, patient room entrance, dispenser, and hallway	Commercial (Ekahau)	Patient area entry/exit events
Infrared receiver	HCWs (tag)	Commercial (Ekahau)	Patient area entry/exit events
Dispenser	Patient room	Commercial (Ekahau)	Patient area entry/exit events
Boyce et al [74]			
Infrared transmitter	Patient bed, dispenser, hallway, and nurse station	Research	Patient area entry/exit events
Infrared receiver	HCWs (tag)	Research	Patient area entry/exit events
Dispenser	N/A	Research	Patient area entry/exit events
Levchenko et al [86-89] and Pong et al [98]			
Infrared transmitter	Individual patient environments, room entrances, shared bathrooms, dirty utility rooms (ceiling), and dispenser	Research	Patient room entry/exit events
Infrared receiver	HCWs (tag)	Research	Patient room entry/exit events
Wall-mount dispenser	N/A	Research	Patient room entry/exit events
Wearable gel dispenser	HCWs	Research	Patient room entry/exit events
Dyson et al [77]			
Infrared transmitter	Patient room and area entrance and sink (ceiling)	N/A	Patient area entry/exit events
Infrared receiver	HCWs (tag)	N/A	Patient area entry/exit events
Ethanol sensor	HCWs (tag)	N/A	Patient area entry/exit events
Ultrasound			
Fisher et al [79]			
Ultrasound transmitter	Patient bed and dispenser	N/A	Patient area entry/exit events
Ultrasound receiver	HCWs (tag)	N/A	Patient area entry/exit events
Dispenser	Patient room	N/A	Patient area entry/exit events
Srigley et al [100]			
Ultrasound transmitter	HCWs (tag)	N/A	Hand hygiene events
Ultrasound receiver	Patient room, hallway, and dispenser	N/A	Hand hygiene events
Dispenser	N/A	N/A	Hand hygiene events
Bluetooth low energy (BLE)			
Karimpour et al [85]			
BLE transmitter	Room	Research	Patient area entry/exit events
BLE receiver	HCWs (smartphone)	Research	Patient area entry/exit events
Misra et al [94]			
BLE transmitter	Patient bed and dispenser	Research	Patient area entry/exit events
BLE receiver	HCWs (smartphone)	Research	Patient area entry/exit events
Dispenser	Patient bed	Research	Patient area entry/exit events
Marques et al [91]			
BLE transmitter	Patient room and area entrance, sink, and dispenser	Research	Patient area entry/exit events
BLE receiver	HCWs (smartphone)	Research	Patient area entry/exit events
Dispenser	Patient room and area entrance	Research	Patient area entry/exit events
IEEE 802.15.4/ZigBee			
Marra et al [67] and Filho et al [78]			

Paper and system description	Device location	System type	System metrics (hand hygiene opportunities)
ZigBee transmitter	HCWs (tag)	Commercial (Infectrack System)	Patient area entry/exit events
ZigBee receiver	Patient bed and dispenser	Commercial (Infectrack System)	Patient area entry/exit events
Dispenser	Patient room	Commercial (Infectrack System)	Patient area entry/exit events
Fries et al [80], Herman et al [81], Hornbeck et al [82], Polgreen et al [92], and Monsalve et al [95,96]			
IEEE 802.15.4 transmitter	Patient bed and dispenser	Research	Patient area entry/exit events
IEEE 802.15.4 receiver	HCWs (tag)	Research	Patient area entry/exit events
Dispenser	Patient room	Research	Patient area entry/exit events
Wi-Fi			
Wan et al [101]			
Wi-Fi transmitter	Room and sink	Research	Hand hygiene events
Wi-Fi receiver	HCWs (tag)	Research	Hand hygiene events
Sink	Room	Research	Hand hygiene events

[a]HCW: health care worker.

[b]N/A: not applicable.

Of the 32 studies, 3 (9%) studies developed RTLSs based on BLE technology [85,91,94]. BLE or Bluetooth is a wireless technology standard used for exchanging data between devices through ultra–high-frequency radio waves. These BLE-based RTLSs also contained transmitters (or beacons), BLE receivers, and dispensers. These transmitters were used as location reference points by placing BLE transmitters in health care settings. BLE receivers brought by HCWs could detect HCWs' real-time location to infer patient room entry/exit events. Unlike the aforementioned RTLSs, BLE receivers could be HCWs' own smartphones instead of carrying additional equipment. To measure hand hygiene events, dispensers triggered the embedded BLE transmitters once they were actuated.

Of the 32 studies, 8 (25%) studies used IEEE 802.15.4 or ZigBee-based RTLSs [67,78,80-82,92,95,96]. IEEE 802.15.4 is a wireless standard capable of low-power, low-cost wireless communication between devices with lower power consumption. ZigBee is a wireless mesh network specification based on the IEEE 802.15.4 standard [118]. Similar to other RTLSs, they comprise transmitters, receivers, and dispensers. Transmitters were either carried by HCWs or placed in a health care environment. Two individual systems were used in the studies, including one commercial system (Infectrack System, i-HealthSys) based on ZigBee and one in-house system based on IEEE 802.15.4. After collecting the relative distance and/or HCWs' identity from transmitters, receivers could identify HCWs' movement when HCWs entered or exited patient areas. The transmitters or receivers were also embedded inside dispensers to recognize hand hygiene events.

The last technology used in RTLSs was Wi-Fi [101]. Wi-Fi is a family of wireless network protocols for building wireless network connections between devices through radio waves. Wi-Fi transmitters were deployed across a room and above a sink, and when HCWs triggered the dispenser next to the sink, the dispenser transmitted the dispensing event to a server through the sink transmitter. The receivers were carried by HCWs, scanned for transmitters in the environment, and periodically uploaded their location to a server.

Quality Monitoring Systems

Of the 89 studies, 21 (24%) studies evaluated hand hygiene quality as performed by HCWs, grouped into 2 categories based on their measurement methods: (1) compliance with the WHO 6-step hand hygiene techniques (14/21, 67%) and (2) surface coverage or illumination reduction of fluorescent substances (7/21, 33%).

Compliance With WHO 6-Step Hand Hygiene Techniques

Of the 21 studies, 14 (67%) studies used a variety of sensors to monitor hand hygiene quality based on compliance with the WHO 6-step hand hygiene techniques (Figure 2). A common practice was to detect the duration of hand hygiene, which is considered a key indicator of quality [13,119]. Furthermore, these systems could recognize HCWs' hand motions as belonging to the individual steps from the WHO 6-step hand hygiene techniques. As such, these systems provided more details regarding HCWs' hand hygiene performance, including missed steps and out-of-order sequences, as noncompliance with all steps of hand hygiene procedures fails to cover all skin surfaces [14,20]. In these studies, sensors were either placed in the environment or attached to HCWs to monitor their hand hygiene performance (details are included in Table 5).

Table 5. Description of studies monitoring compliance with the WHOa 6-step hand hygiene techniques.

Paper and system description	Device location	System type	System metrics (compliance with hand hygiene techniques)
Environmental sensor			
Khan et al [106]			
RGB[b] camera	Sink	Research	Hand hygiene duration
Motion sensor	Sink	Research	Hand hygiene duration
Lacey et al [103]			
RGB camera	Sink	Commercial (SureWash)	An unknown number of individual steps (WHO 6-step hand hygiene technique)
Camilus et al [102]			
Depth camera	Sink	Research	6 individual steps (WHO 6-step hand hygiene technique) and 1 wild hand hygiene technique
Zhong et al [104]			
Depth camera	Sink	Research	9 individual steps (WHO 6-step hand hygiene technique)
Khamis et al [105]			
mmWave radar	Sink	Research	9 individual steps (WHO 6-step hand hygiene technique)
Wearable sensor			
Galluzzi et al [52,68]			
IMU[c]	HCWs[d] (wristwatch)	Research	12 individual steps (WHO 6-step hand hygiene technique), 1 wild hand hygiene technique
Li et al [69]			
IMU	HCWs (wristwatch)	Research	13 individual steps (WHO 6-step hand hygiene technique)
Wijayasingha et al [70]			
IMU	HCWs (wristwatch)	Research	9 individual steps (WHO 6-step hand hygiene technique)
Microphone	HCWs (wristwatch)	Research	9 individual steps (WHO 6-step hand hygiene technique)
Banerjee et al [107]			
IMU	HCWs (armband)	Research	6 individual steps (self-defined hand hygiene technique)
Kutafina et al [108,109]			
IMU	HCWs (armband)	Research	9 individual steps (WHO 6-step hand hygiene technique)
sEMG[e]	HCWs (armband)	Research	9 individual steps (WHO 6-step hand hygiene technique)
Wang et al [110]			
IMU	HCWs (armband)	Research	14 individual steps (WHO 6-step hand hygiene technique)
sEMG	HCWs (armband)	Research	14 individual steps (WHO 6-step hand hygiene technique)
Zhong et al [41]			
RGB camera	HCWs (chest)	Research	7 individual steps (self-defined hand hygiene technique)

[a]WHO: World Health Organization.

[b]RGB: red green blue.

[c]IMU: inertial measurement unit.

[d]HCW: health care worker.

[e]sEMG: surface electromyography.

Of the 14 studies, 5 (36%) studies measured compliance with the WHO 6-step hand hygiene techniques by placing sensors in the environment [102-106]. Khan et al [106] placed an RGB camera and a motion sensor above the sink in operation rooms to monitor HCWs' hand hygiene duration. Lacey et al [103] used a commercial automatic video auditing system (SureWash,

GLANTA Ltd) to monitor HCWs' compliance with the WHO 6-step techniques. Camilus et al [102] and Zhong et al [104] installed an RGB-depth camera (Kinect) above a sink to record hand hygiene events. Hand hygiene videos with stereo information were then analyzed by classifying each frame as an individual step from the 6-step hand hygiene techniques. Instead of using optical sensors, Khanmis et al [105] installed an mmWave sensor above a sink to measure hand hygiene performance. The mmWave is a sensing technology for detecting objects and provides the range, velocity, and angle of these objects. By using the generated frames from mmWave signals, they could classify each frame as one of the nine individual steps in line with the 6-step hand hygiene techniques.

Of the 14 studies, 9 (64%) studies monitored compliance with hand hygiene guidelines by attaching wearable sensors to HCWs [41,52,68-70,107-110]. Of these, the IMU was the most popular sensor and was used in 89% (8/9) of studies with several supplementary sensors. As mentioned above, the IMU can measure a body's specific force, angular rate, and orientation. Approximately 44% (4/9) of studies used the IMU of wristwatches to collect physical signals during hand hygiene events and classified hand motion within a certain time frame as one of the several individual steps of the 6-step hand hygiene techniques [52,68-70]. In addition, microphones have been combined with IMUs to evaluate hand hygiene performance, as the additional audio data could further improve the system accuracy [70]. Owing to hygiene reasons, 44% (4/9) of studies used sensor armbands (Myo armband, North Inc) with IMU to detect HCWs' compliance with hand hygiene techniques [107-110]. Of these 4 studies, 3 (75%) studies used both IMU and surface electromyography (sEMG) sensors from Myo armbands to recognize individual steps in line with 6-step hand hygiene techniques [108-110]. The sEMG sensor is an electrochemical sensor that detects biopotentials using electrodes placed on the skin. In contrast to the aforementioned studies, Zhong et al [41] attached an RGB camera to HCWs' chests. The camera recorded HCWs' hand hygiene practices, and then the collected RGB videos were processed by a deep learning algorithm (two-stream convolutional neural network) to classify hand motions into 7 self-defined hand hygiene steps.

Surface Coverage or Illumination Reduction of Fluorescent Substances

Of the 21 studies, 7 (33%) studies used fluorescent substances to automatically examine hand hygiene quality by computer vision algorithms. However, the means of detecting the quality of handwash and hand rub were distinct. For handwash, participants first applied fluorescent dye on their entire hands and then washed their hands with soap and tap water thoroughly. For hand rub, a hand disinfectant was mixed with a fluorescent dye, and participants used the disinfectant to perform an episode of hand rub. Then, their hands were checked under a UV light lamp and photographed using RGB cameras for further analysis. By comparing the disinfected areas that glowed under UV light and were free from pathogens, Lehotsky et al [120] stated that fluorescent substances could highlight the areas of the hand surface that were adequately disinfected with acceptable accuracy (95% sensitivity and 98% specificity). UV tests have been widely used to assess hand hygiene quality in medical education because of their easy application, low associated costs, and well-visible results [22].

There were two main ways to automatically analyze the collected RGB images: detecting illumination reduction before and after an episode of handwash or measuring the surface coverage of fluorescent substances (details included in Table 6). Approximately 29% (2/7) of studies calculated the illumination difference of fluorescent substances before and after an episode of handwash using Adobe Photoshop (Adobe Inc) and MATLAB (The Math Works, Inc) [25,111]. Hand hygiene quality was then measured by the value of illumination difference, where a bigger difference indicates better hand hygiene performance and vice versa.

Of the 7 studies, 5 (71%) studies analyzed the collected images from both handwash and hand rub by measuring the surface coverage of fluorescent substances [112-116]. For hand rub, the hand rub quality was acceptable if all areas were bright without dark spots, therefore suggesting that all parts of the hand were covered homogeneously with disinfectant [22]. Approximately 40% (2/5) of studies focused on measuring the surface coverage of fluorescent substances after hand rub by applying clustering algorithms [112,113]. For handwash, as fluorescent substances contaminated hands in advance, the handwash quality was measured by the range of cleaned hand areas (dark areas). Approximately 60% (3/5) of studies applied specific threshold values or deep learning algorithms to measure handwash quality [114-116].

Table 6. Description of studies monitoring surface coverage or illumination reduction of fluorescent substances.

Paper and system description	Device location	System type	System metrics (illumination reduction or surface coverage)
Illumination reduction			
Deochand et al [25]			
Fluorescent substance	HCWs[a] (hand)	Research	Illumination reduction (whole hand)
UV lamp	Opaque box	Research	Illumination reduction (whole hand)
RGB[b] camera	Opaque box	Research	Illumination reduction (whole hand)
Pellegrino et al [111]			
Fluorescent substance	HCWs (hand)	Research	Illumination reduction (whole hand)
UV lamp	Dark room	Research	Illumination reduction (whole hand)
RGB camera	Dark room	Research	Illumination reduction (whole hand)
Surface coverage			
Srisomboon et al [112]			
Fluorescent substance	HCWs (hand)	Research	Surface coverage (pixel)
UV lamp	Opaque box	Research	Surface coverage (pixel)
RGB camera	Opaque box	Research	Surface coverage (pixel)
Szilágyi et al [113]			
Fluorescent substance	HCWs (hand)	Research	Surface coverage (pixel)
UV lamp	Opaque box	Research	Surface coverage (pixel)
RGB camera	Opaque box	Research	Surface coverage (pixel)
Yamamoto et al [114,115]			
Fluorescent substance	HCWs (hand)	Research	Surface coverage (segment)
UV lamp	Opaque box	Research	Surface coverage (segment)
RGB camera	Opaque box	Research	Surface coverage (segment)
Naim et al [116]			
Fluorescent substance	HCWs (hand)	Research	Surface coverage (pixel)
UV lamp	Opaque box	Research	Surface coverage (pixel)
RGB camera	Opaque box	Research	Surface coverage (pixel)

[a]HCW: health care worker.

[b]RGB: red green blue.

Discussion

Recently, there has been increased interest in developing electronic monitoring systems to serve as an alternative or supplementary hand hygiene monitoring approach [19]. However, electronic hand hygiene monitoring systems do have limitations. The following sections discuss the limitations related to accuracy, data integration, privacy and confidentiality, potential risks, usability, associated costs, and infrastructure improvements [19,121].

System Accuracy

The system accuracy of electronic hand hygiene monitoring systems is the top concern for HCWs [121,122]. However, systems come with different metrics without standardized measurement tools. System accuracy is also affected by technical issues and geometric constraints.

The metrics often vary substantially in different types of electronic hand hygiene monitoring systems. For electronic hand hygiene compliance monitoring systems, the metrics are based on the number of detectable moments for hand hygiene described by the WHO (Figure 1). A total of 4 different metrics were mentioned in the included studies: (1) hand hygiene events, (2) patient room entry/exit events, (3) patient area entry/exit events, and (4) the WHO 5 moments for hand hygiene. Similarly, the metrics for electronic hand hygiene quality monitoring systems are also disparate. One way to measure HCWs' hand hygiene quality is through detecting their compliance with the WHO 6-step hand hygiene techniques (Figure 2). However, different systems often recognize different sets of individual steps of standardized techniques, which can vary between 6 and 14 individual steps. Detecting illumination reduction or surface coverage of fluorescent substances is another way to measure hand hygiene quality; however, different studies come with different metrics. Several systems can detect

pixel or segment levels of fluorescent areas from the collected RGB images; however, others measure the illumination reduction of the entire hand. Therefore, system results may not accurately reflect HCWs' hand hygiene compliance and quality, and results cannot be compared between different studies without further processing.

Technical issues dramatically affect system accuracy. One of the major concerns is hardware limitations, which result in systems not functioning well under certain situations. For instance, infrared-based RTLS could fail to work if an infrared transmitter or receiver taken by a person is obscured by objects or cloths as the infrared wave cannot penetrate opaque materials [123]. Systems using ethanol sensors to track alcohol-based hand rubs cannot sense HCWs' handwash events [77]. Systems solely relying on motion sensors (ie, without user identity) cannot provide information on who enters or exits patient rooms. Other systems also suffer from reflected signals, signal noise, and interference. Moreover, the algorithms used in these systems may introduce a variety of errors. An example is that machine learning algorithms used to recognize HCWs' compliance with WHO 6-step hand hygiene techniques can generate incorrect classifications [110]. In some extreme cases, these algorithms may not correctly recognize any individual steps and provide an entire sequence of erroneous predictions. Thus, both hardware and algorithm limitations need to be considered when implementing hand hygiene monitoring systems, and effective validation of an electronic hand hygiene monitoring system is required to identify associated technical issues.

System accuracy is also influenced by geometric constraints. To protect patient privacy, studies may attach a curtain in front of cameras [36] or point them toward nonsensitive regions only (handwashing sinks and sanitizer dispensers) [38], which may not allow observation of all hand hygiene opportunities and events and further affect system accuracy. Furthermore, systems based on wearable devices are restricted by device position. For example, recent studies have relied on sensor armbands to detect hand hygiene quality; however, their system accuracy is greatly affected by the actual armband position on the arm [110].

Data Integration

The use of multiple types of sensor data and system records raises new challenges for data integration. Systems use multiple sensors to collect more reliable, accurate, and useful information required for hand hygiene monitoring; however, sensor data fusion comes with problems and issues. One of the most common issues is sensor registration and calibration, as individual sensors have their own local reference frames [124]. Studies applied varying technologies to convert different data from multiple sensors (eg, IMU and sEMG) into one reference frame and starting time, including network time protocols, event-based synchronization methods, and their combination [125,126]. During data fusion and calibration, diverse formats of sensor data could also generate noise and ambiguity, resulting in competitive and conflicting errors, and adding redundancy of sensor data is one of the solutions to increase system reliability [124]. Other issues with multiple sensor data include granularity, timescale, and frequency [124].

Integrating hand hygiene data observed by different systems is another challenge. To increase result accuracy and credibility, studies might use multiple complementary systems to monitor hand hygiene compliance or quality among the same group of HCWs. However, the metric for each observation method was different, and a lack of correlation with their results raised concerns regarding data validity [32]. In addition, different data and result formats raise issues of data integration and require conversion. Moreover, systems could simultaneously observe hand hygiene compliance and quality; however, the means to store and retrieve the records of compliance rate and quality are unclear [41,52,68-70].

Privacy and Confidentiality

Privacy and confidentiality are two other major concerns associated with electronic hand hygiene monitoring systems. Privacy concerns are known to influence HCWs' attitudes toward electronic hand hygiene monitoring systems [19]. Some HCWs perceive these systems as an invasion of their privacy and a pretext for constant surveillance of their daily activities, which makes HCWs distrust these systems and refuse to change their hand hygiene behaviors [121]. Electronic hand hygiene monitoring systems also create special challenges regarding patient privacy [127]. Studies using video cameras to monitor all 5 moments of hand hygiene would require constant video surveillance of patients and patient rooms, resulting in violation of patient privacy [26]. However, limited studies have mentioned patient privacy protection before implementing electronic hand hygiene systems. Moreover, constant surveillance through electronic hand hygiene monitoring systems might raise legal issues, resulting in systems that are unpractical in health care settings, especially when involving cameras and microphones.

The continuous collection of personal data in unprecedented volumes also raises data security concerns [128]. During data collection and storage, users' personal information can be exposed to unauthorized third parties, and the collected data can also be modified or altered through communication protocols (eg, Wi-Fi and Bluetooth) [128]. Furthermore, use scenarios of the collected data are another noticeable concern in hand hygiene monitoring systems for HCWs. Ellingson et al [122] noted that HCWs were worried about the potential use of adherence data for punitive purposes. Thus, an efficient communication mechanism should be established to provide information to HCWs on what data will be collected and stored and how data will be used [121].

Potential Risks

HCWs may face some potential risks caused by electronic hand hygiene monitoring systems. One potential risk is UV-related skin and eye damage caused by UV lamps, which are used to detect HCWs' hand hygiene quality [129,130]. Efficient preventive measures should be placed to protect HCWs' safety and control their daily exposure under a threshold limit of 3.0 mJ/cm^2 [129]. Wearable sensors have gained popularity to assess HCWs' hand hygiene quality, especially wristwatches. However, wearing rings, wristwatches, and bracelets could cause hand contamination [131]; therefore, it is challenging to use wristwatches to monitor hand hygiene procedure compliance, as it can possibly defeat the purpose. Moreover, Ward et al [26]

noted that during the demolition and installation of monitoring systems in health care, the released particulates such as mold or fungus might increase the risk of infection.

Another risk of deploying electronic hand hygiene systems is radio-frequency interference (RFI) with medical devices. RFI, known as a subset of electromagnetic interference, has been reported to cause medical device failure because of interference from various emitters of radio-frequency energy [132]. Badizadegan et al [133] reported that RFI could also result in erroneous laboratory results. Specifically, van der Togt et al [134] noted that RFID might induce potentially hazardous incidents in medical devices. To prevent RFI-associated medical device failures, system designers and device manufacturers should ensure conformance with current RFI standards, and on-site electromagnetic interference tests are required during implementation [132].

Usability

Another challenge for implementing electronic hand hygiene monitoring systems in health care is usability, as the technology may interrupt HCWs' daily workflow to ensure the proper functioning of systems. These usability problems consist of hardware and information delivery. Conway et al [121] summarized hardware-associated usability problems of compliance monitoring systems, including wearable tags (1) as heavy, bulky, and difficult to use; (2) requiring battery power, but batteries are not durable with frequent battery failures; and (3) requiring HCWs to wear them in certain positions. Other usability problems, such as limited sensing range and angles, require HCWs to change their behavior to ensure that systems work properly [77].

Similarly, usability issues also exist when delivering HCWs' hand hygiene performance information. For hand hygiene compliance monitoring, systems use different types of instant prompts (eg, visual reminders, auditory reminders, vibrations, face-to-face feedback, and olfactory stimulus) to remind HCWs regarding missed hand hygiene opportunities; however, these prompts are associated with several usability problems. For example, Dyson et al [77] noted that systems using visual prompts with a red light could cause patient anxiety. Regarding instant prompts for inadequate hand hygiene quality, most systems are designed for medical training purposes, and thus, efficient delivery of instant feedback to HCWs about hand hygiene quality and integrating these systems into their daily routines are still open challenges.

Associated Costs and Infrastructure Improvements

Implementing an electronic hand hygiene monitoring system in health care facilities comes with high costs and infrastructure improvements [19,26,121]. Using electronic systems first requires expenditure on equipment and installation costs, which vary with the selected systems [19,26,121]. Morgan et al [59] estimated that the installation of electronic dispenser–assisted systems in a 15-bed intensive care unit requires a cost between US $30,000 and US $40,000. Another study installed 21 video cameras in the hallways and patient rooms of a 17-bed intensive care unit, costing US $50,000 [38]. For community settings, installing a complete set of electronic hand hygiene monitoring systems is not realistic. Instead of fixing sensors in the environment, studies attached wearable sensors to HCWs or embedded sensors into soap bars to track HCWs' hand hygiene events from their daily routines, which are more scalable and economical.

Except for expenditures on equipment and installation costs, maintenance and personnel costs represent a larger part of system-associated costs. Maintenance costs include system updates, hand rub and soap supplies, an increase in monitored HCWs, and replacement of batteries and defective devices [19]. For in-house systems, technology does not guarantee accurate measurements and requires continuous iteration developments, resulting in maintenance costs and increased personnel needs. Application-assisted direct observation and camera-assisted observation with human auditors are associated with high personnel costs, as these systems require in-house or remote auditors to continually observe hand hygiene opportunities and events.

The installation of electronic hand hygiene systems may disrupt physical infrastructure and require infrastructure improvements. Conway et al [121] noted that infrastructure improvements comprise existing dispenser replacement and fixed hard wiring. As wireless network infrastructure also dramatically affects the system performance, it should be arranged and updated when deploying such systems in health care facilities with outdated network infrastructure.

Performance Feedback

An important but sometimes overlooked aim of deploying electronic hand hygiene monitoring systems in health care settings is to provide educational interventions to HCWs and improve their practices. The intervention methods used in the included studies comprised instant prompts and periodic summaries.

To remind HCWs about missed hand hygiene opportunities, systems may provide instant prompts when noncompliance is detected. Instant prompts comprise visual reminders, auditory reminders, vibrations, face-to-face feedback, olfactory stimuli, and their combinations. To improve HCWs' hand hygiene quality, systems also provide instant prompts when detecting hand hygiene events with inadequate quality. Instant prompts include reminding HCWs about missed steps and disordered sequences of the WHO 6-step hand hygiene techniques and visualizing unclean areas from recorded UV test images. Periodic summaries are also widely adopted to improve HCWs' hand hygiene compliance and quality. Systems deliver periodic summaries to HCWs through reports, dashboards, games, notice boards/monitors, face-to-face feedback, and their combinations.

The included studies also delivered hand hygiene feedback by combining both instant prompts and periodic summaries. For example, Ellison et al [51] adopted auditory reminders as instant prompts and delivered periodic summaries through specific monitor screen savers to remind HCWs of hand hygiene compliance.

Nevertheless, each instant prompt type is associated with specific drawbacks. For visual reminders, Dyson et al [77] noted that red light light-emitting diodes (LEDs) on badges might

cause patient anxiety, so the color of badge LEDs should be adjustable and provide an option to disable the LEDs when necessary. Regarding auditory reminders, Baslyman et al [72] noted that sending audible alerts during the night is not acceptable as most patients are sleeping. Face-to-face feedback is associated with the Hawthorne effect, which causes different hand hygiene behaviors from their daily routines [30]. Using unpleasant odors is also not suitable for most health care facilities as they may cause physical discomfort.

Regarding periodic summaries, designing understandable periodic summaries for HCWs with different educational backgrounds is a challenge [121]. Conway et al [48] noted that HCWs or managers might have difficulty reading and interpreting periodic reports with charts. Efficiently disseminating collected information to HCWs and keeping them informed is challenging as well, as many HCWs have reported never or inconsistently receiving their performance information [48]. Moreover, ensuring that periodic summaries are used to drive hand hygiene improvement instead of punishment is another challenge. Hand hygiene improvement might be short-lived and moderate without HCWs' engagement, constant feedback delivery, detailed action plans, and leadership support [121].

By constantly delivering feedback to HCWs and educating HCWs and medical students on the importance of hand hygiene and the correct procedures, HCWs are likely to improve their hand hygiene techniques and habits. In Multimedia Appendices 3 [53,66,67,77,79,89,98,111], 4 [35,38,39,44,48,51,79,106], and 5 [30,51,88,89], we summarize the performance improvements of HCWs in studies that implemented instant prompts, periodic summaries, or their combinations. However, HCWs have diverse feedback needs. For example, Conway et al [121] and Levchenko et al [89] noted that most HCWs prefer instant prompts rather than periodic summaries, and their compliance rates increased immediately after receiving instant prompts. Nevertheless, Levchenko et al [89] also mentioned that a few HCWs improved their compliance only after they reviewed their individual results.

Implications

Owing to the high level of heterogeneity of the included studies, it is difficult to compare and analyze data across studies. A noticeable difference across the included studies was the variety of system metrics. To generate quantitative analyses, a high degree of standardization is required. Thus, standardized metrics across different hand hygiene monitoring systems need to be established based on system hardware limitations and WHO recommendations. For instance, the number of individual steps of the WHO 6-step hand hygiene techniques can be set to 9 in line with the WHO guideline as steps 3, 6, and 7 (shown in Figure 2) require repeats for both hands.

Given the recent advancements in sensing technologies, hand hygiene monitoring systems can adopt previously unused technology infrastructure or sensors to monitor HCWs' hand hygiene performance. For example, the aforementioned systems require a dedicated device being carried by HCWs to trace their indoor locations. Li et al [135] achieved device-free indoor location tracking by using commodity Wi-Fi, which has been installed in most health care facilities. Conversely, hand hygiene monitoring systems can apply new algorithms to improve their system accuracy. For example, previous studies adopted a hidden Markov model to classify the individual steps of 6-step techniques or smooth classification results, which assumes that HCWs will perform hand hygiene procedures according to predefined orders. However, once this assumption is relaxed, the performance of these systems dramatically drops [69]. Instead, classification results smoothed by change point detection algorithms (eg, E.Divisive [136]) might ease the performance decrease.

Hand hygiene monitoring systems and collected data can also be used to solve other hand hygiene–related issues. For example, systems detecting surface coverage of fluorescent substances could be considered as an alternative method to validate the efficacy of newly proposed hand hygiene techniques instead of microbiological tests, as fluorescent substances could highlight the hand surface areas that are adequately disinfected with acceptable accuracy [120]. Similarly, studies have used hand hygiene behavior data to monitor participants' levels of dementia, Alzheimer disease, and obsessive-compulsive disorder [137,138]. Furthermore, hand hygiene compliance history has been used to simulate the transmission of HAIs in health care settings [139].

Limitations

This study has several limitations. Some relevant studies may have been missed because of the keywords and databases chosen for the search query. Furthermore, some relevant studies may not have been included if they were not published in English, were outside the specified time frame, or did not provide adequate technical information.

Specifically, we included all types of studies regardless of their maturity, as it helps summarize the latest technological developments in electronic hand hygiene monitoring systems. However, early-stage or preliminary studies or methodology studies may present incomplete data or a lack of results. Owing to the heterogeneity of the studies and sparse metrics, we could not conduct a meta-analysis for the study population, system accuracy, and intervention effectiveness. In addition, because of the significant heterogeneity, we could not evaluate the risk of bias for each study using standardized automation tools and assess the certainty of the included studies.

This review describes different technologies for hand hygiene monitoring. Nevertheless, since we adopted the narrative approach to synthesize the outcomes rather than a meta-analysis, we did not assess the risk of bias because of missing results.

Conclusions

Our review provides an overview of the latest technological developments in electronic hand hygiene monitoring systems that measure compliance or quality. Systems utilize application-assisted direct observation, camera-assisted observation, sensor-assisted observation, and RTLS to monitor HCWs' compliance rates. For quality monitoring, systems either measure compliance with the WHO 6-step hand hygiene techniques or detect surface coverage or illumination reduction of fluorescent substances. Despite the technologies used in these

systems, we identify system-associated issues and challenges, including system accuracy, data integration, privacy and confidentiality, potential risks, usability, and associated costs and infrastructure improvements. Owing to the narrative approach adopted in these studies, more research is required to establish standardized metrics to measure system performance differences among electronic hand hygiene monitoring systems. With sensing technologies and algorithms continually advancing, more research is needed on their implementation to improve system performance and address other hand hygiene–related issues.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy for PubMed, IEEE Xplore Digital Library, and ACM Digital Library.
[XLSX File (Microsoft Excel File), 10 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Data extraction form.
[XLSX File (Microsoft Excel File), 11 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Hand hygiene improvements of studies with instant prompts.
[XLSX File (Microsoft Excel File), 10 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Hand hygiene improvements of studies with periodic summaries.
[XLSX File (Microsoft Excel File), 10 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Hand hygiene improvements of studies with instant prompts and periodic summaries.
[XLSX File (Microsoft Excel File), 10 KB-Multimedia Appendix 5]

References

1. Allegranzi B, Pittet D. Role of hand hygiene in healthcare-associated infection prevention. J Hosp Infect 2009 Dec;73(4):305-315. [doi: 10.1016/j.jhin.2009.04.019] [Medline: 19720430]
2. World Health Organization. WHO guidelines on hand hygiene in health care. Geneva: World Health Organization; 2009:1-270.
3. Pittet D. Improving adherence to hand hygiene practice: a multidisciplinary approach. Emerg Infect Dis 2001 Apr;7(2):234-240 [FREE Full text] [doi: 10.3201/eid0702.010217] [Medline: 11294714]
4. Haque M, Sartelli M, McKimm J, Bakar M. Health care-associated infections - an overview. Infect Drug Resist 2018;11:2321-2333 [FREE Full text] [doi: 10.2147/IDR.S177247] [Medline: 30532565]
5. Institute of Medicine, Committee on Quality of Health Care in America. In: Donaldson MS, Corrigan JM, Kohn LT, editors. To Err Is Human: Building a Safer Health System. Washington (DC): National Academies Press (US); 2000.
6. Klevens RM, Edwards JR, Richards CL, Horan TC, Gaynes RP, Pollock DA, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep 2007 Aug 02;122(2):160-166 [FREE Full text] [doi: 10.1177/003335490712200205] [Medline: 17357358]
7. De Angelis G, Murthy A, Beyersmann J, Harbarth S. Estimating the impact of healthcare-associated infections on length of stay and costs. Clin Microbiol Infect 2010 Dec;16(12):1729-1735 [FREE Full text] [doi: 10.1111/j.1469-0691.2010.03332.x] [Medline: 20673257]
8. Graves N, Halton K, Paterson D, Whitby M. Economic rationale for infection control in Australian hospitals. Healthc Infect 2009 Sep;14(3):81-88. [doi: 10.1071/hi09010]

9. Stone PW, Hasan S, Quiros D, Larson EL. Effect of guideline implementation on costs of hand hygiene. Nurs Econ 2007;25(5):279-284 [FREE Full text] [Medline: 18080624]
10. How to handrub? / how to handwash? World Health Organization. 2009. URL: https://www.who.int/gpsc/5may/How_To_HandWash_Poster.pdf [accessed 2021-10-21]
11. Pittet D, Simon A, Hugonnet S, Pessoa-Silva CL, Sauvan V, Perneger TV. Hand hygiene among physicians: performance, beliefs, and perceptions. Ann Intern Med 2004 Jul 06;141(1):1-8. [doi: 10.7326/0003-4819-141-1-200407060-00008] [Medline: 15238364]
12. Erasmus V, Daha TJ, Brug H, Richardus JH, Behrendt MD, Vos MC, et al. Systematic review of studies on compliance with hand hygiene guidelines in hospital care. Infect Control Hosp Epidemiol 2010 Mar 02;31(3):283-294. [doi: 10.1086/650451] [Medline: 20088678]
13. Korhonen A, Ojanperä H, Puhto T, Järvinen R, Kejonen P, Holopainen A. Adherence to hand hygiene guidelines - significance of measuring fidelity. J Clin Nurs 2015 Nov 01;24(21-22):3197-3205. [doi: 10.1111/jocn.12969] [Medline: 26331437]
14. Arias AV, Garcell HG, Ochoa YR, Arias KF, Miranda FR. Assessment of hand hygiene techniques using the World Health Organization's six steps. J Infect Public Health 2016 May;9(3):366-369 [FREE Full text] [doi: 10.1016/j.jiph.2015.11.006] [Medline: 26707705]
15. Szilágyi L, Haidegger T, Lehotsky A, Nagy M, Csonka E, Sun X, et al. A large-scale assessment of hand hygiene quality and the effectiveness of the "WHO 6-steps". BMC Infect Dis 2013 May 30;13(1):249 [FREE Full text] [doi: 10.1186/1471-2334-13-249] [Medline: 23718728]
16. Boyce JM. Measuring healthcare worker hand hygiene activity: current practices and emerging technologies. Infect Control Hosp Epidemiol 2011 Oct 02;32(10):1016-1028. [doi: 10.1086/662015] [Medline: 21931253]
17. Stewardson A, Sax H, Longet-Di Pietro S, Pittet D. Impact of observation and analysis methodology when reporting hand hygiene data. J Hosp Infect 2011 Apr;77(4):358-359. [doi: 10.1016/j.jhin.2010.12.008] [Medline: 21316121]
18. Boyce JM. Hand hygiene compliance monitoring: current perspectives from the USA. J Hosp Infect 2008 Oct;70:2-7. [doi: 10.1016/s0195-6701(08)60003-1]
19. Boyce JM. Electronic monitoring in combination with direct observation as a means to significantly improve hand hygiene compliance. Am J Infect Control 2017 May 01;45(5):528-535. [doi: 10.1016/j.ajic.2016.11.029] [Medline: 28456322]
20. Tschudin-Sutter S, Sepulcri D, Dangel M, Schuhmacher H, Widmer AF. Compliance with the World Health Organization hand hygiene technique: a prospective observational study. Infect Control Hosp Epidemiol 2015 Apr 20;36(4):482-483. [doi: 10.1017/ice.2014.82] [Medline: 25782907]
21. Reilly JS, Price L, Lang S, Robertson C, Cheater F, Skinner K, et al. A pragmatic randomized controlled trial of 6-step vs 3-step hand hygiene technique in acute hospital care in the United Kingdom. Infect Control Hosp Epidemiol 2016 Jun 07;37(6):661-666. [doi: 10.1017/ice.2016.51] [Medline: 27050843]
22. Vanyolos E, Peto K, Viszlai A, Miko I, Furka I, Nemeth N, et al. Usage of ultraviolet test method for monitoring the efficacy of surgical hand rub technique among medical students. J Surg Educ 2015 May;72(3):530-535. [doi: 10.1016/j.jsurg.2014.12.002] [Medline: 25656633]
23. Kampf G, Ostermeyer C, Heeg P, Paulson D. Evaluation of two methods of determining the efficacies of two alcohol-based hand rubs for surgical hand antisepsis. Appl Environ Microbiol 2006 Jun;72(6):3856-3861. [doi: 10.1128/aem.02746-05]
24. Michaud RN, McGrath MB, Goss WA. Application of a gloved-hand model for multiparameter measurements of skin-degerming activity. J Clin Microbiol 1976 Apr;3(4):406-413 [FREE Full text] [doi: 10.1128/jcm.3.4.406-413.1976] [Medline: 1262452]
25. Deochand N, Deochand ME. Brief report on hand-hygiene monitoring systems: a pilot study of a computer-assisted image analysis technique. J Environ Health 2016 Jun;78(10):14-20. [Medline: 27348978]
26. Ward MA, Schweizer ML, Polgreen PM, Gupta K, Reisinger HS, Perencevich EN. Automated and electronically assisted hand hygiene monitoring systems: a systematic review. Am J Infect Control 2014 May;42(5):472-478. [doi: 10.1016/j.ajic.2014.01.002] [Medline: 24773785]
27. Marra AR, Edmond MB. Hand hygiene: state-of-the-art review with emphasis on new technologies and mechanisms of surveillance. Curr Infect Dis Rep 2012 Dec 28;14(6):585-591. [doi: 10.1007/s11908-012-0288-y] [Medline: 22922997]
28. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev 2015 Jan 01;4(1):1 [FREE Full text] [doi: 10.1186/2046-4053-4-1] [Medline: 25554246]
29. Kariyawasam N, Wong M, Turner P. User centred design and nosocomials in surgical ICUs: a mobile application for peer monitoring and training in hand hygiene. Stud Health Technol Inform 2017;245:743-747. [Medline: 29295197]
30. Sickbert-Bennett EE, DiBiase LM, Willis TM, Wolak ES, Weber DJ, Rutala WA. Reducing health care-associated infections by implementing a novel all hands on deck approach for hand hygiene compliance. Am J Infect Control 2016 May 02;44(5 Suppl):13-16. [doi: 10.1016/j.ajic.2015.11.016] [Medline: 27131129]
31. Wiemken TL, Furmanek SP, Mattingly WA, Haas J, Ramirez JA, Carrico RM. Googling your hand hygiene data: using Google Forms, Google Sheets, and R to collect and automate analysis of hand hygiene compliance monitoring. Am J Infect Control 2018 Jun;46(6):617-619. [doi: 10.1016/j.ajic.2018.01.010] [Medline: 29496338]

32. Magnus TP, Marra AR, Camargo TZ, Victor ED, da Costa LS, Cardoso VJ, et al. Measuring hand hygiene compliance rates in different special care settings: a comparative study of methodologies. Int J Infect Dis 2015 Apr;33:205-208 [FREE Full text] [doi: 10.1016/j.ijid.2015.02.016] [Medline: 25722282]
33. da Costa LS, Neves VM, Marra AR, Camargo TZ, dos Santos Cardoso MF, da Silva Victor E, et al. Measuring hand hygiene compliance in a hematology-oncology unit: a comparative study of methodologies. Am J Infect Control 2013 Nov;41(11):997-1000. [doi: 10.1016/j.ajic.2013.03.301] [Medline: 23769833]
34. Brotfain E, Livshiz-Riven I, Gushansky A, Erblat A, Koyfman L, Ziv T, et al. Monitoring the hand hygiene compliance of health care workers in a general intensive care unit: use of continuous closed circle television versus overt observation. Am J Infect Control 2017 Aug 01;45(8):849-854. [doi: 10.1016/j.ajic.2017.03.015] [Medline: 28479008]
35. Sánchez-Carrillo LA, Rodríguez-López JM, Galarza-Delgado D, Baena-Trejo L, Padilla-Orozco M, Mendoza-Flores L, et al. Enhancement of hand hygiene compliance among health care workers from a hemodialysis unit using video-monitoring feedback. Am J Infect Control 2016 Aug 01;44(8):868-872. [doi: 10.1016/j.ajic.2016.01.040] [Medline: 27068027]
36. Diller T, Kelly JW, Blackhurst D, Steed C, Boeker S, McElveen DC. Estimation of hand hygiene opportunities on an adult medical ward using 24-hour camera surveillance: validation of the HOW2 Benchmark Study. Am J Infect Control 2014 Jun;42(6):602-607. [doi: 10.1016/j.ajic.2014.02.020] [Medline: 24837110]
37. Diefenbacher S, Pfattheicher S, Keller J. On the role of habit in self-reported and observed hand hygiene behavior. Appl Psychol Health Well Being 2020 Mar 28;12(1):125-143. [doi: 10.1111/aphw.12176] [Medline: 31353823]
38. Armellino D, Hussain E, Schilling ME, Senicola W, Eichorn A, Dlugacz Y, et al. Using high-technology to enforce low-technology safety measures: the use of third-party remote video auditing and real-time feedback in healthcare. Clin Infect Dis 2012 Jan 01;54(1):1-7 [FREE Full text] [doi: 10.1093/cid/cir773] [Medline: 22109950]
39. Armellino D, Trivedi M, Law I, Singh N, Schilling ME, Hussain E, et al. Replicating changes in hand hygiene in a surgical intensive care unit with remote video auditing and feedback. Am J Infect Control 2013 Oct;41(10):925-927. [doi: 10.1016/j.ajic.2012.12.011] [Medline: 23489740]
40. Diefenbacher S, Sassenrath C, Tatzel J, Keller J. Evaluating healthcare workers' hand hygiene performance using first-person view video observation in a standardized patient-care scenario. Am J Infect Control 2020 May;48(5):496-502. [doi: 10.1016/j.ajic.2019.11.032] [Medline: 32334725]
41. Zhong C, Reibman AR, Cordoba HM, Deering AJ. Hand-hygiene activity recognition in egocentric video. In: Proceedings of the IEEE 21st International Workshop on Multimedia Signal Processing (MMSP). 2019 Presented at: IEEE 21st International Workshop on Multimedia Signal Processing (MMSP); Sept. 27-29, 2019; Kuala Lumpur, Malaysia. [doi: 10.1109/mmsp.2019.8901753]
42. Snoek J, Taati B, Eskin Y, Mihailidis A. Automatic segmentation of video to aid the study of faucet usability for older adults. In: Proceedings of the IEEE Computer Society Conference on Computer Vision and Pattern Recognition - Workshops. 2010 Presented at: IEEE Computer Society Conference on Computer Vision and Pattern Recognition - Workshops; June 13-18, 2010; San Francisco, CA, USA. [doi: 10.1109/cvprw.2010.5543266]
43. Awwad S, Tarvade S, Piccardi M, Gattas DJ. The use of privacy-protected computer vision to measure the quality of healthcare worker hand hygiene. Int J Qual Health Care 2019 Feb 01;31(1):36-42. [doi: 10.1093/intqhc/mzy099] [Medline: 29767747]
44. Arai A, Tanabe M, Nakamura A, Yamasaki D, Muraki Y, Kaneko T, et al. Utility of electronic hand hygiene counting devices for measuring physicians' hand hygiene adherence applied to outpatient settings. Am J Infect Control 2016 Dec 01;44(12):1481-1485 [FREE Full text] [doi: 10.1016/j.ajic.2016.08.002] [Medline: 27665030]
45. Asai T, Kanazawa A, Hayashi H, Minazuki A. Development of a system to raise awareness of hand hygiene in various environments. In: Proceedings of the International Conference on Signal-Image Technology & Internet-Based Systems. 2013 Presented at: International Conference on Signal-Image Technology & Internet-Based Systems; Dec. 2-5, 2013; Kyoto, Japan. [doi: 10.1109/sitis.2013.150]
46. Boyce JM, Cooper T, Dolan MJ. Evaluation of an electronic device for real-time measurement of alcohol-based hand rub use. Infect Control Hosp Epidemiol 2009 Nov 02;30(11):1090-1095. [doi: 10.1086/644756] [Medline: 19775238]
47. Cohen B, Murray M, Jia H, Jackson O, Saiman L, Neu N, et al. Is hand hygiene frequency associated with the onset of outbreaks in pediatric long-term care? Am J Infect Control 2016 Dec 01;44(12):1492-1494 [FREE Full text] [doi: 10.1016/j.ajic.2016.06.022] [Medline: 27566873]
48. Conway LJ, Riley L, Saiman L, Cohen B, Alper P, Larson EL. Implementation and impact of an automated group monitoring and feedback system to promote hand hygiene among health care personnel. Jt Comm J Qual Patient Saf 2014 Sep;40(9):408-417. [doi: 10.1016/s1553-7250(14)40053-9]
49. Macedo RC, Jacob EM, Silva VP, Santana EA, Souza AF, Gonçalves P, et al. Positive deviance: using a nurse call system to evaluate hand hygiene practices. Am J Infect Control 2012 Dec;40(10):946-950. [doi: 10.1016/j.ajic.2011.11.015] [Medline: 22418606]
50. Diefenbacher S, Fliss P, Tatzel J, Wenk J, Keller J. A quasi-randomized controlled before-after study using performance feedback and goal setting as elements of hand hygiene promotion. J Hosp Infect 2019 Apr;101(4):399-407. [doi: 10.1016/j.jhin.2019.02.001] [Medline: 30738912]

51. Ellison RT, Barysauskas CM, Rundensteiner EA, Wang D, Barton B. A prospective controlled trial of an electronic hand hygiene reminder system. Open Forum Infect Dis 2015 Dec;2(4):ofv121 [FREE Full text] [doi: 10.1093/ofid/ofv121] [Medline: 26430698]
52. Galluzzi V, Herman T, Shumaker DJ, Macinga DR, Arbogast JW, Segre EM, et al. Electronic recognition of hand hygiene technique and duration. Infect Control Hosp Epidemiol 2014 Oct 10;35(10):1298-1300. [doi: 10.1086/678059] [Medline: 25203186]
53. Geilleit R, Hen ZQ, Chong CY, Loh AP, Pang NL, Peterson GM, et al. Feasibility of a real-time hand hygiene notification machine learning system in outpatient clinics. J Hosp Infect 2018 Oct;100(2):183-189. [doi: 10.1016/j.jhin.2018.04.004] [Medline: 29649558]
54. Helder OK, van Goudoever JB, Hop WC, Brug J, Kornelisse RF. Hand disinfection in a neonatal intensive care unit: continuous electronic monitoring over a one-year period. BMC Infect Dis 2012 Oct 08;12(1):248 [FREE Full text] [doi: 10.1186/1471-2334-12-248] [Medline: 23043639]
55. Kato H, Takeda R, Ideno Y, Suzuki T, Sano K, Nakamura K. Physicians' compliance for hand hygiene in medical outpatient clinics: automated hand-hygiene monitoring with touch sensor and wireless internet. Am J Infect Control 2021 Jan;49(1):50-54. [doi: 10.1016/j.ajic.2020.05.037] [Medline: 32512079]
56. Marra AR, Moura DF, Paes T, dos Santos OF, Edmond MB. Measuring rates of hand hygiene adherence in the intensive care setting: a comparative study of direct observation, product usage, and electronic counting devices. Infect Control Hosp Epidemiol 2010 Aug 02;31(8):796-801. [doi: 10.1086/653999] [Medline: 20565261]
57. Scheithauer S, Batzer B, Dangel M, Passweg J, Widmer A. Workload even affects hand hygiene in a highly trained and well-staffed setting: a prospective 365/7/24 observational study. J Hosp Infect 2017 Sep;97(1):11-16. [doi: 10.1016/j.jhin.2017.02.013] [Medline: 28389091]
58. Miyazaki K, Tobita H. SinkAmp: interactive sink to detect living habits for healthcare and quality of life. In: Proceedings of the 23rd International Conference on Intelligent User Interfaces Companion. 2018 Presented at: Proceedings of the 23rd International Conference on Intelligent User Interfaces Companion; March 7 - 11, 2018; Tokyo Japan p. 1-2. [doi: 10.1145/3180308.3180339]
59. Morgan DJ, Pineles L, Shardell M, Young A, Ellingson K, Jernigan JA, et al. Automated hand hygiene count devices may better measure compliance than human observation. Am J Infect Control 2012 Dec;40(10):955-959. [doi: 10.1016/j.ajic.2012.01.026] [Medline: 22633134]
60. Ram PK, Halder AK, Granger SP, Jones T, Hall P, Hitchcock D, et al. Is structured observation a valid technique to measure handwashing behavior? Use of acceleration sensors embedded in soap to assess reactivity to structured observation. Am J Trop Med Hyg 2010 Nov;83(5):1070-1076 [FREE Full text] [doi: 10.4269/ajtmh.2010.09-0763] [Medline: 21036840]
61. Sharma D, Thomas GW, Foster ED, Iacovelli J, Lea KM, Streit JA, et al. The precision of human-generated hand-hygiene observations: a comparison of human observation with an automated monitoring system. Infect Control Hosp Epidemiol 2012 Dec 02;33(12):1259-1261 [FREE Full text] [doi: 10.1086/668426] [Medline: 23143367]
62. Tobita H, Matsumoto M, Maida Y, Eguchi Y, Terada K. SinkNet: Interactive sink to detect living habits for healthcare and quality of life using private networks. In: Proceedings of the IEEE International Conference on Artificial Intelligence and Virtual Reality (AIVR). 2018 Presented at: IEEE International Conference on Artificial Intelligence and Virtual Reality (AIVR); Dec. 10-12, 2018; Taichung, Taiwan. [doi: 10.1109/aivr.2018.00020]
63. Uddin M, Salem A, Nam I, Nadeem T. Wearable sensing framework for human activity monitoring. In: Proceedings of the 2015 workshop on Wearable Systems and Applications`. 2015 Presented at: MobiSys'15: The 13th Annual International Conference on Mobile Systems, Applications, and Services; May 18, 2015; Florence Italy p. 21-26. [doi: 10.1145/2753509.2753513]
64. Wright RL, Zillmer R, Biran A, Hall P, Sidibe M. Use of electronic loggers to measure changes in the rates of hand washing with soap in low-income urban households in India. PLoS One 2015 Jun 23;10(6):e0131187 [FREE Full text] [doi: 10.1371/journal.pone.0131187] [Medline: 26101886]
65. Zillmer R, Wright R, Bates S, Mahers I. A robust device for large-scale monitoring of bar soap usage in free-living conditions. Pers Ubiquit Comput 2014 Feb 1;18(8):2057-2064. [doi: 10.1007/s00779-014-0760-9]
66. Gaube S, Tsivrikos D, Dollinger D, Lermer E. How a smiley protects health: a pilot intervention to improve hand hygiene in hospitals by activating injunctive norms through emoticons. PLoS One 2018 May 21;13(5):e0197465 [FREE Full text] [doi: 10.1371/journal.pone.0197465] [Medline: 29782516]
67. Marra AR, Camargo TZ, Magnus TP, Blaya RP, Dos Santos G, Guastelli LR, et al. The use of real-time feedback via wireless technology to improve hand hygiene compliance. Am J Infect Control 2014 Jun;42(6):608-611. [doi: 10.1016/j.ajic.2014.02.006] [Medline: 24725515]
68. Galluzzi V, Herman T, Polgreen P. Hand hygiene duration and technique recognition using wrist-worn sensors. In: Proceedings of the 14th International Conference on Information Processing in Sensor Networks. 2015 Presented at: IPSN '15: The 14th International Conference on Information Processing in Sensor Networks; April 13 - 16, 2015; Seattle Washington p. 106-117. [doi: 10.1145/2737095.2737106]
69. Li H, Chawla S, Li R, Jain S, Abowd G, Starner T, et al. Wristwash: towards automatic handwashing assessment using a wrist-worn device. In: Proceedings of the 2018 ACM International Symposium on Wearable Computers. 2018 Presented

at: UbiComp '18: The 2018 ACM International Joint Conference on Pervasive and Ubiquitous Computing; October 8 - 12, 2018; Singapore p. 132-139. [doi: 10.1145/3267242.3267247]
70. Wijayasingha L, Lo B. A wearable sensing framework for improving personal and oral hygiene for people with developmental disabilities. In: Proceedings of the IEEE Wireless Health (WH). 2016 Presented at: IEEE Wireless Health (WH); Oct. 25-27, 2016; Bethesda, MD, USA. [doi: 10.1109/wh.2016.7764550]
71. Bal M, Abrishambaf R. A system for monitoring hand hygiene compliance based-on Internet-of-Things. In: Proceedings of the IEEE International Conference on Industrial Technology (ICIT). 2017 Presented at: IEEE International Conference on Industrial Technology (ICIT); March 22-25, 2017; Toronto, ON, Canada. [doi: 10.1109/icit.2017.7915560]
72. Baslyman M, Rezaee R, Amyot D, Moutthamt A, Chreyh R, Geiger G, et al. Real-time and location-based hand hygiene monitoring and notification: proof-of-concept system and experimentation. Pers Ubiquit Comput 2015 Jun 16;19(3-4):667-688. [doi: 10.1007/s00779-015-0855-y]
73. Boudjema S, Dufour JC, Aladro AS, Desquerres I, Brouqui P. MediHandTrace: a tool for measuring and understanding hand hygiene adherence. Clin Microbiol Infect 2014 Jan;20(1):22-28 [FREE Full text] [doi: 10.1111/1469-0691.12471] [Medline: 24261513]
74. Boyce JM, Cooper T, Yin J, Li F, Arbogast JW. Challenges encountered and lessons learned during a trial of an electronic hand hygiene monitoring system. Am J Infect Control 2019 Dec;47(12):1443-1448. [doi: 10.1016/j.ajic.2019.05.019] [Medline: 31324492]
75. Brouqui P, Boudjema S, Soto Aladro A, Chabrière E, Florea O, Nguyen H, et al. New approaches to prevent healthcare-associated infection. Clin Infect Dis 2017 Aug 15;65(suppl_1):50-54. [doi: 10.1093/cid/cix433] [Medline: 28859352]
76. Decker AS, Cipriano GC, Tsouri G, Lavigne JE. Monitoring pharmacy student adherence to World Health Organization hand hygiene indications using radio frequency identification. Am J Pharm Educ 2016 Apr 25;80(3):51 [FREE Full text] [doi: 10.5688/ajpe80351] [Medline: 27170822]
77. Dyson J, Madeo M. Investigating the use of an electronic hand hygiene monitoring and prompt device: influence and acceptability. J Infect Prev 2017 Nov 04;18(6):278-287 [FREE Full text] [doi: 10.1177/1757177417714045] [Medline: 29344097]
78. Filho MA, Marra AR, Magnus TP, Rodrigues RD, Prado M, de Souza Santini TR, et al. Comparison of human and electronic observation for the measurement of compliance with hand hygiene. Am J Infect Control 2014 Nov;42(11):1188-1192. [doi: 10.1016/j.ajic.2014.07.031] [Medline: 25234045]
79. Fisher DA, Seetoh T, May-Lin HO, Viswanathan S, Toh Y, Yin WC, et al. Automated measures of hand hygiene compliance among healthcare workers using ultrasound: validation and a randomized controlled trial. Infect Control Hosp Epidemiol 2013 Sep 02;34(9):919-928. [doi: 10.1086/671738] [Medline: 23917905]
80. Fries J, Segre AM, Thomas G, Herman T, Ellingson K, Polgreen PM. Monitoring hand hygiene via human observers: how should we be sampling? Infect Control Hosp Epidemiol 2012 Jul 02;33(7):689-695 [FREE Full text] [doi: 10.1086/666346] [Medline: 22669230]
81. Herman T, Pemmaraju S, Segre AM, Polgreen PM, Curtis DE, Fries J, et al. Wireless applications for hospital epidemiology. In: Proceedings of the 1st ACM international workshop on Medical-grade wireless networks. 2009 Presented at: MobiHoc '09: The Tenth ACM International Symposium on Mobile Ad Hoc Networking and Computing; May 18, 2009; New Orleans Louisiana USA p. 45-50. [doi: 10.1145/1540373.1540384]
82. Hornbeck T, Naylor D, Segre AM, Thomas G, Herman T, Polgreen PM. Using sensor networks to study the effect of peripatetic healthcare workers on the spread of hospital-associated infections. J Infect Dis 2012 Nov 15;206(10):1549-1557 [FREE Full text] [doi: 10.1093/infdis/jis542] [Medline: 23045621]
83. Jain S, Mane S, Lopez J, Lie D, Dallas T, Dissanaike S, et al. A low-cost custom HF RFID system for hand washing compliance monitoring. In: Proceedings of the IEEE 8th International Conference on ASIC. 2009 Presented at: IEEE 8th International Conference on ASIC; Oct. 20-23, 2009; Changsha, China. [doi: 10.1109/asicon.2009.5351530]
84. Johnson R, Tsouri GR, Walsh E. Continuous and automated measuring of compliance of hand-hygiene procedures using finite state machines and RFID. IEEE Instrum Meas Mag 2012 Apr;15(2):8-12. [doi: 10.1109/mim.2012.6174572]
85. Karimpour N, Karaduman B, Ural A, Challengerl M, Dagdeviren O. IoT based hand hygiene compliance monitoring. In: Proceedings of the International Symposium on Networks, Computers and Communications (ISNCC). 2019 Presented at: International Symposium on Networks, Computers and Communications (ISNCC); June 18-20, 2019; Istanbul, Turkey. [doi: 10.1109/isncc.2019.8909151]
86. Levchenko AI, Boscart VM, Ibbett JP, Fernie GR. Distributed IR based technology to monitor hand hygiene of healthcare staff. In: Proceedings of the IEEE Toronto International Conference Science and Technology for Humanity (TIC-STH). 2009 Presented at: IEEE Toronto International Conference Science and Technology for Humanity (TIC-STH); Sept. 26-27, 2009; Toronto, ON, Canada. [doi: 10.1109/tic-sth.2009.5444496]
87. Levchenko AI, Boscart VM, Fernie GR. Automated monitoring: a potential solution for achieving sustainable improvement in hand hygiene practices. Comput Inform Nurs 2014 Aug;32(8):397-403. [doi: 10.1097/CIN.0000000000000067] [Medline: 24859431]

88. Levchenko AI, Boscart VM, Fernie GR. Hand hygiene monitoring and real-time prompting system. In: Proceedings of the IEEE International Systems Conference SysCon 2012. 2012 Presented at: IEEE International Systems Conference SysCon 2012; March 19-22, 2012; Vancouver, BC, Canada. [doi: 10.1109/syscon.2012.6189435]
89. Levchenko AI, Boscart VM, Fernie GR. The effect of automated monitoring and real-time prompting on nurses' hand hygiene performance. Comput Inform Nurs 2013 Oct;31(10):498-504. [doi: 10.1097/01.NCN.0000432124.53902.1d] [Medline: 23924823]
90. Levin PD, Razon R, Schwartz C, Avidan A, Sprung CL, Moses AE, et al. Obstacles to the successful introduction of an electronic hand hygiene monitoring system, a cohort observational study. Antimicrob Resist Infect Control 2019 Feb 22;8(1):43 [FREE Full text] [doi: 10.1186/s13756-019-0498-2] [Medline: 30834111]
91. Marques R, Gregório J, Pinheiro F, Póvoa P, da Silva MM, Lapão LV. How can information systems provide support to nurses' hand hygiene performance? Using gamification and indoor location to improve hand hygiene awareness and reduce hospital infections. BMC Med Inform Decis Mak 2017 Jan 31;17(1):15 [FREE Full text] [doi: 10.1186/s12911-017-0410-z] [Medline: 28143613]
92. Polgreen PM, Hlady CS, Severson MA, Segre AM, Herman T. Method for automated monitoring of hand hygiene adherence without radio-frequency identification. Infect Control Hosp Epidemiol 2010 Dec 02;31(12):1294-1297 [FREE Full text] [doi: 10.1086/657333] [Medline: 20973724]
93. Meydanci MA, Adali C, Ertas M, Dizbay M, Akan A. RFID based hand hygiene compliance monitoring station. In: IEEE International Conference on Control System, Computing and Engineering. 2013 Presented at: IEEE International Conference on Control System, Computing and Engineering; Nov. 29 - Dec. 1, 2013; Penang, Malaysia. [doi: 10.1109/iccsce.2013.6720030]
94. Misra P, Rajaraman V, Aishwarya SN, Dwivedi B, Warrior J. CleanHands: an integrated monitoring system for control of hospital acquired infections. In: Proceedings of the 14th International Conference on Information Processing in Sensor Networks. 2015 Presented at: IPSN '15: The 14th International Conference on Information Processing in Sensor Networks; April 13 - 16, 2015; Seattle Washington p. 348-349. [doi: 10.1145/2737095.2742928]
95. Monsalve M, Pemmaraju S, Polgreen PM. Interactions in an intensive care unit: experiences pre-processing sensor network data. In: Proceedings of the 4th Conference on Wireless Health. 2013 Presented at: WH '13: Wireless Health 2013; November 1 - 3, 2013; Baltimore Maryland p. 1-8. [doi: 10.1145/2534088.2534105]
96. Monsalve MN, Pemmaraju SV, Thomas GW, Herman T, Segre AM, Polgreen PM. Do peer effects improve hand hygiene adherence among healthcare workers? Infect Control Hosp Epidemiol 2014 Oct 10;35(10):1277-1285 [FREE Full text] [doi: 10.1086/678068] [Medline: 25203182]
97. Pleteršek A, Sok M, Trontelj J. Monitoring, control and diagnostics using RFID infrastructure. J Med Syst 2012 Dec 22;36(6):3733-3739. [doi: 10.1007/s10916-012-9846-y] [Medline: 22438102]
98. Pong S, Holliday P, Fernie G. Effect of intermittent deployment of an electronic monitoring system on hand hygiene behaviors in healthcare workers. Am J Infect Control 2019 Apr;47(4):376-380 [FREE Full text] [doi: 10.1016/j.ajic.2018.08.029] [Medline: 30502113]
99. Radhakrishna K, Waghmare A, Ekstrand M, Raj T, Selvam S, Sreerama SM, et al. Real-time feedback for improving compliance to hand sanitization among healthcare workers in an open layout ICU using radiofrequency identification. J Med Syst 2015 Jun 10;39(6):68 [FREE Full text] [doi: 10.1007/s10916-015-0251-1] [Medline: 25957165]
100. Srigley JA, Furness CD, Baker GR, Gardam M. Quantification of the Hawthorne effect in hand hygiene compliance monitoring using an electronic monitoring system: a retrospective cohort study. BMJ Qual Saf 2014 Dec 07;23(12):974-980 [FREE Full text] [doi: 10.1136/bmjqs-2014-003080] [Medline: 25002555]
101. Wan Y, Stombaugh TS, Wang N. Human-subject tracking and localization for a hand hygiene monitoring system. In: Proceedings of the Ubiquitous Positioning Indoor Navigation and Location Based Service (UPINLBS). 2014 Presented at: Ubiquitous Positioning Indoor Navigation and Location Based Service (UPINLBS); Nov. 20-21, 2014; Corpus Christi, TX, USA. [doi: 10.1109/upinlbs.2014.7033719]
102. Camilus S, Lee YM. Automated hand hygiene compliance monitoring. In: Proceedings of the 2020 2nd International Conference on Image, Video and Signal Processing. 2020 Presented at: IVSP '20: 2020 2nd International Conference on Image, Video and Signal Processing; March 20 - 22, 2020; Singapore p. 64-69. [doi: 10.1145/3388818.3388824]
103. Lacey G, Zhou J, Li X, Craven C, Gush C. The impact of automatic video auditing with real-time feedback on the quality and quantity of handwash events in a hospital setting. Am J Infect Control 2020 Feb;48(2):162-166 [FREE Full text] [doi: 10.1016/j.ajic.2019.06.015] [Medline: 31358419]
104. Zhong H, Kanhere SS, Chou CT. WashInDepth: Lightweight hand wash monitor using depth sensor. In: Proceedings of the 13th International Conference on Mobile and Ubiquitous Systems: Computing, Networking and Services. 2016 Presented at: MOBIQUITOUS 2016: Computing, Networking and Services; November 28 - December 1, 2016; Hiroshima Japan p. 28-37. [doi: 10.1145/2994374.2994386]
105. Khamis A, Kusy B, Chou CT, McLaws M, Hu W. Poster abstract: a weakly supervised tracking of hand hygiene technique. In: Proceedings of the 19th ACM/IEEE International Conference on Information Processing in Sensor Networks (IPSN). 2020 Presented at: 19th ACM/IEEE International Conference on Information Processing in Sensor Networks (IPSN); April 21-24, 2020; Sydney, NSW, Australia. [doi: 10.1109/ipsn48710.2020.00-21]

106. Khan A, Nausheen S. Compliance of surgical hand washing before surgery: role of remote video surveillance. J Pak Med Assoc 2017 Jan;67(1):92-96 [FREE Full text] [Medline: 28065962]
107. Banerjee A, Amperyani VN, Gupta SK. Hand hygiene compliance checking system with explainable feedback. In: Proceedings of the 6th ACM Workshop on Wearable Systems and Applications. 2020 Presented at: MobiSys '20: The 18th Annual International Conference on Mobile Systems, Applications, and Services; June 19, 2020; Toronto Ontario Canada p. 34-36. [doi: 10.1145/3396870.3400015]
108. Kutafina E, Laukamp D, Jonas SM. Wearable sensors in medical education: supporting hand hygiene training with a forearm EMG. Stud Health Technol Inform 2015;211:286-291. [Medline: 25980884]
109. Kutafina E, Laukamp D, Bettermann R, Schroeder U, Jonas SM. Wearable sensors for elearning of manual tasks: using forearm EMG in hand hygiene training. Sensors (Basel) 2016 Aug 03;16(8):1221 [FREE Full text] [doi: 10.3390/s16081221] [Medline: 27527167]
110. Wang C, Sarsenbayeva Z, Chen X, Dingler T, Goncalves J, Kostakos V. Accurate measurement of handwash quality using sensor armbands: instrument validation study. JMIR Mhealth Uhealth 2020 Mar 26;8(3):e17001 [FREE Full text] [doi: 10.2196/17001] [Medline: 32213469]
111. Pellegrino R, Crandall PG, Seo HS. Using olfaction and unpleasant reminders to reduce the intention-behavior gap in hand washing. Sci Rep 2016 Jan 06;6(1):18890 [FREE Full text] [doi: 10.1038/srep18890] [Medline: 26732033]
112. Srisomboon K, Malathum K, Skuntaniyom S, Duangthongkham J, Phanthuna N. Hand hygiene auditing algorithm using image processing for hand hygiene evaluation machine. In: Proceedings of the 16th International Conference on Electrical Engineering/Electronics, Computer, Telecommunications and Information Technology (ECTI-CON). 2019 Presented at: 16th International Conference on Electrical Engineering/Electronics, Computer, Telecommunications and Information Technology (ECTI-CON); July 10-13, 2019; Pattaya, Thailand. [doi: 10.1109/ecti-con47248.2019.8955358]
113. Szilágyi L, Lehotsky A, Nagy M, Haidegger T, Benyó B, Benyó Z. Stery-hand: a new device to support hand disinfection. In: Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology. 2010 Presented at: Annual International Conference of the IEEE Engineering in Medicine and Biology; Aug. 31 - Sept. 4, 2010; Buenos Aires, Argentina. [doi: 10.1109/iembs.2010.5626377]
114. Yamamoto K, Miyanaga K, Miyahara H, Yoshii M, Kinoshita F, Touyama H. Toward the evaluation of handwashing skills based on image processing. In: Proceedings of the Joint 10th International Conference on Soft Computing and Intelligent Systems (SCIS) and 19th International Symposium on Advanced Intelligent Systems (ISIS). 2018 Presented at: Joint 10th International Conference on Soft Computing and Intelligent Systems (SCIS) and 19th International Symposium on Advanced Intelligent Systems (ISIS); Dec. 5-8, 2018; Toyama, Japan. [doi: 10.1109/scis-isis.2018.00141]
115. Yamamoto K, Yoshii M, Kinoshita F, Touyama H. Classification vs regression by CNN for handwashing skills evaluations in nursing education. In: International Conference on Artificial Intelligence in Information and Communication (ICAIIC). 2020 Presented at: International Conference on Artificial Intelligence in Information and Communication (ICAIIC); Feb. 19-21, 2020; Fukuoka, Japan. [doi: 10.1109/icaiic48513.2020.9064974]
116. Naim F, Jaafar R, Arshad NW, Hamid R, Razali M. Unclean hand detection machine using vision sensor. In: Proceedings of the Saudi International Electronics, Communications and Photonics Conference. 2013 Presented at: Saudi International Electronics, Communications and Photonics Conference; April 27-30, 2013; Riyadh, Saudi Arabia. [doi: 10.1109/siecpc.2013.6550750]
117. Hlady CS, Severson MA, Segre AM, Polgreen PM. A mobile handheld computing application for recording hand hygiene observations. Infect Control Hosp Epidemiol 2010 Sep 02;31(9):975-977 [FREE Full text] [doi: 10.1086/655834] [Medline: 20636134]
118. Kinney P. ZigBee Technology: wireless control that simply works. Commun Des Conf. 2003. URL: https://www.itk.ntnu.no/fag/TTK4545/TTK2/PDF/ZigBee%20Technology%20-%20Wireless%20control%20that%20simply%20works.pdf [accessed 2021-10-22]
119. Goroncy-Bermes P, Koburger T, Meyer B. Impact of the amount of hand rub applied in hygienic hand disinfection on the reduction of microbial counts on hands. J Hosp Infect 2010 Mar;74(3):212-218. [doi: 10.1016/j.jhin.2009.09.018] [Medline: 20061058]
120. Lehotsky A, Szilágyi L, Bánsághi S, Szerémy P, Wéber G, Haidegger T. Towards objective hand hygiene technique assessment: validation of the ultraviolet-dye-based hand-rubbing quality assessment procedure. J Hosp Infect 2017 Sep;97(1):26-29. [doi: 10.1016/j.jhin.2017.05.022] [Medline: 28579470]
121. Conway LJ. Challenges in implementing electronic hand hygiene monitoring systems. Am J Infect Control 2016 May 02;44(5 Suppl):7-12. [doi: 10.1016/j.ajic.2015.11.031] [Medline: 27131139]
122. Ellingson K, Polgreen PM, Schneider A, Shinkunas L, Kaldjian LC, Wright D, et al. Healthcare personnel perceptions of hand hygiene monitoring technology. Infect Control Hosp Epidemiol 2011 Nov 02;32(11):1091-1096. [doi: 10.1086/662179] [Medline: 22011536]
123. Gu Y, Lo A, Niemegeers I. A survey of indoor positioning systems for wireless personal networks. IEEE Commun Surv Tutorials 2009;11(1):13-32. [doi: 10.1109/surv.2009.090103]

124. Fung ML, Chen MZ, Chen YH. Sensor fusion: A review of methods and applications. In: Proceedings of the 29th Chinese Control And Decision Conference (CCDC). 2017 Presented at: 29th Chinese Control And Decision Conference (CCDC); May 28-30, 2017; Chongqing, China. [doi: 10.1109/ccdc.2017.7979175]
125. Wang C, Sarsenbayeva Z, Luo C, Goncalves J, Kostakos V. Improving wearable sensor data quality using context markers. In: Proceedings of the 2019 ACM International Joint Conference on Pervasive and Ubiquitous Computing and Proceedings of the 2019 ACM International Symposium on Wearable Computers. 2019 Presented at: UbiComp '19: The 2019 ACM International Joint Conference on Pervasive and Ubiquitous Computing; September 9 - 13, 2019; London United Kingdom p. 598-601. [doi: 10.1145/3341162.3349334]
126. Bannach D, Amft O, Lukowicz P. Automatic event-based synchronization of multimodal data streams from wearable and ambient sensors. In: Barnaghi P, Moessner K, Presser M, Meissner S, editors. Smart Sensing and Context. Berlin, Heidelberg: Springer; 2009:135-148.
127. Palmore T, Henderson DK. Big brother is washing...Video surveillance for hand hygiene adherence, through the lenses of efficacy and privacy. Clin Infect Dis 2012 Jan 01;54(1):8-9 [FREE Full text] [doi: 10.1093/cid/cir781] [Medline: 22109949]
128. Cilliers L. Wearable devices in healthcare: privacy and information security issues. Health Inf Manag 2020 May 30;49(2-3):150-156. [doi: 10.1177/1833358319851684] [Medline: 31146589]
129. American Conference of Governmental Industrial Hygienists. TLVs and BEIs : Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, OH: ACGIH Worldwide; 2016.
130. Zarb P, Coignard B, Griskeviciene J, Muller A, Vankerckhoven V, Weist K, National Contact Points for the ECDC pilot point prevalence survey, Hospital Contact Points for the ECDC pilot point prevalence survey. The European Centre for Disease Prevention and Control (ECDC) pilot point prevalence survey of healthcare-associated infections and antimicrobial use. Euro Surveill 2012 Nov 15;17(46):20316 [FREE Full text] [doi: 10.2807/ese.17.46.20316-en] [Medline: 23171822]
131. Trick WE, Vernon MO, Hayes RA, Nathan C, Rice TW, Peterson BJ, et al. Impact of ring wearing on hand contamination and comparison of hand hygiene agents in a hospital. Clin Infect Dis 2003 Jun 01;36(11):1383-1390. [doi: 10.1086/374852] [Medline: 12766832]
132. Bassen HI. Radiofrequency interference with medical devices. A technical information statement. IEEE Eng Med Biol Mag 1998;17(3):111-114. [Medline: 9604711]
133. Badizadegan ND, Greenberg S, Lawrence H, Badizadegan K. Radiofrequency interference in the clinical laboratory. Am J Clin Pathol 2019 Apr 02;151(5):522-528 [FREE Full text] [doi: 10.1093/ajcp/aqy174] [Medline: 30668626]
134. van der Togt R, van Lieshout EJ, Hensbroek R, Beinat E, Binnekade JM, Bakker PJ. Electromagnetic interference from radio frequency identification inducing potentially hazardous incidents in critical care medical equipment. J Am Med Assoc 2008 Jun 25;299(24):2884-2890. [doi: 10.1001/jama.299.24.2884] [Medline: 18577733]
135. Li X, Zhang D, Lv Q, Xiong J, Li S, Zhang Y, et al. IndoTrack: Device-free indoor human tracking with commodity Wi-Fi. Proc ACM Interact Mob Wearable Ubiquitous Technol 2017 Sep 11;1(3):1-22. [doi: 10.1145/3130940]
136. Matteson DS, James NA. A nonparametric approach for multiple change point analysis of multivariate data. J Am Stat Assoc 2014 Mar 19;109(505):334-345. [doi: 10.1080/01621459.2013.849605]
137. Fasching J, Walczak N, Bernstein GA, Hadjiyanni T, Cullen K, Morellas V, et al. Automated coding of activity videos from an OCD study. In: Proceedings of the IEEE International Conference on Robotics and Automation (ICRA). 2016 Presented at: IEEE International Conference on Robotics and Automation (ICRA); May 16-21, 2016; Stockholm, Sweden. [doi: 10.1109/icra.2016.7487783]
138. Ashraf A, Taati B. Automated video analysis of handwashing behavior as a potential marker of cognitive health in older adults. IEEE J Biomed Health Inform 2016 Mar;20(2):682-690. [doi: 10.1109/jbhi.2015.2413358]
139. Barnes S, Golden B, Wasil E, Furuno J, Harris A. An application of factorial design to compare the relative effectiveness of hospital infection control measures. In: Proceedings of the 2011 Winter Simulation Conference (WSC). 2011 Presented at: Winter Simulation Conference (WSC); Dec. 11-14, 2011; Phoenix, AZ, USA. [doi: 10.1109/wsc.2011.6147849]

Abbreviations

BLE: Bluetooth low energy
HAI: health care–associated infections
HCW: health care worker
IMU: inertial measurement unit
LED: light-emitting diode
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RFI: radio-frequency interference
RFID: radio-frequency identification
RGB: red green blue
RTLS: real-time locating system
sEMG: surface electromyography
WHO: World Health Organization

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Original Paper

Noncontact Sleep Monitoring With Infrared Video Data to Estimate Sleep Apnea Severity and Distinguish Between Positional and Nonpositional Sleep Apnea: Model Development and Experimental Validation

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Abstract

Background: Sleep apnea is a respiratory disorder characterized by frequent breathing cessation during sleep. Sleep apnea severity is determined by the apnea-hypopnea index (AHI), which is the hourly rate of respiratory events. In positional sleep apnea, the AHI is higher in the supine sleeping position than it is in other sleeping positions. Positional therapy is a behavioral strategy (eg, wearing an item to encourage sleeping toward the lateral position) to treat positional apnea. The gold standard of diagnosing sleep apnea and whether or not it is positional is polysomnography; however, this test is inconvenient, expensive, and has a long waiting list.

Objective: The objective of this study was to develop and evaluate a noncontact method to estimate sleep apnea severity and to distinguish positional versus nonpositional sleep apnea.

Methods: A noncontact deep-learning algorithm was developed to analyze infrared video of sleep for estimating AHI and to distinguish patients with positional vs nonpositional sleep apnea. Specifically, a 3D convolutional neural network (CNN) architecture was used to process movements extracted by optical flow to detect respiratory events. Positional sleep apnea patients were subsequently identified by combining the AHI information provided by the 3D-CNN model with the sleeping position (supine vs lateral) detected via a previously developed CNN model.

Results: The algorithm was validated on data of 41 participants, including 26 men and 15 women with a mean age of 53 (SD 13) years, BMI of 30 (SD 7), AHI of 27 (SD 31) events/hour, and sleep duration of 5 (SD 1) hours; 20 participants had positional sleep apnea, 15 participants had nonpositional sleep apnea, and the positional status could not be discriminated for the remaining 6 participants. AHI values estimated by the 3D-CNN model correlated strongly and significantly with the gold standard (Spearman correlation coefficient 0.79, $P<.001$). Individuals with positional sleep apnea (based on an AHI threshold of 15) were identified with 83% accuracy and an F1-score of 86%.

Conclusions: This study demonstrates the possibility of using a camera-based method for developing an accessible and easy-to-use device for screening sleep apnea at home, which can be provided in the form of a tablet or smartphone app.

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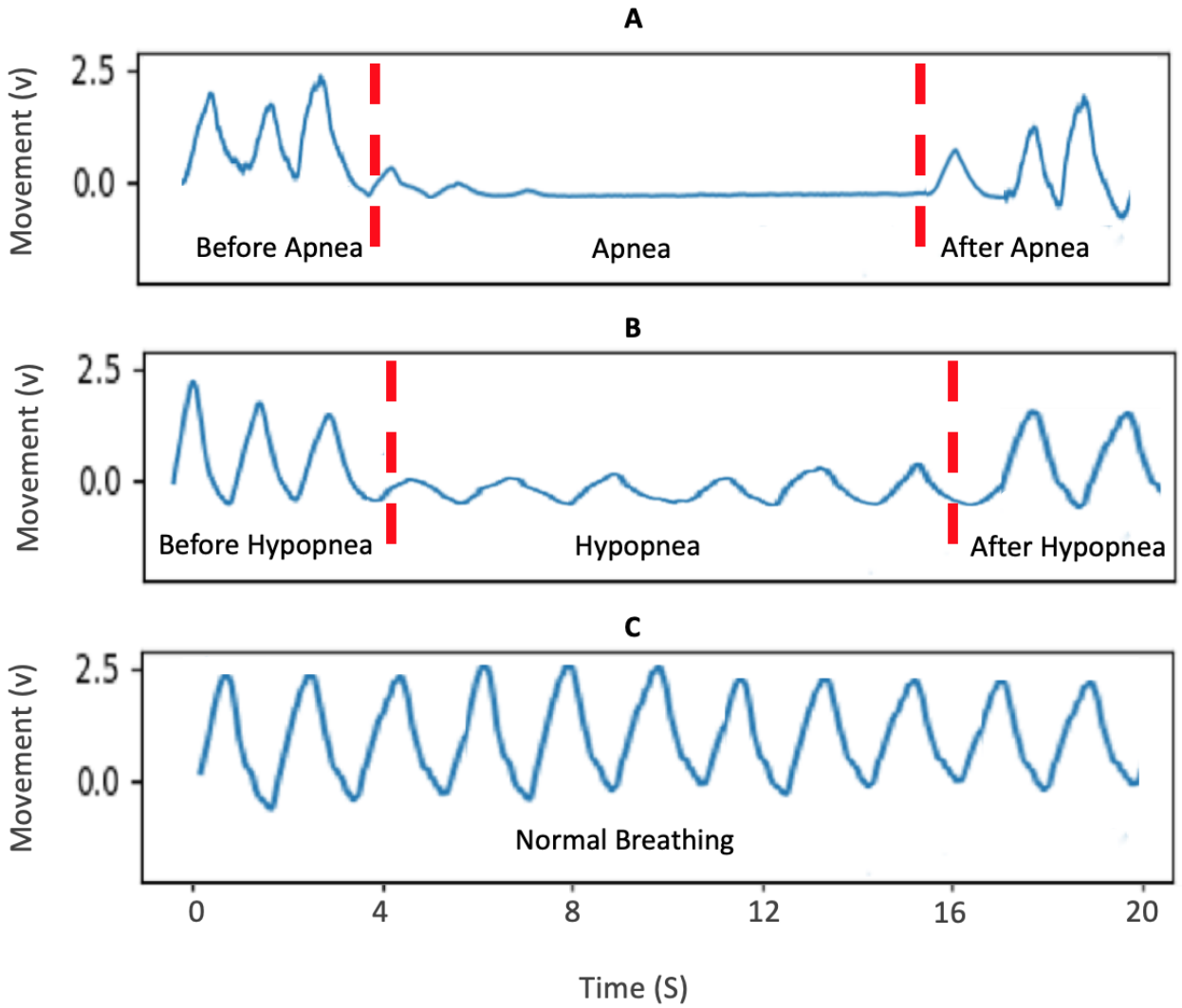
KEYWORDS

sleep apnea; deep learning; noncontact monitoring; computer vision; positional sleep apnea; 3D convolutional neural network; 3D-CNN

Introduction

Sleep apnea is a chronic respiratory disorder occurring due to frequent respiratory airflow reduction during sleep. Cessation of airflow lasting for more than 10 seconds is called apnea, whereas partial reduction in airflow by more than 30% for at least 10 seconds—in association with more than a 3% drop in blood oxygen saturation level or arousals—is called hypopnea. Sample images indicating the chest movements during normal breathing, hypopnea, and apnea are shown in Figure 1. The apnea-hypopnea index (AHI) is an indicator of the severity of sleep apnea, which measures the hourly occurrence rate of apneas and hypopneas [1]. Untreated sleep apnea raises the risk of hypertension, heart diseases, and stroke [2].

Figure 1. Sample sum of chest and abdomen movements in (A) apnea, (B) hypopnea, and (C) normal breathing.



Positional sleep apnea refers to sleep apnea patients for whom the AHI in the supine sleeping position is at least 50% higher than that in the nonsupine sleeping positions [3]. Recent studies have shown that changing to a lateral sleeping position can decrease the AHI for patients with positional sleep apnea [4]. This behavioral intervention is known as “positional therapy,” and is an effective noninvasive and nonpharmaceutical treatment for those with positional sleep apnea [5].

The current clinical approach to diagnose sleep apnea and to determine whether or not it is positional is based on polysomnography (PSG). However, PSG requires connecting more than 20 sensors to a user, which is inconvenient. A trained sleep technician manually analyzes recorded PSG signals and annotates the sleep position overnight. Moreover, PSG is expensive (>US $400) and has a long waiting time in some areas (4-36 months in Canada [6]). As a result, up to 85% of the population at risk of sleep apnea remain undiagnosed [7]. It is therefore useful to investigate screening technologies that could identify individuals at high risk via a simpler test. Increasing access to testing, diagnosis, and subsequent treatment could improve the patient’s quality of life by decreasing

hypertension and sleepiness, and can also reduce overall health care costs [8-10].

Researchers have developed several easy-to-use, convenient, and accessible methods for sleep apnea monitoring. Merchant et al [11] developed a skin-adhesive patch recording nasal pressure, blood oxygen saturation, pulse rate, respiratory effort, sleep time, and body position to estimate the AHI. Ayas et al [12] evaluated the performance of a wrist-worn device utilizing a peripheral arterial tonometer, actigraphy, and arterial oxygen saturation to diagnose sleep apnea. Varon et al [13] introduced a method for the automatic detection of sleep apnea from single-lead electrocardiogram by training a least-squares support vector machines classifier on the features extracted from the electrocardiogram signal. Several studies estimated AHI and respiratory events from analyzing tracheal sound or tracheal movements, or the combination of tracheal sound with oxygen saturation [14-18]. Lévy et al [19] utilized pulse oximetry to quantify arterial oxygen saturation and to diagnose sleep apnea.

Although these methods are more convenient than PSG, sensors attached to the body could potentially disrupt the user's regular sleep pattern. Therefore, researchers have continued to develop noncontact methods to screen individuals at risk of sleep apnea. For example, we previously developed a deep-learning model to distinguish between different types of apnea. However, as the model was not capable of detecting events, we used ground truth labels for this purpose [20]. Jakkaew et al [21] used a thermal camera to estimate breathing rate and body movements; however, they did not analyze the breathing pattern to identify sleep apnea, and the method was not designed to detect sleep position. Deng et al [22] used six active infrared cameras and a Kinect sensor to detect body position and breathing pattern (abnormal vs normal breathing). However, they did not evaluate their method in a clinical environment to demonstrate the performance for the detection of sleep apnea or positional sleep apnea. In addition, using six cameras and the Kinect will be difficult to set up in clinical or home settings, which hinders large-scale adoption. Davidovich et al [23] developed a new framework to extract the breathing pattern from a piezo-electric sensor placed under the patient's mattress through extracting time and frequency domain features and then calculating the AHI. Nandakumar et al [24] used a smartphone to emit inaudible waves and to analyze the waves' echoes from the user's body to detect respiratory events. However, these noncontact methods did not present cross-validation performance, and due to restriction in their modalities, they are not able to identify positional sleep apnea patients, which is crucial for proper treatment.

To identify patients at risk of sleep apnea and to distinguish those with positional sleep apnea, an alternative is to use computer vision and machine-learning techniques. We here propose a noncontact algorithm that analyzes infrared videos captured from a participant during sleep to estimate the AHI and to distinguish patients with positional vs nonpositional sleep apnea. Specifically, we used a 3D convolutional neural network (CNN) to analyze movements in infrared videos, to detect apneas, and to estimate the AHI. In experimental evaluation, this model outperformed a baseline model that previously reported state-of-the-art results in noncontact AHI estimation [25]. We also combined this technique with another CNN-based approach that detects the sleeping position [26] to calculate the AHI in different sleeping positions and to identify patients with positional sleep apnea. The methods and results developed in this study represent the first noncontact approach to automatically distinguish positional from nonpositional sleep apnea.

Methods

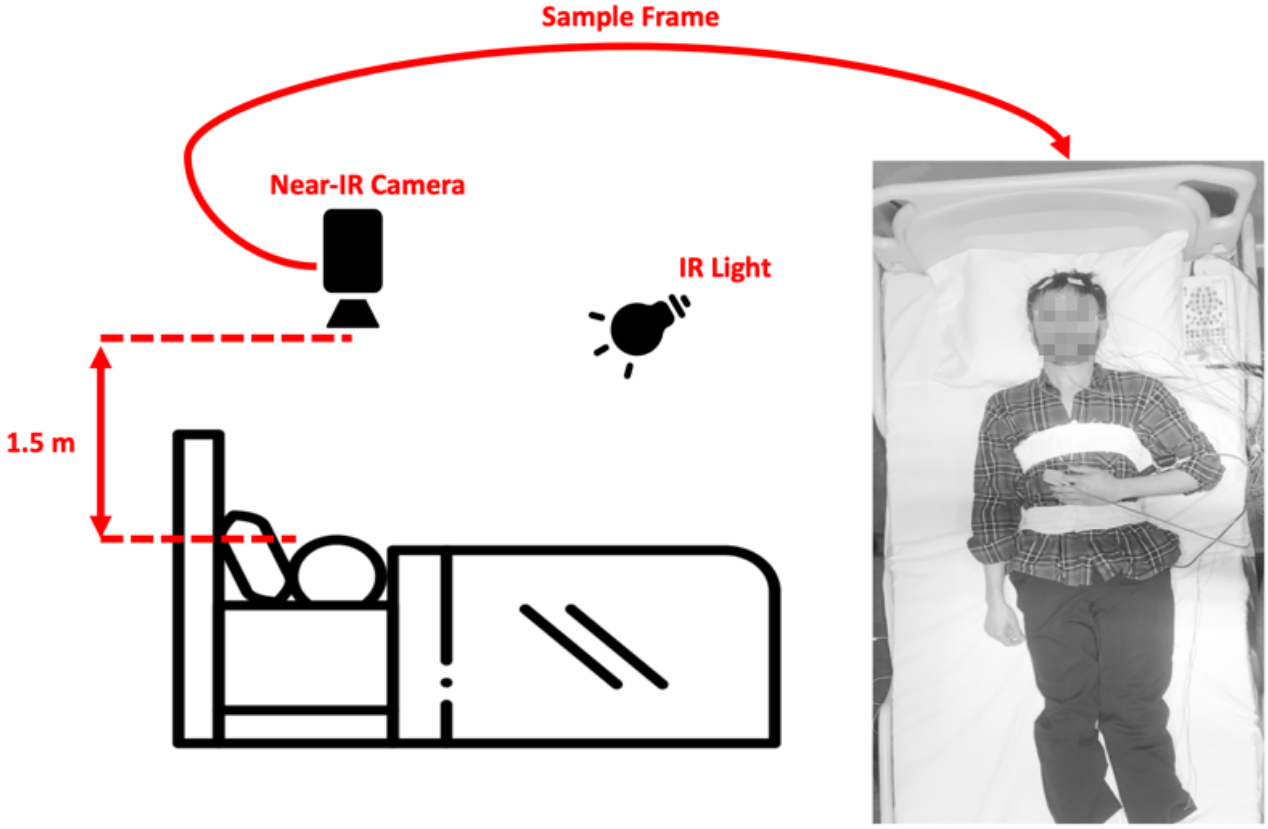
Data Collection

The University Health Network Research Ethics Board approved this study (approval number 13-7210-DE). Participants aged 18 to 85 years and without a history of cardiovascular or renal diseases were recruited for this study. Participants were recruited among patients referred for sleep diagnosis at the sleep laboratory of the Toronto Rehabilitation Institute, University Health Network. All participants signed a written consent form before taking part in the study. There were no limitations on blanket usage, movement, or clothing worn during sleep.

Simultaneously with overnight PSG (Embla s4500) that was used for a clinical diagnosis of sleep, infrared videos of participants were recorded at a resolution of 640×480 with 30 frames per second. The participants' video data were collected and synchronized with PSG signals all night for 5 (±1) hours while sleeping in a single session.

The infrared camera (Point Grey Firefly MV, 0.3 MP, FMVU-03MTM) was mounted approximately 1.5 meters above the bed. For illumination, a separate infrared light source (Raytec RM25-F-50) was mounted on the ceiling. A schematic of the camera setup and sample frame is shown in Figure 2.

Figure 2. Data collection setup and a sample anonymized image frame on the right. IR: infrared.

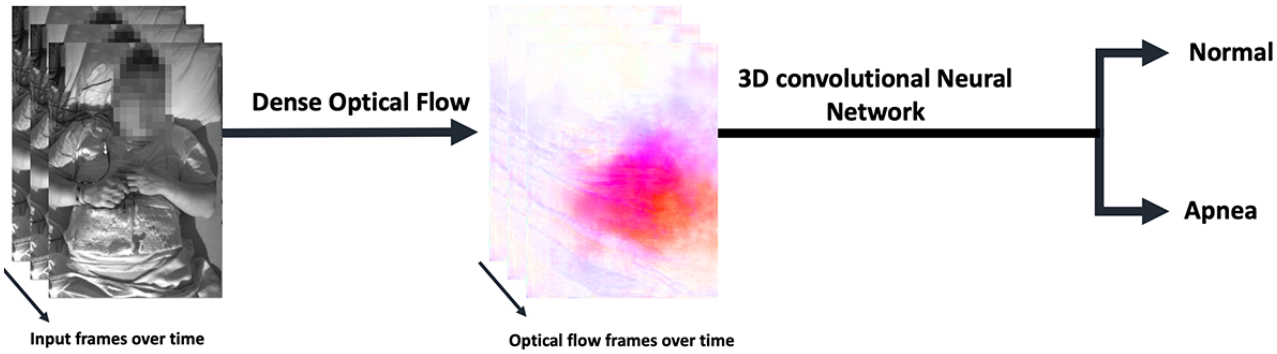


Respiratory events (apneas and hypopneas) and sleep positions (supine, lateral) of the participant throughout the night were annotated by a trained sleep technician who was blinded to the study. Since the video data were synchronized with PSG data, once the technician annotated the PSG data, all video frames were automatically labeled.

AHI Estimation

The video frames were first downsampled from 30 Hz to 2 Hz to reduce the computational cost. As breathing frequency is approximately 0.5 Hz during sleep, the reduced frequency of 2 Hz exceeds the Nyquist rate by a factor of 2. To track respiratory movements in the infrared video frames, a CNN dense optical flow (Flownet 2.0 [27]) was used, which provides accurate optical flow at a fast frame rate. Optical flow extracts movement in the *x* (side to side) and *y* (up and down) directions for each pixel in one video frame to the next. The minimum duration of an apnea is 10 seconds. This translates to 20 (or 19 in the worst case) video frames within the duration of an event. To estimate respiratory events, a 3D-CNN was trained on a sliding window of 18 optical flow images (ie, resulting from 19 consecutive video frames). Infrared videos were captured at a resolution of 640×480 pixels, resulting in optical images with a size of 640×480×2. The architecture of the 3D-CNN that was trained on the input tensors with a size of 640×480×2×18 is shown in Multimedia Appendix 1. Sample input and dense optical flow images are shown in Figure 3.

Figure 3. Sample input and dense optical flow images.



The 3D-CNN was trained with class-weighted cross-entropy loss (5 for events and 1 for normal) and the Adam optimizer. An initial value of 0.001 for the learning rate and a batch size of 25 for 25,000 epochs were chosen. The total number of parameters in this network was 8,284,265, including 8,281,829 trainable parameters and 2436 nontrainable parameters. Depending on the sleep apnea severity, respiratory events are less frequent in comparison to normal breathing; thus, the data

sets were highly imbalanced. In training time, to balance the data set, stride lengths of 0.5 and 15 seconds were used for apneas and normal breathing, respectively. In test time, a stride length of 0.5 seconds was used to predict the binary label of normal breathing versus apneas. The threshold of the trained binary classification (event vs normal) was set to 0.1 to maximize the area under the curve on the training data.

To estimate the AHI, a linear regression model was trained on the following three features: (1) the number of detected events, (2) the total duration of detected events longer than 9 seconds divided by sleep duration, and (3) sleep duration.

The performance of the 3D-CNN was compared against another approach developed by our group, which previously demonstrated state-of-the-art performance in noncontact vision-based estimation of the AHI [25]. A brief overview of this baseline approach is presented here. To extract respiratory-related motion, movements of 768 uniformly scattered points in the video frames were extracted using a sparse optical flow. Principal component analysis (PCA) was applied on the extracted point trajectories over 30-second sliding windows with a stride of 1 second to compute the predominant movements, which were associated with breathing during sleep [28]. This approach was previously validated by Zhu et al [29] and was shown to accurately track breathing rate in overnight infrared videos. To identify respiratory events from the respiratory-related motion, three features were extracted, including the respiratory rate, average power of respiratory movement, and total displacement of tracked points. Compared to normal breathing, the respiratory rate drops during respiratory events. To extract the respiratory rate, the energy of extracted respiratory movements was calculated using fast Fourier transform with a window of 10 seconds. The frequency associated with the highest energy was then considered as the respiratory rate. The second feature was the average power of respiratory movement, which decreases during a respiratory event. This feature was computed as the mean of absolute squares of respiratory displacement within a 10-second window. The last feature was total displacement, which indicates nonrespiratory movement (eg, arousals), and was determined by the summation of all of the raw optical flow movements (before applying PCA). Using these 3 features, a random forest binary classifier with 50 trees was trained to estimate sleep apnea events (apneas and hypopneas). Finally, to estimate the AHI, a linear regression model was trained using 2 features: (1) the number of predicted sleep apnea events normalized by the estimated events' duration and (2) the estimated events' duration normalized by the total sleep duration obtained from the total recording time.

Detecting Positional vs Nonpositional Sleep Apnea

For sleep position detection, a previously developed algorithm [26] was used. This method estimates body position (supine vs lateral) from a video frame using a CNN. Sample supine and lateral images are shown in Figure 4. This position detector was applied to the first video frame of each video. After each large movement (detected by thresholding the total displacement of tracked featured points extracted by optical flow over 1 second), the detector was used again to estimate the new sleeping position. As a result, a body position (supine vs lateral) was assigned to each video frame during the entire sleeping period. Once respiratory events and their associated sleep positions were detected, 6 features were calculated per person: (1) number of detected events in supine position, (2) number of detected events in lateral position, (3) total recording time in supine position, (4) total recording time in lateral position, (5) supine AHI, and (6) lateral AHI. These features were then used to train a binary random forest classifier with three trees to distinguish between positional and nonpositional sleep apnea patients.

Figure 4. Sample supine (left) and lateral (right) frames.

Validation

Leave-one-person-out cross-validation was used to evaluate the performance of AHI estimation as well as the performance of positional vs nonpositional sleep apnea detection algorithms. Bland-Altman plots and Spearman correlation coefficients were used to evaluate the performance of AHI estimation. Since an AHI of 15 is commonly used as a threshold for screening sleep apnea [30], the algorithm performance on classifying subjects as having sleep apnea was evaluated based on the threshold of AHI=15. Confusion matrices, accuracy, precision, recall, and F1-score measures were used to assess classification performance. The same measures were used to assess the performance of positional vs nonpositional sleep apnea classification.

Results

Demographic information of the 41 individuals (26 men and 15 women) recruited for this study is shown in Table 1. There were 20 participants with positional sleep apnea, 15 participants with nonpositional sleep apnea, and 6 participants that only slept in one position and as such the apnea could not be identified as either positional or nonpositional.

Table 1. Participants' demographic features for apnea-hypopnea index (AHI) estimation (N=41).[a]

Characteristics	Value, mean (SD)
Age (years)	53 (13)
BMI (kg/m^2)	30 (7)
Sleep duration (hours)	5 (1)
Number of changes in body position	9 (6)
Sleep efficiency (%)	75 (18)
REM[b] sleep percentage (%)	15 (7)
Mean wake heart rate (bpm[c])	68 (16)
Mean REM heart rate (bpm)	67 (16)
Minimum SaO_2[d]	82 (9)
Mean SaO_2	94 (3)
AHI (events/hour)	27 (31)
Supine AHI (events/hour)	41 (39)
Lateral AHI (events/hour)	21 (34)

[a]Participants' information was obtained from the sleep reports of the overnight sleep study annotated by sleep technicians.

[b]REM: rapid eye movement.

[c]bpm: beats per minute.

[d]SaO_2: arterial oxygen saturation.

The threshold used in this study for detecting position changes and ignoring the small movements (eg, breathing or pulse) was empirically set to 20,000 pixels. The total displacement was calculated by summing the displacement of all optical flow feature points [28] over 1 second and was checked against this threshold.

To evaluate the performance of AHI detection, Figure 5 and Figure 6 show the scatterplots and Bland-Altman plots between the estimated AHI and PSG-based AHI for both the 3D-CNN model and the baseline model (Zhu et al [25]).

Figure 5. Scatterplots of polysomnography (PSG) apnea-hypopnea index (AHI) vs estimated AHI values. The blue and red lines indicate fitted and unity lines, respectively. CNN: convolutional neural network.

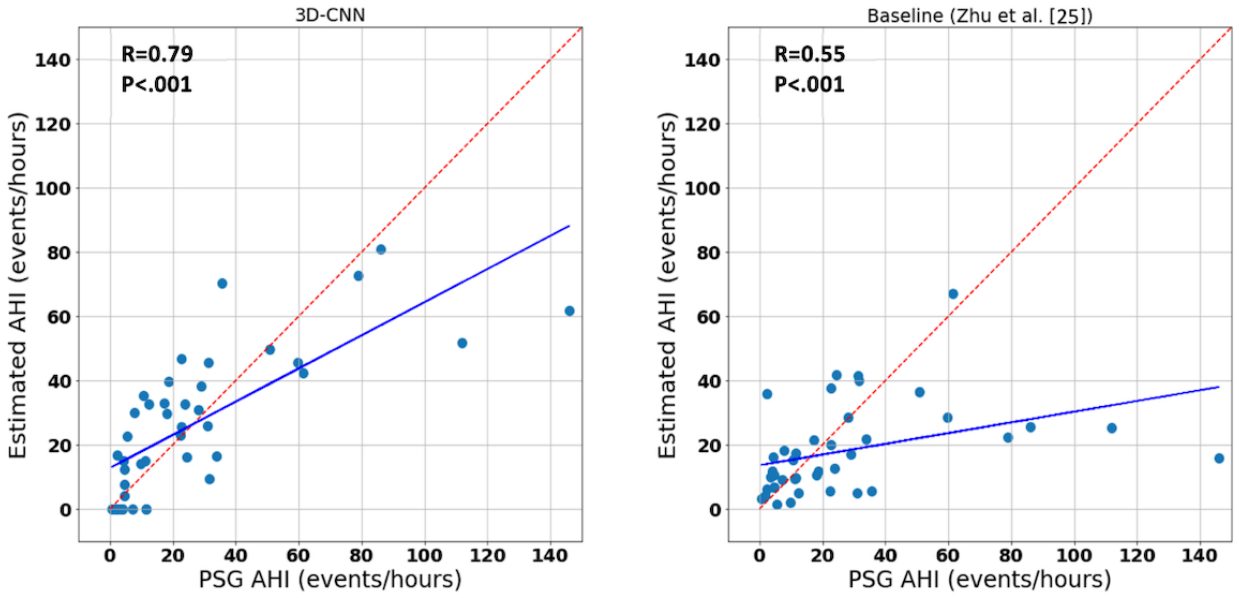
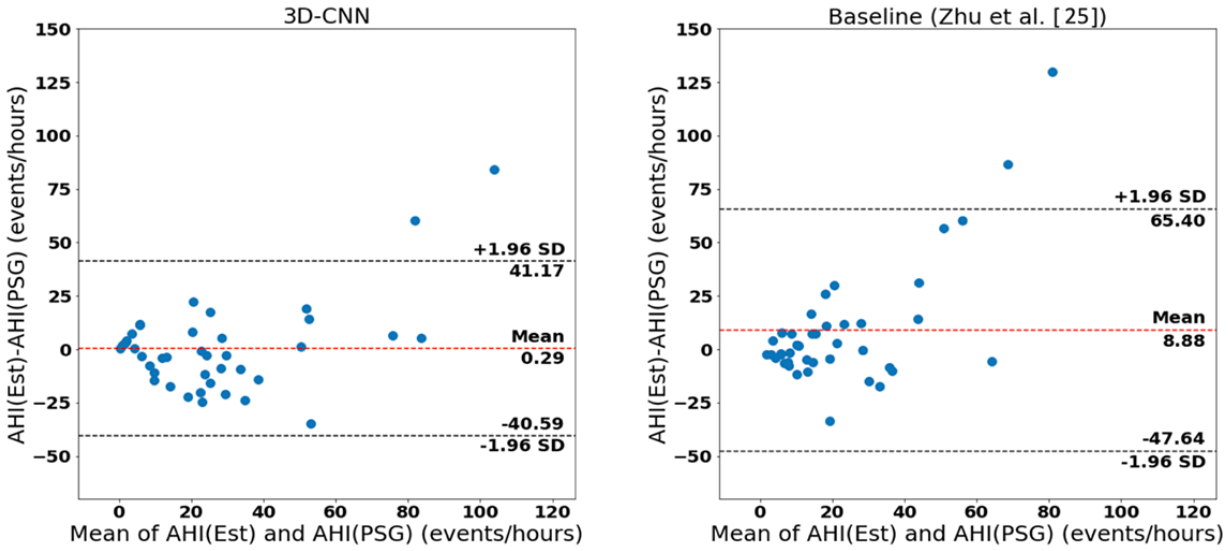


Figure 6. Bland-Altman plots of apnea-hypopnea index (AHI) estimation algorithms. PSG: polysomnography; Est: estimated; CNN: convolutional neural network.



The Spearman correlation coefficients (ρ) for AHI estimation were 0.55 and 0.79 for the baseline and 3D-CNN approach, respectively (P<.001 in both cases). In addition, the Bland-Altman plot indicated that our method outperformed the baseline according to the smaller mean (0.3 vs 8.9) and tighter 95% limits of agreement (ie, a smaller value for 1.96 of the standard deviation: 40.9 vs 56.5). Confusion matrices and the performance measures for identifying sleep apnea patients based on the AHI=15 threshold are shown in Figure 7 and in Table 2, respectively. The 3D-CNN approach obtained 83% accuracy and an F1-score of 86%, outperforming the baseline approach, which obtained an accuracy of 73% and an F1-score of 74%.

Figure 7. Confusion matrices for screening patients with sleep apnea based on the apnea-hypopnea index threshold of 15. CNN: convolutional neural network.

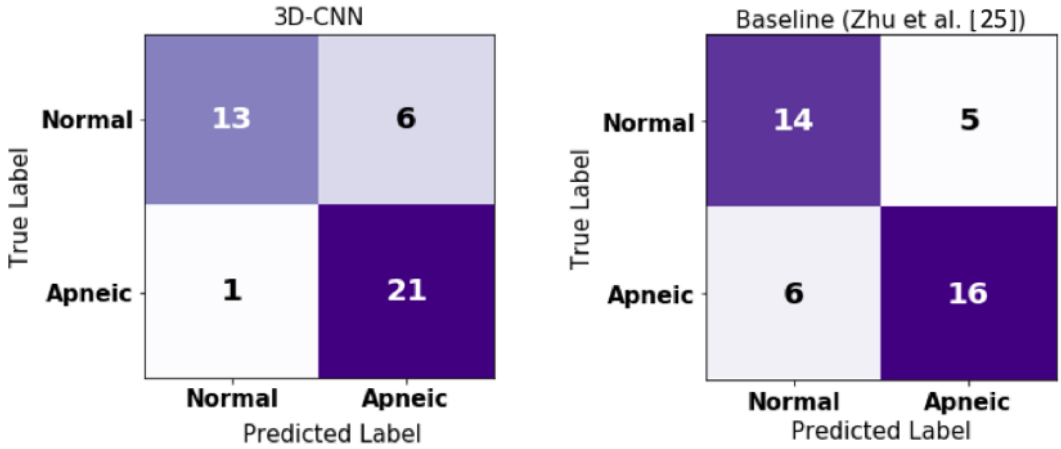


Table 2. Performance of models on screening patients with sleep apnea.

Method	Accuracy	Precision	Recall	F1-score
3D-CNN[a]	82.93	77.78	95.45	85.71
Baseline (Zhu et al [25])	73.17	76.19	72.73	74.42

[a]CNN: convolutional neural network.

The position detection algorithm estimated the body position with 83% accuracy, an F1-score of 83%, 77% precision, and 91% recall. The performance of the combination of the position detection algorithm with AHI detection on patients with positional sleep is shown in Figure 8. The 3D-CNN model classified 13 out of 20 patients with positional sleep apnea correctly. Performance measures for detecting positional vs nonpositional sleep apnea are presented in Table 3.

Figure 8. Confusion matrix for identifying positional sleep apnea. CNN: convolutional neural network.

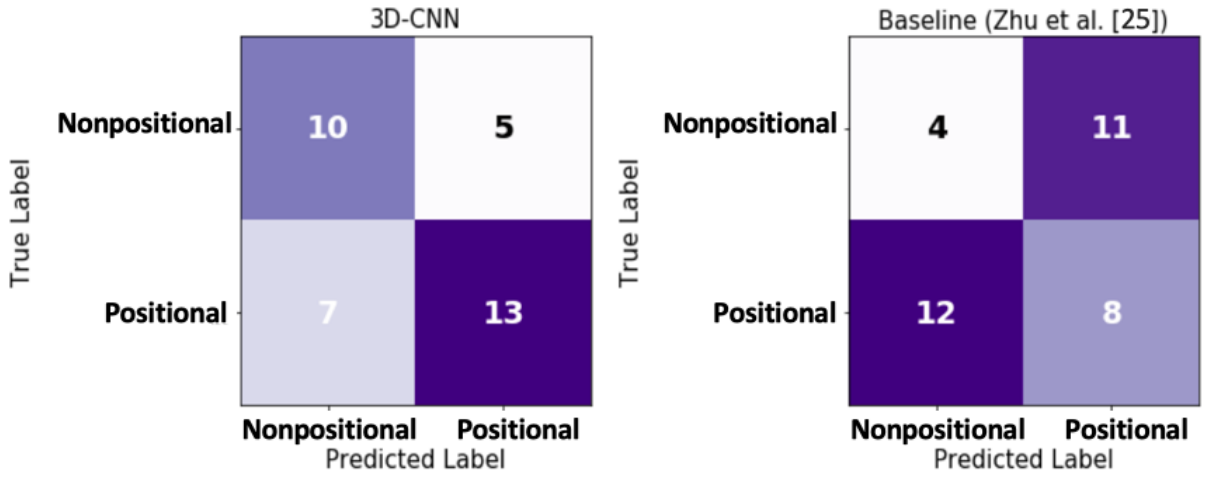


Table 3. Performance of the models in detecting positional vs nonpositional sleep apnea.

Method	Accuracy	Precision	Recall	F1-score
3D-CNN[a]	65.71	72.22	65.00	68.42
Baseline (Zhu et al [25])	34.29	42.11	40.00	41.03

[a]CNN: convolutional neural network.

Discussion

Principal Findings

The main contributions of this study are: (1) the development and experimental validation of a new noncontact approach to estimate AHI, and (2) application of this method to automatically identify individuals with positional sleep apnea. The newly developed 3D-CNN–based method outperformed the baseline model in estimating the AHI in infrared video data. However, it was ~4 times slower than the baseline algorithm. Nevertheless, the new model could still process 5 hours of sleep data in ~20 hours. Through combining estimated sleeping position information with estimated AHI, this is the first noncontact method that can identify a positional sleep apnea patient.

The developed algorithm achieved comparable performance to existing contact methods (eg, those using a single wearable sensor or a sensor placed under the mattress). For example, Hafezi et al [15] analyzed tracheal movements captured by an accelerometer to estimate AHI and to identify patients with sleep apnea. They reported a Spearman correlation of 0.86 between estimated and ground-truth (PSG) AHI values, and accuracy and F1-score values of 84% and 82%, respectively, in detecting individuals with AHI≥15. As such, they achieved a higher correlation coefficient (0.86 vs 0.79) but a lower F1-score (82% vs 86%) than our noncontact approach. An advantage of using a noncontact method over contact-based approaches is ease of use and convenience. Davidovich et al [23] used a piezo-electric sensor under a mattress to estimate the AHI. They obtained an R^2 value of 0.86 for AHI estimation, and accuracy and F1-score values of 88% and 84%, respectively, in identifying individuals with AHI≥15. Using a camera has the potential to result in a more accessible assessment technology, as it can be implemented in the form of a tablet or mobile phone app.

Limitations

Our study has some limitations. One limitation is the failure of the event detection algorithm when the participant moved out of the field of view of the camera or when the room lighting condition suddenly changed. Another limitation is the small number of participants (N=41). The algorithm was validated via leave-one-person-out cross-validation. Future work should examine the generalizability of these models to data collected in new environments.

Conclusion and Future Work

This study applied machine learning and computer vision approaches to develop a CNN-based method to detect respiratory events in different sleeping positions from data collected via an infrared camera. This method was validated on data from 41 participants to estimate AHI and to identify patients with positional sleep apnea.

This model could be used toward the development of affordable and easy-to-use technologies for screening sleep apnea at home (eg, in the form of a tablet or smartphone app). Such a system could help physicians in choosing suitable treatments for sleep apnea patients. Ultimately, improved treatment will reduce the consequences of untreated sleep apnea such as car accidents, heart disease, diabetes, and high blood pressure.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Architecture of a 3D convolutional neural network used to detect apneas.
[DOCX File , 15 KB-Multimedia Appendix 1]

References

1. American Academy of Sleep Medicine Task Force. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep 1999 Aug 01;22(5):667-689. [Medline: 10450601]
2. Kim NH. Obstructive sleep apnea and abnormal glucose metabolism. Diabetes Metab J 2012 Aug;36(4):268-272 [FREE Full text] [doi: 10.4093/dmj.2012.36.4.268] [Medline: 22950056]
3. Joosten SA, O'Driscoll DM, Berger PJ, Hamilton GS. Supine position related obstructive sleep apnea in adults: pathogenesis and treatment. Sleep Med Rev 2014 Mar;18(1):7-17. [doi: 10.1016/j.smrv.2013.01.005] [Medline: 23669094]
4. Oksenberg A, Silverberg DS, Arons E, Radwan H. Positional vs nonpositional obstructive sleep apnea patients: anthropomorphic, nocturnal polysomnographic, and multiple sleep latency test data. Chest 1997 Sep;112(3):629-639. [doi: 10.1378/chest.112.3.629] [Medline: 9315794]
5. Permut I, Diaz-Abad M, Chatila W, Crocetti J, Gaughan JP, D'Alonzo GE, et al. Comparison of positional therapy to CPAP in patients with positional obstructive sleep apnea. J Clin Sleep Med 2010 Jun 15;06(03):238-243. [doi: 10.5664/jcsm.27820]
6. Flemons WW, Douglas NJ, Kuna ST, Rodenstein DO, Wheatley J. Access to diagnosis and treatment of patients with suspected sleep apnea. Am J Respir Crit Care Med 2004 Mar 15;169(6):668-672. [doi: 10.1164/rccm.200308-1124PP] [Medline: 15003950]
7. Young T, Evans L, Finn L, Palta M. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep 1997 Sep;20(9):705-706. [doi: 10.1093/sleep/20.9.705] [Medline: 9406321]
8. Potts KJ, Butterfield DT, Sims P, Henderson M, Shames CB. Cost savings associated with an education campaign on the diagnosis and management of sleep-disordered breathing: a retrospective, claims-based US study. Popul Health Manag 2013 Mar;16(1):7-13. [doi: 10.1089/pop.2011.0102] [Medline: 22823227]
9. Diamanti C, Manali E, Ginieri-Coccossis M, Vougas K, Cholidou K, Markozannes E, et al. Depression, physical activity, energy consumption, and quality of life in OSA patients before and after CPAP treatment. Sleep Breath 2013 Dec 6;17(4):1159-1168. [doi: 10.1007/s11325-013-0815-6] [Medline: 23386373]
10. Bratton DJ, Gaisl T, Wons AM, Kohler M. CPAP vs mandibular advancement devices and blood pressure in patients with obstructive sleep apnea: a systematic review and meta-analysis. JAMA 2015 Dec 01;314(21):2280-2293. [doi: 10.1001/jama.2015.16303] [Medline: 26624827]
11. Merchant M, Farid-Moyer M, Zobnin Y, Kuznetcov A, Savitski A, Askeland J, et al. Clinical validation of a diagnostic patch for the detection of sleep apnea. In: Sleep Medicine. 2017 Dec Presented at: SLEEP 2017: 31st Annual Meeting of the Associated Professional Sleep Societies; June 3-7, 2017; Boston, Massachusetts p. e221. [doi: 10.1016/j.sleep.2017.11.644]
12. Ayas N. Assessment of a wrist-worn device in the detection of obstructive sleep apnea. Sleep Medicine 2003 Sep;4(5):435-442. [doi: 10.1016/s1389-9457(03)00111-4]
13. Varon C, Caicedo A, Testelmans D, Buyse B, Van Huffel S. A novel algorithm for the automatic detection of sleep apnea from single-lead ECG. IEEE Trans Biomed Eng 2015 Sep;62(9):2269-2278. [doi: 10.1109/TBME.2015.2422378] [Medline: 25879836]
14. Nakano H, Hayashi M, Ohshima E, Nishikata N, Shinohara T. Validation of a new system of tracheal sound analysis for the diagnosis of sleep apnea-hypopnea syndrome. Sleep 2004 Aug 01;27(5):951-957. [doi: 10.1093/sleep/27.5.951] [Medline: 15453554]
15. Hafezi M, Montazeri N, Saha S, Zhu K, Gavrilovic B, Yadollahi A, et al. Sleep apnea severity estimation from tracheal movements using a deep learning model. IEEE Access 2020;8:22641-22649. [doi: 10.1109/access.2020.2969227]
16. Yadollahi A, Giannouli E, Moussavi Z. Sleep apnea monitoring and diagnosis based on pulse oximetry and tracheal sound signals. Med Biol Eng Comput 2010 Nov 24;48(11):1087-1097. [doi: 10.1007/s11517-010-0674-2] [Medline: 20734154]
17. Saha S, Kabir M, Montazeri Ghahjaverestan N, Hafezi M, Gavrilovic B, Zhu K, et al. Portable diagnosis of sleep apnea with the validation of individual event detection. Sleep Med 2020 May;69:51-57. [doi: 10.1016/j.sleep.2019.12.021] [Medline: 32045854]

18. Yadollahi A, Moussavi Z. Acoustic obstructive sleep apnea detection. Annu Int Conf IEEE Eng Med Biol Soc 2009;2009:7110-7113. [doi: 10.1109/IEMBS.2009.5332870] [Medline: 19963947]
19. Lévy P, Pépin JL, Deschaux-Blanc C, Paramelle B, Brambilla C. Accuracy of oximetry for detection of respiratory disturbances in sleep apnea syndrome. Chest 1996 Mar;109(2):395-399. [doi: 10.1378/chest.109.2.395] [Medline: 8620711]
20. Akbarian S, Montazeri Ghahjaverestan N, Yadollahi A, Taati B. Distinguishing obstructive versus central apneas in infrared video of sleep using deep learning: validation study. J Med Internet Res 2020 May 22;22(5):e17252 [FREE Full text] [doi: 10.2196/17252] [Medline: 32441656]
21. Jakkaew P, Onoye T. Non-contact respiration monitoring and body movements detection for sleep using thermal imaging. Sensors (Basel) 2020 Nov 05;20(21):6307 [FREE Full text] [doi: 10.3390/s20216307] [Medline: 33167556]
22. Deng F, Dong J, Wang X, Fang Y, Liu Y, Yu Z, et al. Design and implementation of a noncontact sleep monitoring system using infrared cameras and motion sensor. IEEE Trans Instrum Meas 2018 Jul;67(7):1555-1563. [doi: 10.1109/tim.2017.2779358]
23. Davidovich MLY, Karasik R, Tal A, Shinar Z. Sleep apnea screening with a contact-free under-the-mattress sensor. 216 Presented at: Computing in Cardiology Conference (CinC); 2016; Vancouver, BC p. 849-852. [doi: 10.22489/CinC.2016.246-183]
24. Nandakumar R, Gollakota S, Watson N. Contactless sleep apnea detection on smartphones. GetMobile: Mobile Comp and Comm 2015 Dec 23;19(3):22-24. [doi: 10.1145/2867070.2867078]
25. Zhu K, Yadollahi A, Taati B. Non-contact apnea-hypopnea index estimation using near infrared video. In: Annu Int Conf IEEE Eng Med Biol Soc. 2019 Jul Presented at: International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC); 2019; Berlin, Germany p. 792-795. [doi: 10.1109/EMBC.2019.8857711]
26. Akbarian S, Delfi G, Zhu K, Yadollahi A, Taati B. Automated non-contact detection of head and body positions during sleep. IEEE Access 2019;7:72826-72834. [doi: 10.1109/access.2019.2920025]
27. Ilg E, Mayer N, Saikia T, Dosovitskiy A, Keuper M, Brox T. FlowNet 2.0: Evolution of optical flow estimation with deep networks. 2017 Presented at: IEEE Conference on Computer Vision and Pattern Recognition (CVPR); 2017; Hawaii p. 1647-1655 URL: http://lmb.informatik.uni-freiburg.de/Publications/2017/IMSKDB17 [doi: 10.1109/CVPR.2017.179]
28. Li MH, Yadollahi A, Taati B. Noncontact vision-based cardiopulmonary monitoring in different sleeping positions. IEEE J Biomed Health Inform 2017 Sep;21(5):1367-1375. [doi: 10.1109/jbhi.2016.2567298]
29. Zhu K, Li M, Akbarian S, Hafezi M, Yadollahi A, Taati B. Vision-based heart and respiratory rate monitoring during sleep – a validation study for the population at risk of sleep apnea. IEEE J Transl Eng Health Med 2019;7:1-8. [doi: 10.1109/jtehm.2019.2946147]
30. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med 2017 Mar 15;13(3):479-504. [doi: 10.5664/jcsm.6506] [Medline: 28162150]

Abbreviations

AHI: apnea-hypopnea index
CNN: convolutional neural network
PCA: principal component analysis
PSG: polysomnography

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Review

Effects of Digital Technologies on Older People's Access to Health and Social Care: Umbrella Review

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Abstract

Background: The 2020 COVID-19 pandemic prompted the rapid implementation of new and existing digital technologies to facilitate access to health and care services during physical distancing. Older people may be disadvantaged in that regard if they are unable to use or have access to smartphones, tablets, computers, or other technologies.

Objective: In this study, we synthesized evidence on the impact of digital technologies on older adults' access to health and social services.

Methods: We conducted an umbrella review of systematic reviews published from January 2000 to October 2019 using comprehensive searches of 6 databases. We looked for reviews in a population of adults aged ≥65 years in any setting, reporting outcomes related to the impact of technologies on access to health and social care services.

Results: A total of 7 systematic reviews met the inclusion criteria, providing data from 77 randomized controlled trials and 50 observational studies. All of them synthesized findings from low-quality primary studies, 2 of which used robust review methods. Most of the reviews focused on digital technologies to facilitate remote delivery of care, including consultations and therapy. No studies examined technologies used for first contact access to care, such as online appointment scheduling. Overall, we found no reviews of technology to facilitate first contact access to health and social care such as online appointment booking systems for older populations.

Conclusions: The impact of digital technologies on equitable access to services for older people is unclear. Research is urgently needed in order to understand the positive and negative consequences of digital technologies on health care access and to identify the groups most vulnerable to exclusion.

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KEYWORDS

digital health; social care; access; older adults; review of reviews; umbrella review

Introduction

For at least a decade, the World Health Organization has encouraged member states to become leaders in serving citizens online, using digital technology to improve health and social care services [1]. Digital technologies are electronic tools, systems, and resources that generate, store, or process data [2]. The emergence of a novel coronavirus (SARS-CoV-2, which causes COVID-19) has led to the rapid rollout of digital technologies to support patient access to health and social care, while ensuring physical distancing [3]. Digital technologies were playing a growing role in connecting health and social care services with their users before the COVID-19 pandemic. A survey of patients aged 65 years and over in 9 countries in 2013 reported that over three-quarters preferred to book and manage their medical appointments online, and over three-quarters felt that online access to medical records was important [4]. The annual survey of 770,000 patients in UK family practice has described small increases in the proportion of people booking appointments (14.9% in 2019, up from 12.9% in 2018) and ordering repeat prescriptions online (16.2% in 2019, up from 14.3% in 2018) [5].

Supporting people to use digital health resources may help improve access to services, improve physical and mental well-being, and encourage shared decision-making [5]. However, estimates suggest that 37% of the world's estimated 7.8 billion population are digitally excluded [6], with older people, people on low incomes, and other marginalized groups most likely to be affected [5,7]. In the United States, around 80% of the population accesses the internet, but its use falls sharply with increasing age. Approximately 70% of the people aged 65 to 74 years are online, compared with 52% of those aged 75 to 84 years, and 38% aged ≥85 years [8]. In the United Kingdom, out of a total population of 66.4 million, approximately 11 million (20%) lack digital skills, and 8.4 million (8.5%) never go online [9], and just over half of the latter are aged over 65 [5]. There is a clear relationship between internet use and health, with increasing age, female gender, and greater deprivation being associated with lower internet use [10]. Potential barriers to digital access include lack of awareness, confidence, capacity, or skills [11,12], a reluctance to change established behaviors, and poor internet access [5]. Affordability and acceptability of digital technology is important in later life, and it is noteworthy that many devices have been developed without the involvement of older people [13]. The involvement of older adults in technological design and development can facilitate acceptability, although it is a complex matter and requires careful consideration [14].The recent widespread introduction of digital alternatives to face-to-face interactions makes it vital that we understand their impact on older adults' ability to access health and social care services that they need. In the United Kingdom, the National Health Service (NHS) roadmap sets out the milestones for digital health and social care to support people to live healthier lives and use fewer care services using technologies such as mobile phones and smartphones, tablets, and smart televisions [15]. It includes NHS digital health and wellbeing apps, such as the NHS app, which provides access to a range of NHS services via smartphones or tablets, and NHS login, which allows patients to view and access their personal health information online [16]. These technologies could potentially improve access to services by (1) facilitating first contact with services, (2) replacing face-to-face care with remote service delivery, and (3) providing access to professional support through remote patient monitoring [2]. Therefore, this review of reviews aims to answer the question of whether digital technologies improve access to health and social care for older adults and identify the characteristics of any digital interventions that are effective in increasing access to services for older adults.

Methods

Reporting Standards

We employed an umbrella review methodology to summarize the findings of previously published reviews [17]. The review adheres to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) checklist for the reporting of systematic reviews [18]. The PRISMA checklist for this study is provided in Multimedia Appendix 1. Moreover, a review protocol was registered in the PROSPERO database [19].

Inclusion Criteria

The inclusion criteria were based on the PICOS (Population, Interventions, Comparator, Outcomes, and Study Designs) [20] criteria, which will be described in the following section.

Participants

Reviews of studies on older adults aged ≥65 or a combination of older and younger populations were selected in order to compare the effects of digital technologies on health care access between younger and older people.

Intervention

We used studies on any form of digital technology intended to facilitate access to appropriate health and social care services. These technologies enable first contact access (eg, online appointment scheduling) and are used as platforms for consultations and therapy interventions. They are also used in the remote care of patients. Furthermore, we recognized the fact that access to health and social care services would encompass availability and supply (ie, the degree of availability and quantity of supply at hand, regardless of whether they are used), utilization, equity, effectiveness, and quality of care [21].

Outcomes

We aimed to study the impact of digital technology on access to health and social care, which included the changes made in access and use of services as well as the cost-effectiveness of interventions that facilitate access and delivery of health and social care.

Study Designs

The study design of this paper encompassed any type of systematic review.

Search Strategy

We searched the following databases: Epistemonikos, MEDLINE (Ovid), Cochrane Database of Systematic Reviews (Wiley), ASSIA (ProQuest), PROSPERO, and for gray literature in Health Management Information Consortium (Ovid) and King's Fund. We used thesaurus headings along with title and abstract terms to search for digital technologies combined with specified outcomes for older people. The Canadian Agency for Drugs and Technologies in Health systematic review filter was adapted for databases that contained multiple study designs [22]. Searches were limited to the English language and the material published from January 1, 2000, to October 2019. The MEDLINE strategy is reported in Multimedia Appendix 2. The search results were downloaded to Endnote X9 (Clarivate Analytics) and deduplicated.

Data Collection

Two-stage screening was conducted by 2 reviewers independently using the Rayyan (Rayyan Systems) systematic review application [23]. We first tested and refined the inclusion and exclusion criteria on a sample of titles and abstracts to ensure that they were robust enough to capture relevant articles. The titles and abstracts of the reviews were screened against the refined inclusion criteria, followed by full text assessment of the selected articles. We resolved disagreements between the reviewers by discussion or by arbitration from another member of the review team.

Data Extraction

We extracted data into an Excel (Microsoft Corporation) spreadsheet, using a form based on the Cochrane Data Extraction and Assessment Template [20] to record the relevant review characteristics. The extracted data included: (1) author and year of publication; (2) title; (3) objective of the review; (4) description of the included population; (5) total number of older people; (6) intervention; (7) technology type; (8) what the intervention is enhancing; (9) primary outcomes; (10) secondary outcomes; (11) overall statement on quality appraisal; and (12) review authors' summary. To ensure comprehensiveness, we piloted the abstraction form on 2 reviews, which identified a need for minor modifications. Risk of bias was assessed using the ROBIS (Risk of Bias in Systematic Reviews) tool [24]. We chose to use ROBIS as opposed to AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews) because we are experienced with the former, and a comparative analysis of the two tools showed little difference between them [25].

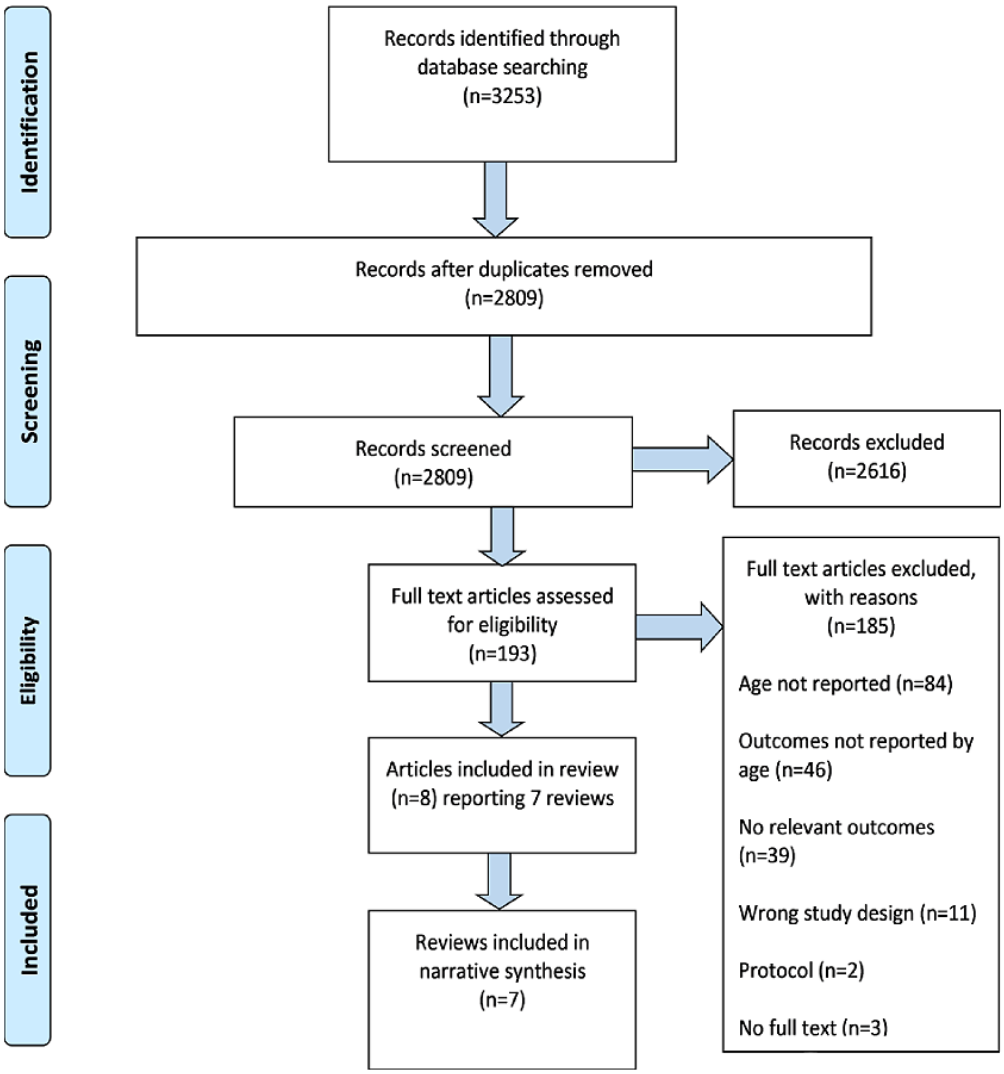
Data Analysis

We presented our main results in tabular format with a narrative synthesis. We grouped the results according to the three purposes of digital health technology, which consist of enabling first contact access, consultations and therapy, and remote monitoring. Due to a lack of data, we were unable to analyze the effects of interventions at ages over 65 years.

Results

Database searches identified 2809 unique records. The initial screening of title and abstracts excluded 2616 records, leaving 193 for full text assessment (Figure 1). We identified 7 reviews eligible for inclusion.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) flow diagram.



Characteristics of the Included Reviews

A total of 7 reviews published between 2006 and 2019 met the inclusion criteria [26-32]. A descriptive summary of review characteristics is presented in Table 1. The 7 included reviews include a total of 77 randomized controlled trials (RCTs) and 50 observational studies. We assessed the overlap across the reviews and identified 7 RCTs [33-39] reported in more than 1 review, but no observational studies that were included in more than 1 review. The studies in the reviews included 49 from the United States, 40 from Europe (including 7 from the United Kingdom), 9 from Australia, 6 from Canada, and 6 from the rest of the world. Country of origin was not stated for the remaining 17 studies. All of the studies reported outcomes for adults aged 65 and older, and 2 reviews included adults from age 18 [26,32].

Table 1. Summary of included systematic reviews.

Author	Study designs included in the review	Population	Intervention	Type of technology	Outcome
Bauce [26]	RCT,[a] observational	Adults aged >65 (in 10 out of 11 studies)	Telemonitoring	Videophones, smartphone, and mobile phone	Hospital admissions and emergency department visits
Harerimana [27]	RCT, observational	Adults aged ≥65 with a diagnosis of depression or self-reported depressive symptoms	Telehealth (mental health)	Telephone and computers	Hospital admissions and emergency department visits
Husebo [28]	Observational	Adults aged >65, either living alone or receiving informal care	Telehealth	Videophones, personal computers or laptops, and TV	Hospital admissions and readmissions
Inglis [29,40]	RCT	Adults with heart failure (8 studies included people with a mean age of ≥70)	Structured telephone support or telemonitoring (heart failure)	Telephone	Heart failure and all-cause hospitalizations
Martinez [30]	RCT, observational	Adults with heart failure (11 studies included people with a mean age of ≥65)	Home telecare	Not reported	Hospital readmissions
Marx [31]	RCT, observational	Adults with a mean age of ≥65 years living independently, in receipt of intervention for management risk of malnutrition	Telehealth for managing risk of malnutrition	Telephone and computer	Hospital readmission and healthcare costs
Sanyal [32]	RCT, observational	Older adults (11 studies included people with a mean age of ≥65 years)	Telehealth, cognitive behavior therapy	Computer	Cost-effectiveness or utility of eHealth technologies

[a]RCT: randomized controlled trial.

Risk of Bias Assessment

Details of the risk of bias assessment can be found in Table 2. Overall, the risk of bias was high for 5 reviews [26-28,30,32], and low for 2 reviews [29,31]. The main issues were the absence of clear inclusion criteria and the lack of publicly available protocols with predefined criteria. A detailed description of risk of bias assessment is reported in Multimedia Appendix 3.

Table 2. Risk of bias using ROBIS (Risk of Bias in Systematic Reviews) assessment.

Review	Phase 2				Phase 3
	Study Eligibility Criteria	Identification and selection of studies	Data collection and study appraisal	Synthesis and findings	Overall risk of bias
Bauce [26]	High	Unclear	High	High	High
Harerimana [27]	High	Unclear	High	High	High
Husebo [28]	High	High	High	High	High
Inglis [29,40]	Low	Low	Low	Low	Low
Martinez [30]	High	High	High	High	High
Marx [31]	Low	Low	Low	Low	Low
Sanyal [32]	High	Low	Unclear	High	High

Outcomes

Table 3 summarizes the identified evidence, presenting it according to the purpose of the digital technology and the reported outcomes. None of the reviews reported outcomes that were related to the changes in access to services. In total, 6 reviews reported on hospital admissions [26-31], 1 reported on healthcare costs [31], and 1 on the cost-effectiveness of digital technology [32]. A variety of digital technologies were used by healthcare professionals and older adults to support interventions for telemonitoring or telecare: videophones or video conferencing equipment, internet-based applications, and smartphones.

Table 3. Overview of the identified evidence by type of digital technology and outcome.

Objective	Outcome	
Purpose of digital technology	Health service utilization	Costs and cost-effectiveness
Digital technology to enable first point of contact access (eg, online appointment scheduling)	No reviews identified	No reviews identified
Digital technologies or platforms for consultations and therapy interventions	Harerimana [27]; Marx [31]; Husebo [28]; Inglis [29]; Martinez [30]	Sanyal [32]
Digital technology for remote monitoring interventions	Bauce [26]	Sanyal [32]

First Point of Contact Access

No systematic reviews reported evidence about the impact of digital technology to facilitate first point of contact access with health services, such as online appointment scheduling.

Consultations and Therapies

In total, 5 reviews reported on health care service utilization, in malnutrition [31], heart failure [29,30], and mental health [27,28], as outcomes of digital technologies, but only 2 reviews were judged to be at low risk of bias and thus of higher quality [29,31].

Malnutrition

Marx and colleagues [31] reported weak evidence for the effectiveness of telehealth interventions to address malnutrition among community-dwelling older adults. They identified 9 studies (7 RCTs and 2 observational); 2 of the 9 studies reported significant reductions in hospital readmissions in the intervention groups. However, when the data were pooled, the reduction in hospital admissions was not significant; (odds ratio 0.52, 95% CI 0.24-1.16); P=.11; n=160; I^2=0%).

Heart Failure

Inglis and colleagues [29] focused on whether structured telephone support and telemonitoring were effective for older people with heart failure. They found 41 RCTs that assessed heart failure–related hospitalizations. A meta-analysis of some of the included studies reported a 15% reduction in risk for heart failure–related hospitalizations with structured telephone support (relative risk 0.85, 95% CI 0.77-0.93; n=7030; 16 studies; I^2=27%) and a 29% reduction in telemonitoring (relative risk 0.71, 95% CI 0.60 to 0.83; n=2148; 8 studies; I^2=20%). There were no impacts reported on all-cause hospitalizations. The quality of the evidence reported for these heart failures and all-cause hospitalization studies was rated very low [29]. Evidence from the lower-quality reviews reported positive impacts of digital technology interventions on service utilization. Martinez and colleagues [30] reviewed 42 articles on the value of home monitoring for heart failure patients, 5 of which reported findings for older people. Remote consultations and follow-up care were associated with lower admission and readmission rates.

Mental Health

Husebo and colleagues [28] sought to understand the care content and utilization of virtual visits, particularly the uses and experiences of adults aged 65 and over. In their review, 1 study reported that all-cause readmissions were lower in the telehealth group (n=102) compared with standard care (n=116). At 30 days, 16 (16%) versus 22 (19%) and at over 6 months, 46 (46%) versus 60 (52%) of intervention versus control patients were readmitted [41]. Telehealth has also been used to deliver mental health care for older adults with depressive symptoms (telemental health). In a 6-month single (quasi-experimental) study of 76 patients, identified by Harerimana and colleagues [27], telemental health reduced hospital admissions by 80% (46 versus 9 admissions) and emergency room visits 60% (80 versus 32 visits) [42]. Evidence for the impact of digital technologies on economic outcomes was sparse. Moreover, 1 single review of eHealth technologies in the management of chronic diseases reported limited evidence, which did not support the assessment of cost-effectiveness [32].

Remote Monitoring

Two reviews reported evidence about technologies for remote monitoring, both of which were judged to be of poor quality. Bauce and colleagues [26] assessed the effectiveness of telemonitoring (videoconferencing) interventions on heart failure outcomes in 11 studies (10 RCTs and 1 single-group study). Five studies reported significant reductions in hospital admissions, and 2 others reported significant reductions in emergency department visits. The authors speculated that the reduction in healthcare use was likely to be due to the early detection and treatment of symptoms attributable to the intervention. Reduction in hospital admissions due to telemonitoring was supported by Queirós and colleagues [43]. Their systematic review assessed the use of technologies in the remote care of patients with long-term conditions such as diabetes, congestive heart failure, chronic obstructive pulmonary disease, and mental disorders [43].

Discussion

Principal Results

We identified evidence on a variety of digital technologies to facilitate interaction between older people and services at different parts of the care pathway. However, we found no reviews of technology to facilitate first point of contact access such as online appointment booking systems. There was no significant difference in hospital admissions for telehealth interventions (but this may have been due to the studies' lack of power as there were only 160 participants in the pooled analysis) [31]. However, for heart failure, structured telephone support resulted in 15% reduction in admissions [29]. Other reviews were of too low a quality to permit confidence in findings, however, and there were no signs that a focus on

reviews with too low a risk of bias would change anything. From the 7 overlapping RCTs [33-39], benefits to the older population in access were poorly measured and not clearly reported. In these RCTs, focus was on reducing hospital admissions, and there was little account of whether these technologies are enabling older people to interact with or access health and social care services more effectively. There was also no review evidence for newer technologies such as smartphone apps (eg, the NHS app in the United Kingdom), some of which were already in widespread use before COVID-19 [15].

The 2020 COVID-19 pandemic prompted the rapid implementation of alternatives to face-to-face interactions in health and social care [3]. This was a pragmatic response to a novel emergency that allowed care delivery to continue. As the pandemic evolves, digital innovations that have been implemented at speed should be evaluated to ensure that they are effective and affordable so that they can promote equitable access and do not selectively overlook certain sections of the population [14]. However, none of the included reviews addressed the issue of affordability and acceptability of digital technology in later life. For sections of the population who lack digital literacy or a means of digital engagement, the benefits are less clear, and there is every possibility that they will be harmed by losing the ability to access services in traditional, nondigital ways.

Most of the evidence [26-31] was concerned with digital technologies to facilitate remote delivery of care, including consultations and therapy, reflecting a research focus congruent with policy priorities [15]. However, these evaluations were more focused on reducing hospital utilization rather than enhancing access to services. Whether digital technologies do reduce hospital admissions and visits by facilitating timely access to appropriate alternative care is impossible to determine from the evidence presented. Evidence on the cost-effectiveness of digital health technologies was confined to 1 low-quality review, from which no clear conclusions can be drawn [32].

Limitations

To the best of our knowledge, this is the first rapid synthesis of systematic reviews on digital technology aimed at enhancing access to health and social care services for older adults. We followed a rapid evidence synthesis approach, and our database searching, handling of data, and reporting adhered to published guidelines for undertaking a robust standard systematic review [18,44]. We restricted our searches to English language publications due to time constraints and acknowledge that this may have excluded relevant material. Two limitations of the material should be highlighted. First, most of the studies contained within our included reviews were randomized trials of effectiveness and cost-effectiveness. However, we found that the benefits to the older population in access are poorly measured and not clearly reported in studies of digital technology. Second, most of the reviews failed to adequately report their findings, and formal assessments of the methodological quality indicated a low-quality evidence base. This leads us to be cautious in our interpretation of the evidence and any conclusions drawn.

Comparison With Prior Work

Our assessment of the dearth of evidence on first point of contact digital technology is supported by other works. A recent review of approaches to the evaluation of digital health interventions identified little evidence from randomized controlled trials and carried out measurement of service utilization in only a minority of the studies [45]. Our review suggests that digital health technologies may be associated with reductions in health service use. This is supported by multiple systematic reviews in younger populations of patients with long-term conditions [43]. There is a particular gap in the evaluation of any digital technologies used in social care.

Implications for Policy, Research, and Practice

The COVID-19 pandemic has resulted in the rapid implementation of digital interventions to allow continued access to services when infection risk was high. This rapid rollout went beyond any evidence for effectiveness, driven by the extraordinary need to reduce face-to-face contact. However, prepandemic concerns about the adverse effects of digital technologies on access to services for older people remain valid. For older people who are digitally excluded, these digital interventions risk exacerbating any problems they already faced when trying to access health and social care services. This, in turn, has implications for workload in primary care, and health care providers must take on greater responsibility to ensure that this important section of the population receives the care it needs. There is a notable gap in the evidence for studies assessing the impact of technologies to enable first point of contact for health and social care services (eg, online platforms to book appointments). A mapping review of primary studies is required to understand this impact on different population subgroups, but this is unlikely to be sufficient. Further work is needed to understand the effectiveness and cost-effectiveness of digital technologies and their effect on equity of access to health and social care services. This should encompass access to appropriate care, which may lead to reductions in the use of other services as well as changes in health outcomes. The paucity of evidence in this area points to the need for a broad research program in partnership with older people and service providers in order to understand the characteristics of digital technologies, which can enhance access to services.

Conclusions

The current systematic review evidence on the potential for digital technologies to improve access to health and social care for older adults is limited in both scope and quality. However, these limited attempts raise the possibility that providing digital interventions in addition to or as a replacement for face-to-face services may reduce demands on hospitals. Further research is required, and the widespread use of digital technologies to facilitate access to health and social care during the COVID-19 pandemic offers an ideal opportunity to better understand the barriers, facilitators, and limitations of their use.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) checklist.
[PDF File (Adobe PDF File), 395 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Example of search strategy.
[DOCX File , 18 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Risk of bias assessment of the included reviews.
[DOCX File , 17 KB-Multimedia Appendix 3]

References

1. Draft global strategy on digital health 2020-2024. World Health Organization. 2019. URL: https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf?sfvrsn=f112ede5_42 [accessed 2020-05-18]
2. Bhavnani SP, Narula J, Sengupta PP. Mobile technology and the digitization of healthcare. Eur Heart J 2016 Dec 07;37(18):1428-1438 [FREE Full text] [doi: 10.1093/eurheartj/ehv770] [Medline: 26873093]
3. Gasser U, Ienca M, Scheibner J, Sleigh J, Vayena E. Digital tools against COVID-19: taxonomy, ethical challenges, and navigation aid. The Lancet Digital Health 2020 Aug;2(8):e425-e434 [FREE Full text] [doi: 10.1016/S2589-7500(20)30137-0]
4. 2013 Accenture Consumer Survey on Patient Engagement. Accenture. 2013. URL: https://www.criticaleye.com/inspiring/insights-servfile.cfm?id=3869 [accessed 2020-11-15]
5. Digital inclusion for health and social care: What we mean by digital inclusion. National Health Service. 2019. URL: https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion/what-digital-inclusion-is [accessed 2020-01-27]
6. World Internet Users and 2021 Population Stats. Internet World Stats. 2020. URL: https://www.internetworldstats.com/stats.htm [accessed 2020-05-20]
7. Leist AK. Social media use of older adults: a mini-review. Gerontology 2013;59(4):378-384 [FREE Full text] [doi: 10.1159/000346818] [Medline: 23594915]
8. NTIA Data Reveal Shifts in Technology Use, Persistent Digital Divide. National Telecommunications and Information Administration. 2020. URL: https://www.ntia.doc.gov/blog/2020/ntia-data-reveal-shifts-technology-use-persistent-digital-divide [accessed 2020-07-21]
9. Estimates of the population for the UK. Office for National Statistics. 2017. URL: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/populationestimatesforukenglandandwalesscotlandandnorthernireland [accessed 2020-01-27]
10. Matthews K, Nazroo J, Marshall A. Digital inclusion in later life: cohort changes in internet use over a ten-year period in England. Ageing and Society 2018 Aug 02;39(9):1914-1932. [doi: 10.1017/s0144686x18000326]
11. Measuring the Information Society Report 2018. International Telecommunications Union. 2018. URL: https://www.itu.int/en/ITU-D/Statistics/Pages/publications/misr2018.aspx [accessed 2020-05-18]
12. GP Patient Survey 2019. National Health Service. 2019. URL: https://www.england.nhs.uk/statistics/2019/07/11/gp-patient-survey-2019/ [accessed 2020-01-27]
13. Connected Health: How digital technology is transforming health and social care. The Deloitte Centre for Health Soultions. 2015. URL: https://www2.deloitte.com/content/dam/Deloitte/ie/Documents/PublicSector/deloitte-uk-connected-health-sm1.pdf [accessed 2019-12-18]
14. Fischer B, Peine A, Östlund B. The importance of user involvement: a systematic review of involving older users in technology design. Gerontologist 2020 Sep 15;60(7):e513-e523 [FREE Full text] [doi: 10.1093/geront/gnz163] [Medline: 31773145]

15. The Forward View into Action: Paper-free at the Point of Care Guidance for Developing Local Digital Roadmaps. National Health Service. 2016. URL: https://www.england.nhs.uk/digitaltechnology-old/wp-content/uploads/sites/31/2016/11/develp-ldrs-guid.pdf [accessed 2020-01-27]
16. Apps and tools for patient care. NHSX. 2020 Jan 29. URL: https://www.nhsx.nhs.uk/key-information-and-tools/apps-and-tools [accessed 2020-01-29]
17. Papatheodorou S. Umbrella reviews: what they are and why we need them. Eur J Epidemiol 2019 Jun;34(6):543-546. [doi: 10.1007/s10654-019-00505-6] [Medline: 30852716]
18. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Intern Med 2009 Aug 18;151(4):264-9, W64 [FREE Full text] [doi: 10.7326/0003-4819-151-4-200908180-00135] [Medline: 19622511]
19. Kunonga P, Spiers G, Beyer F, Boulton E, Hall A, Craig D. Digital technologies providing access to health and social care: a rapid evidence synthesis. PROSPERO: International prospective register of systematic reviews. 2019. URL: https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=161421 [accessed 2020-01-12]
20. CRD's Guidance for Undertaking Reviews in Health Care. Centre for Reviews and Dissemination. 2009. URL: https://www.york.ac.uk/crd/SysRev/!SSL!/WebHelp/SysRev3.htm [accessed 2019-11-20]
21. Gulliford M, Figueroa-Munoz J, Morgan M, Hughes D, Gibson B, Beech R, et al. What does 'access to health care' mean? J Health Serv Res Policy 2002 Jul;7(3):186-188. [doi: 10.1258/135581902760082517] [Medline: 12171751]
22. Strings Attached: CADTH's Database Search Filters. Canadian Agency for Drugs and Technologies in Health. 2010. URL: https://www.cadth.ca/resources/finding-evidence/strings-attached-cadths-database-search-filters#syst [accessed 2020-01-01]
23. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev 2016 Dec 05;5(1):210 [FREE Full text] [doi: 10.1186/s13643-016-0384-4] [Medline: 27919275]
24. Whiting P, Savović J, Higgins JPT, Caldwell DM, Reeves BC, Shea B, ROBIS group. ROBIS: a new tool to assess risk of bias in systematic reviews was developed. J Clin Epidemiol 2016 Jan;69:225-234 [FREE Full text] [doi: 10.1016/j.jclinepi.2015.06.005] [Medline: 26092286]
25. Pieper D, Puljak L, González-Lorenzo M, Minozzi S. Minor differences were found between AMSTAR 2 and ROBIS in the assessment of systematic reviews including both randomized and nonrandomized studies. J Clin Epidemiol 2019 Apr;108:26-33. [doi: 10.1016/j.jclinepi.2018.12.004] [Medline: 30543911]
26. Bauce K, Fahs DB, Batten J, Whittemore R. Videoconferencing for Management of Heart Failure: An Integrative Review. J Gerontol Nurs 2018 Apr 01;44(4):45-52. [doi: 10.3928/00989134-20180207-01] [Medline: 29437182]
27. Harerimana B, Forchuk C, O'Regan T. The use of technology for mental healthcare delivery among older adults with depressive symptoms: A systematic literature review. Int J Ment Health Nurs 2019 Jun;28(3):657-670. [doi: 10.1111/inm.12571] [Medline: 30666762]
28. Husebø AML, Storm M. Virtual visits in home health care for older adults. ScientificWorldJournal 2014;2014:689873 [FREE Full text] [doi: 10.1155/2014/689873] [Medline: 25506616]
29. Inglis SC, Clark RA, Dierckx R, Prieto-Merino D, Cleland JGF. Structured telephone support or non-invasive telemonitoring for patients with heart failure. Cochrane Database Syst Rev 2015 Oct 31(10):CD007228 [FREE Full text] [doi: 10.1002/14651858.CD007228.pub3] [Medline: 26517969]
30. Martínez A, Everss E, Rojo-Alvarez JL, Figal DP, García-Alberola A. A systematic review of the literature on home monitoring for patients with heart failure. J Telemed Telecare 2006;12(5):234-241. [doi: 10.1258/135763306777889109] [Medline: 16848935]
31. Marx W, Kelly JT, Crichton M, Craven D, Collins J, Mackay H, et al. Is telehealth effective in managing malnutrition in community-dwelling older adults? A systematic review and meta-analysis. Maturitas 2018 May;111:31-46. [doi: 10.1016/j.maturitas.2018.02.012] [Medline: 29673830]
32. Sanyal C, Stolee P, Juzwishin D, Husereau D. Economic evaluations of eHealth technologies: A systematic review. PLoS One 2018;13(6):e0198112 [FREE Full text] [doi: 10.1371/journal.pone.0198112] [Medline: 29897921]
33. Cleland JGF, Louis AA, Rigby AS, Janssens U, Balk AHMM, TEN-HMS Investigators. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network-Home-Care Management System (TEN-HMS) study. J Am Coll Cardiol 2005 May 17;45(10):1654-1664 [FREE Full text] [doi: 10.1016/j.jacc.2005.01.050] [Medline: 15893183]
34. de Lusignan S, Wells S, Johnson P, Meredith K, Leatham E. Compliance and effectiveness of 1 year's home telemonitoring. The report of a pilot study of patients with chronic heart failure. European Journal of Heart Failure 2001 Dec 03;3(6):723-730 [FREE Full text] [doi: 10.1016/s1388-9842(01)00190-8] [Medline: 11738225]
35. Dimmick SL, Burgiss SG, Robbins S, Black D, Jarnagin B, Anders M. Outcomes of an integrated telehealth network demonstration project. Telemed J E Health 2003;9(1):13-23. [doi: 10.1089/153056203763317611] [Medline: 12699604]
36. Goldberg LR, Piette JD, Walsh MN, Frank TA, Jaski BE, Smith AL, et al. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial. American Heart Journal 2003 Oct;146(4):705-712. [doi: 10.1016/S0002-8703(03)00393-4] [Medline: 14564327]

37. Jerant AF, Azari R, Nesbitt TS. Reducing the cost of frequent hospital admissions for congestive heart failure: a randomized trial of a home telecare intervention. Med Care 2001 Nov;39(11):1234-1245. [doi: 10.1097/00005650-200111000-00010] [Medline: 11606877]
38. Wakefield BJ, Ward MM, Holman JE, Ray A, Scherubel M, Burns TL, et al. Evaluation of home telehealth following hospitalization for heart failure: a randomized trial. Telemed J E Health 2008 Oct;14(8):753-761. [doi: 10.1089/tmj.2007.0131] [Medline: 18954244]
39. Woodend A, Fraser M, Sprang M, Stueve L. Readmission and quality of life: the impact of telehomecare in heart failure. J Card Fail 2002;8:98 [FREE Full text]
40. Inglis SC, Conway A, Cleland JG, Clark RA. Is age a factor in the success or failure of remote monitoring in heart failure? Telemonitoring and structured telephone support in elderly heart failure patients. Eur J Cardiovasc Nurs 2015 Jun;14(3):248-255. [doi: 10.1177/1474515114530611] [Medline: 24681423]
41. Bowles KH, Hanlon AL, Glick HA, Naylor MD, O'Connor M, Riegel B, et al. Clinical effectiveness, access to, and satisfaction with care using a telehomecare substitution intervention: a randomized controlled trial. Int J Telemed Appl 2011;2011:540138 [FREE Full text] [doi: 10.1155/2011/540138] [Medline: 22187551]
42. Godleski L, Cervone D, Vogel D, Rooney M. Home telemental health implementation and outcomes using electronic messaging. J Telemed Telecare 2012 Jan;18(1):17-19. [doi: 10.1258/jtt.2011.100919] [Medline: 22052966]
43. Queirós A, Alvarelhão J, Cerqueira M, Silva A, Santos M, Pacheco Rocha N. Remote Care Technology: A Systematic Review of Reviews and Meta-Analyses. Technologies 2018 Feb 10;6(1):22. [doi: 10.3390/technologies6010022]
44. Hunt H, Pollock A, Campbell P, Estcourt L, Brunton G. An introduction to overviews of reviews: planning a relevant research question and objective for an overview. Syst Rev 2018 Mar 01;7(1):39 [FREE Full text] [doi: 10.1186/s13643-018-0695-8] [Medline: 29490699]
45. Zanaboni P, Ngangue P, Mbemba GIC, Schopf TR, Bergmo TS, Gagnon M. Methods to Evaluate the Effects of Internet-Based Digital Health Interventions for Citizens: Systematic Review of Reviews. J Med Internet Res 2018 Jun 07;20(6):e10202 [FREE Full text] [doi: 10.2196/10202] [Medline: 29880470]

Abbreviations

AMSTAR: A Measurement Tool to Assess Systematic Reviews
NHS: National Health Service
NIHR: National Institute for Health Research
PICOS: Population, Interventions, Comparator, Outcomes, and Study Designs
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT: randomized control trial
ROBIS: Risk of Bias in Systematic Reviews

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Original Paper

The Sociological Perspective of Users' Invisible Work: A Qualitative Research Framework for Studying Digital Health Innovations Integration

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Abstract

Background: When new technology is integrated into a care pathway, it faces resistance due to the changes it introduces into the existing context. To understand the success or failure of digital health innovations, it is necessary to pay attention to the adjustments that users must perform to make them work, by reshaping the context and sometimes by altering the ways in which they perform activities. This adaptation work, most of which remains invisible, constitutes an important factor in the success of innovations and the ways in which they transform care practices.

Objective: This work aims to present a sociological framework for studying new health technology uses through a qualitative analysis of the different types of tasks and activities that users, both health professionals and patients, must perform to integrate these technologies and make them work in their daily routine.

Methods: This paper uses a three-part method to structure a theoretical model to study *users' invisible work*. The first part of the method includes a thematic literature review, previously published by one of the coauthors, of major sociological studies conducted on digital health innovations integration into existing care organizations and practices. The second part extends this review to introduce definitions and applications of the *users' invisible work* concept. The third part consists of producing a theoretical framework to study the concept according to the different contexts and practices of the users.

Results: The paper proposes four dimensions (organizational, interactional, practical, and experiential), each composed of a set of criteria that allow a comparative analysis of different users' work according to different health technologies.

Conclusions: This framework can be applied both as an analytical tool in a research protocol and as an agenda to identify less visible adoption criteria for digital health technologies.

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KEYWORDS

digital health innovations; qualitative analysis; sociological framework; invisible work; patient work; user work; participatory health care; chronic illness; self-quantification

Introduction

Background

A large number of digital health technologies are developed every day, each being increasingly less expensive, faster, more connected, and *smarter* than the last. On the one hand, the use of telemedicine among health professionals comes with the promise of revolutionizing the organization of health care, which can now be accessed increasingly at a distance. On the other hand, data-driven applications and new quantification practices

seem to foster a belief in greater autonomy for patients. Increasingly equipped, connected, and measured patients are the active figures of an empowered generation that is becoming digitally engaged in their health by collecting, sorting, interpreting, and deleting many types of health and environment–related data [1]. Although these two examples seem to refer to very different realities, they illustrate a common fact that goes beyond their provisional and circumstantial distinctions: the supply of new digital technologies is only growing in the field of health, whereas it is challenging health care practices. For the sake of this argument, we will use the term *digital health innovations* to refer to the adoption of both professional-centered telemedicine or telehealth technologies (eg, teleconsultation, tele-expertise, telemonitoring) and patient-centered telecare technologies (eg, eHealth, mobile health, u-health, self-monitoring, self-help).

However, providing interesting technologies does not necessarily lead to their adoption or normalization. Some are successfully integrated into everyday practices, while others are used only by the circle of the first experimenters. What makes some of these innovations work? Which factors explain their success or failure? These questions are at the core of a very large body of multidisciplinary literature dealing with the issues of integrating new technologies into existing organizations and care practices [2]. This literature provides a whole set of criteria for assessing the chances of a successful integration [3]. Although it promotes macroscale analysis, it can sometimes overlook the actual practices and their concrete realities as presented to users. The purpose of this paper is to formulate a theoretical framework to better account for practice-related criteria in explaining the success of new health technologies. First, we should present and contextualize the work that we are mobilizing within the existing literature. Earlier studies conducted on telemedicine in the 1990s point mainly to the technical difficulties in explaining its slow diffusion. This focus suggests that it is sufficient to resolve these difficulties for telemedicine to be widely accepted [4]. Numerous studies conducted from the point of view of their acceptability or usefulness develop the idea that practices could be transposed as they are within the new framework. In this regard, May et al [5] state that “the existing literature on telemedicine [in 2001] has for the most part taken as its primary focus the utility and efficacy of the technology itself, as it is applied to particular clinical settings and problems. This is primarily clinical literature that is about establishing the safe practice of medicine using a diverse set of communications technologies.” This clinical approach, which seeks to evaluate telemedicine devices according to the principles of *evidence-based medicine* [6,7], is further coupled by numerous economic analysis models built around their cost-efficiency. However, it has since become clear that the development of innovations depends on much more varied and, more importantly, socially defined factors than merely the technical, clinical, or economic efficiencies. As such, these one-dimensional approaches tend to underestimate the importance of the institutional, organizational, and professional contexts in which these technologies are concretely integrated.

In this regard, many recent studies have focused on socio-organizational factors to assess the likelihood that a new technology will be integrated successfully into existing health care organizations and practices. Some works propose combining different socio-organizational aspects within a multidimensional assessment model [8]. For example, this is the case of the *Model for Assessment of Telemedicine*, which has been established in this field [9]. Although such models do indeed consider multiple aspects in the evaluation of digital health innovations, they are still far from capturing the plurality and complexity of the activities that need to be performed to make these technologies work concretely, on a daily basis, for very different actors who pursue highly varied objectives, in widely differing sociotechnical configurations. In fact, as shown by Pols [10] and, more broadly, by a large corpus of work in *Science and Technology Studies*, it is difficult to accurately predict the success or failure of innovations in telemedicine, nor the concrete integration modalities of digital technologies in existing health care practices. Users do not necessarily turn to these, out of a taste for technology (ie, technophilia). Moreover, a majority integrate them in a context full of uncertainty, where it is unclear how technologies will transform their practice. The only thing that can be predicted in this regard is the unpredictability of the adoption modes of these technologies. This unpredictability is based on the diversity of user profiles (eg, medical doctors, nurses, patients, helpers) and the types of technologies (eg, professional tools, connected objects, web platforms, and mobile apps). It is also based on various places (eg, hospitals or private practices, in cities or in small towns), sociotechnical environments (eg, resources, tools, and information systems), medical situations (eg, routine care, chronic disease monitoring, or emergency), and broader health care contexts (ie, during a health crisis) in which they are integrated, accessed, and used [11].

To understand the success of digital health innovations, it is necessary to examine the efforts or, more precisely, to quote Nicolini [12], “the work to make it work” provided by different stakeholders, not only by innovators and promoters but also by users, both health care professionals and patients. We suggest that all this *user work*, most of which remains invisible, is an important factor in explaining not only the phenomena of adoption of innovations but also the way in which they transform existing organizations and care practices. Here, we understand the notion of innovation as a continuous and evolutionary process in which users (and their practices) play a key role in the successful integration of new technologies.

Scope and Purpose

Sociological studies have shown that the adoption of new health technologies by users is neither straightforward nor given [13]. As soon as a new technology is integrated into a care pathway, it inevitably faces resistance and creates obstacles due to the wide range of changes introduced in the existing context. These changes can concern the social and spatial organization of health care, the division of medical and paramedical work, the interactions between their various actors, the work activities themselves, as well as the knowledge levels and professional identities. To understand the success or failure of digital health innovations, it is necessary to pay attention to this prior context, which is bound to evolve with the integration of new technologies. More precisely, it is necessary to evaluate the

adjustments that users must do to make it work by adapting the pre-existing context and sometimes by altering or even inventing new ways of doing things [14]. These adjustments represent a relatively constrained form of activity. However, without these, new technologies are difficult to normalize or can be abandoned.

A large body of work conducted in *Science and Technology Studies* provides valuable insights on the importance of these activities. This is done specifically by the Actor-Network Theory, which brings to light the unsuspected work of *translation* that must indeed be performed by innovators, both industrials who design and distribute new technologies and coordinators who seek to integrate them into their organizations [15-17]. Beyond traditional project management work, promoters must be able to *align* heterogeneous elements into a coherent whole. They must synchronize not only sociotechnical environments [18] but also practices and interactions that new technologies may suggest organizing in different ways. This alignment refers to work that is often invisible [19]. It requires building meaning (ie, *sensemaking*) and trust around these devices [20] and negotiating collective understanding among various categories of actors, including physicians, nurses, care assistants, patients, and family caregivers. These actors have *a priori* different interests that must be considered and converge to a minimum degree in order to support the normalization of new technologies. This is an eminently delicate task, not only because it requires articulating a variety of interpretations and modalities of action but also because new technologies affect autonomy, which is traditionally very important both for health professionals [21] and for their patients [22]; thus, it is difficult to negotiate.

These studies draw attention to the work that innovators and coordinators need to do to address the organizational complexity of integrating telemedicine devices in existing health care organizations. They also point out the *real work* needed to be done for these technologies to work on a daily basis, not only by promoters but also by users [19,23]. To make digital health technologies work, they must perform a series of additional activities that can be studied as a specific form of work [23]. Thus, to integrate new technologies into existing health care organizations, it is necessary to be able to measure *a priori* what is being asked of users [24]. In this regard, many approaches attempt to assess the acceptance of new technologies through functional, cognitive, or ergonomic analyses of their uses. However, on their own, these approaches are also struggling to produce a conceptual model whose ability to reflect the reality of practices depends on its interdisciplinary nature. A model that allows to do just that is a specific branch of sociology known as *practice studies* (or *practice-based studies*), which has resulted from the dialogue between multiple approaches, including not only *Science and Technology Studies* and innovation studies but also ethnomethodology and theories of distributed cognition that include more contributions of cognitive sciences and ergonomics [25]. Despite their differences, these disciplinary approaches all call for examination of how practices are engaged in and considered by the users themselves in their localized contexts. Inspired by these practice-based studies, this paper explains the success of digital health innovations through an analysis of the concrete activities that users, both health professionals and patients, must perform to make them work in a daily routine in their various socio-organizational contexts. Its purpose is to introduce the concept of *users' invisible work* and to develop a sociological framework for studying it in the case of very different technologies and across several dimensions.

Methods

This paper uses a three-part method to develop a sociological framework for studying *users' invisible work*. First, it includes a thematic literature review that was previously performed and published by one of the coauthors. In this review, Alexandre Mathieu-Fritz organized and discussed major themes emerging from the existing literature conducted by both French and Anglo-Saxon social scientists on digital health innovations integration into existing care organizations and practices [2].

The second part of the method is to extend this review to introduce definitions and applications of *users' invisible work* concept, which is coined at the crossroads of three conceptual models, each of which offers one keyword and one original work that serves as a starting point for building a framework. The first one is the *invisible work* model [26,27] used in the sociology of innovation, *Science and Technology Studies*, and sociology of work, to shed light on all efforts that players must deploy for an innovation to be successfully integrated in the existing organizations. The second model is that of *patient work* [23] coined in the sociology of professions and medical work, to recognize the key role of patients in their own health care. The third model is developed in a French corpus of sociology of work and economic sociology [28] and discussed in internet studies [29]. It refers to the unrecognized activities of consumers and web users that create value for private actors, both manufacturers and digital platforms. The purpose of this extension is not so much to present all these existing works as to identify the original contributions of these respective conceptual models in the study of different kind of work activities that users have to do to successfully integrate new technologies into their routines.

The third and last part of the method consists of producing a theoretical framework to study variations in the users' work according to different types of digital health technologies and users. This framework is built using empirical work performed by the co-authors themselves in three different fields, each of which refers to a particular configuration of digital health practices. It includes teleconsultations between health care professionals and patients (in dermatology, geriatrics, and mental health), tele-expertise between health care professionals (in dermatology), and self-monitoring by patients themselves (monitoring of diabetes and cystic fibrosis). The framework was thus constructed by putting different practice-based criteria identified in the first part of the method, in the thematic literature review, through the filter of these three very different cases. This paper does not present the results of these studies, which will be published separately. However, it relies on this empirical work to generate an analytical grid that can be applied to study work activities in very different technological configurations.

Results

Overview

Users' invisible work concept emanates directly from the perspective of the interactionist sociologist Anselm Strauss who coined the term *patient work* in the early 1980s. We first present the *patient work* model and its different applications in recent works on the use of digital health technologies by patients. We then extend this original definition not only to all technology users, both patients and professionals, but also to all kinds of work activities that remain invisible, including those related to more recent data-driven tracking apps. On the basis of this extended framework, we present an analytical grid that can be used both as an analytical tool in a research protocol and as a research agenda to assess the successful integration of digital health innovations into the existing health care organizations. The research protocol provides a tool to analyze this work through four dimensions related to the integration of new technologies (ie, organization of care, interaction between professionals as well as professionals and patients, clinical practice, and subjective experience of these users). As an agenda, it proposes to study the *users' invisible work* in very different technical configurations and socio-organizational contexts in which it is performed. This qualitative research package is expected to reveal different types of work activities as more subtle criteria to explain variations in uses according to users' specific contexts and to produce a comparative analysis between different type of work that various digital health technologies need them to do.

The Patient Work Model: Old Concepts, New Realities

In his work on medical worlds, Strauss drew attention to the fact that health care activities cannot be performed without the active participation of patients who have to perform a series of practical and cooperative tasks on a daily basis outside of health care facilities [23,30,31]. At first glance, it may seem peculiar to describe these activities as work. Generally, they are not considered as such, either by patients or health professionals [32]. However, this is justified in the case of chronic illnesses, which introduce profound changes in patients' daily practices and experiences [33]. Furthermore, these activities can be expected from chronic patients, and their key roles can be even recognized by professionals. According to Strauss, patients are central actors in the division of medical work [34]. They have to develop certain corporal attention and organize the daily management of their care (ie, *illness work*). Beyond concrete activities, they also have to develop different forms of reflexivity to reconfigure their inner experience of the illness [35], meaning the way they view and build their future lives (ie, *biographical work*).

In traditional care, *technical* tasks, which cover the care practices undertaken for the direct purpose of altering the course of the pathology, are separated from *other forms of work*. Among these, Strauss identifies *clinical safety work* (ie, anticipation, verification, evaluation, and, where necessary, correction), *machine work* (ie, maintenance, monitoring, use and, where necessary, repair), *comfort work* (ie, aiming to reduce pain or discomfort), *information work* (ie, requests, reports, and reassurances), and *sentimental work* (ie, improving emotions of patients and coping with the psychological effects) [31]. These different forms of work are profoundly affected by the integration of new technologies that displace the concrete efforts as well as bodily sensations and thoughts that underlie the management of the illness [36,37]. This implies new forms of task delegation where patients take charge of their own medical surveillance and become true *diagnostic agents* [38]. In the case of telemedicine, Oudshoorn observes, for example, a certain disciplinarization of patients who often end up establishing *self-management techniques* [19]. Hence, they must perform a certain number of diagnostic procedures, acquire new skills related to the use of devices and the interpretation of symptoms, and, *in conclusion*, translate this learning into practical knowledge that they can use in the daily care of their disease [39].

These observations are supported by recent research on data-driven self-tracking apps. For example, the work of Mathieu-Fritz and Guillot conducted on the case of diabetes and self-monitoring devices [40]. The authors illustrated how the use of this device introduces new forms of work, reflexivity, and self-knowledge associated with the illness experience. Through a comparative analysis of old and new glucose meters, the authors showed that the permanent sensor placed on the arm alleviated some of the usual constraints posed by the fingerstick capillary testing methods [40]. Each of these devices refers to a set of constraints that organize the illness experience and its daily management differently. These constraints are not only physical (ie, pain) and material (ie, maintenance and transport of equipment) but also organizational (ie, anticipation and planning), spatial (ie, conditions for use of the devices), symbolic (ie, disclosure of the illness), and social (ie, strategies of discretion and breaking of interactions). This comparison of different types of patient work reveals more subtle criteria for understanding variations in the use of continuous glucose readers: more discreet and rapid, they can be used in social spaces where glycaemia measurement was not previously practiced, allows for more frequent measurements to be taken, and develop a different approach to anticipating treatment. The different forms of activities that the devices allow to perform or avoid transform the reflexive work of patients and, thus, the way in which they administer their own care. These observations are supported by several studies conducted more broadly in the field of prevention and well-being, where new self-quantification practices are being developed [41]. The confrontation of individuals with a *quantified self* not only provides new information to guide individual choices in the management of care but also produces new representations that profoundly affect the subjective experience of the body, the illness, and its daily management [42].

The application of this old concept of patient work to new self-monitoring and self-care practices points to the reflexive nature of new connected devices that are used more frequently in the medical field. The very nature of this work is changing in accordance with the new principles of visibility and recognition of these activities [43]. That said, one must wonder to what extent the action of scanning a sensor, or, even more unconsciously, the action of leaving mobile apps programmed

by default, such as Apple's health watch, to collect and record data, can be studied as new forms of work. This debate, which is at the center of current concerns on the development of digital platforms, renews the interest and heuristic value of this concept to understanding how new *reflexive technologies* [44] affect the organization, practice, and experience of care [45,46]. From a critical perspective, some denounce the tendency of *techno-utopic* discourses to obscure the social, cultural, political, and economic dimensions of self-care technologies. Far from being neutral, these are, in fact, caught up in power relations [1,47]. This idea has been extensively developed in research inspired by *Science and Technology Studies*, which reports on the use of self-tracking devices as a reconfiguration of the physician-patient relationship through a new set of activities to generate and interpret data [48]. Further studies on daily data transmission devices to health care professionals show, for example, that patients can negotiate to redefine the objectives associated with the device by developing unexpected uses to prevent data transmission [49]. The merit of practice-based studies reveals itself through these works that study self-quantification as a particular form of work that must be performed *on* and *with* data [50], not only to contextualize them but also to articulate them with other forms of knowledge that supports the daily care practices [51]. This may represent one of the reasons why it is necessary to extend the analytical framework not only to various users (including health professionals) but also to different dimensions of their work, to include their reflexivity.

An Extended Framework for Studying Users' Invisible Work

Patient work is a powerful concept for highlighting and recognizing patients' role and engagement in their own care. However, an extension is necessary to use it in the assessment of digital health innovations that requires considering all users, not only patients but also health care professionals who must make these devices work during their daily practice. For instance, Oudshoorn shows through the case of telemonitoring that physician not only interpret electrocardiograms but also take on a series of tasks unforeseen by the designers. They assist and reassure patients in the use of medical technology, ease concerns, and contribute to building trust in medical technology [19,52,53]. For the author, this is akin to *affective work*, which is equivalent to the *sentimental work* in Strauss' classification [54]. Here, the notion of user work is clearly different from that of usability. The study of this work is not so much about the capacity or efficiency of uses as about the set of adjustments that users must make to resolve different types of conflicts that these technologies can introduce in the existing context. In that sense, studying users' work is first, to understand how the integration of new technology transforms existing work activities.

In that regard, research have shown that new digital health technologies do not simply equip practices from *outside* but contribute to transform them in a profound way, from the *inside*. Nicolini's work is particularly instructive in this regard. By *zooming in* on the practices and *zooming out* on the broader organizational context [55], the author highlights how work is redistributed among practitioners, as well as with artifacts (ie, *nonhumans*). In this context, the adoption of these devices depends on a series of learnings, settings, and adjustments that must be made in users' working practices [13]. A typical case is that of teleconsultations during which the roles played by each participant will be different from those usually played in a face-to-face setting [56]. Similar to other scholars, Nicolini observed that professional practices were transformed in situations where new forms of task distribution and delegation occur not only between physicians but also between physicians and paramedical professions (ie, nurses and caregivers) [57]. In some cases, important tasks that are considered to be central in the professional practice (ie, *true work* [58], as opposed to *dirty work* [59], which is considered to be peripheral) can be delegated to patients themselves.

These new forms of cooperation can also be observed among actors from different specialties who are placed at different hierarchical levels. In these configurations, they can contribute to the sharing of medical and clinical knowledge and enable certain delegates to *increase in expertise.* Moreover, it can also redefine the boundaries of their professional territory and identity [60]. Research on telemedicine devices show that "the question is not so much what the new activities allow, but rather to what extent they allow existing and appropriate forms of professional knowledge and practice to be put in place" [5]. However, this observation must be nuanced. Professionals may also get round the specific constraints of telemedicine (eg, physical distance and deprivation of *sensory inputs* [19,61]), for example, to develop new therapeutic techniques in the context of teleconsultations in mental health, by testing sooner than usual their *clinical intimacy* or by asking questions more frequently [62]. Thus, the integration of new technologies may end up producing new practices. Here, the technology itself becomes a full actor with whom one, not only redistributes existing work but also jointly produces new information that needs to be interpreted. These new forms of work become just as apparent to patients, for example, in the case of quantification devices that introduce new indicators in self-monitoring practices.

The patient work model must be extended to include not only existing work activities that have to evolve with the integration of new technologies but also new activities that users must perform and skills they need to acquire to use these technologies during their daily activities. Thus, the study of users' work invites a more systematic look at the articulation and coordination of different types of tasks within the socio-organizational context in which technologies are being integrated and used. The work of Mathieu-Fritz et al sheds light in this respect. First, the authors show that coordinating physicians play a key role in solving difficulties and problems that the designers did not foresee [52]. The authors also highlight different types of *framing* work with the purpose of establishing rules and guidelines and ensuring that users become autonomous [63-65]. Technical framing aims to teach how to use devices effectively (eg, synchronized use of mobile camera, dermatoscope, and spirometer), whereas social framing is about establishing ways to interact efficiently during teleconsultations (eg, presenting oneself precisely and systematically, speaking louder, and articulating better). Clinical framing defines the

protocols to follow (eg, patients' clinical history, auscultation, diagnosis, prescriptions, or indications), whereas organizational framing involves cultivating appropriate attitudes and behaviors (eg, being punctual, completing forms and, reminding appointments), to ensure that all actors are present at a given time on both sides of the camera.

The authors are particularly attentive to the additional coordination activities that medical and paramedical actors must perform for the day-to-day operation of these devices [27]. Referring to the work of Strauss, they emphasized the importance of *articulation work* [66,67]. In their research on the medical world, Strauss et al [68] define the social organization of care as a *negotiated order* that results from the constant efforts of the actors to produce, often informally, an agreement on the best ways to organize tasks daily. As Star [26] reminds us, this articulation work is beyond the scope of rational work organizations. It consists of organizing, coordinating, and combining different types of activities conducted by various actors (eg, a clinical examination, an x-ray, a blood or blood pressure test, prescription, and administration of medication) to ensure that "the staff's collective efforts add up to more than discrete and conflicting bits of accomplished work" [31]. The integration of new technologies has transformed coordination work. New coordination tasks are also required to ensure day-to-day operation. These activities are important, even sometimes decisive, so much so that certain works identify their intensity as a rejection factor of new devices [69].

Studying all this background work, most of which remains invisible, is crucial to account for the efforts required to make technologies work. However, most of these work forms are difficult to account for in the design and integration process of new technologies [70,71]. On the basis of the lessons learned from this literature, we propose to define the scope of the *users' invisible work* concept as all the concrete and reflexive activities that both health care professionals and patients perform to make digital health technologies work within their daily routines around health care. One of the original contributions of this framework is to emphasize the importance of reflexivity and experience forms that develop through local and subjective confrontations with the technologies in the trajectory of these innovations. The notion of reflexivity is used here in its two registers. Retrospective reflexivity refers to the ability to return from experiences and past events. Similar to immediate reflexivity, lessons learned from previous experiences serve to restructure action as they unfold [72]. The reflexive dimension is becoming increasingly important with data-driven apps, either because this work is increasingly automated by connected and intelligent objects, to the point that this is done sometimes entirely out of awareness or, on the contrary, because the data are increasingly visible to the patients who produce, interpret, and communicate it. In any case, one of the main contributions of this extended framework concerns precisely the way it suggests analyzing the work activities as they are performed by users, but also, and more importantly, their reflexivity (ie, what they think and feel as they perform them). It is only then that some nuances can be explored to understand resistance to technology. This is the case for some health professionals who reject new technologies not because they resist change but because they believe that these do not allow them to do what they consider to be the core of their work, their *real work* [73]. In other words, rejection can express a transposability issue where users consider that they cannot work or care with the same quality they would usually expect to have. This is clearly a separate issue from a social resistance to change.

A Sociological Research Package to Assess Digital Health Innovations

This theoretical framework can be used both as an analytical tool in a research protocol and as a qualitative research agenda to assess the chances that digital health technologies have to be successfully integrated into existing health care organizations. In a research protocol, for any given technology, it proposes to produce an overview of different actors who constitute the sociotechnical network around their use. All user types (eg, physicians, patients, and family caregivers) and material supports (ie, technical objects, instructions, and protocols) must be fully included as human and nonhuman actors, which must be aligned to some extent for innovations to be successfully integrated into daily routines [17]. This ecological approach must also be applied to cover a variety of tasks and activities without which innovation is difficult to develop or abandoned. In this regard, all forms of work (eg, articulation work, patient work, and information work) and their various definitions (eg, well-done or acceptable work, desired or satisfactory work and prevented work [74]) must be considered. Overall, the goal is to capture the diversity of the actors performing a range of different tasks and activities, both practical and reflexive in nature, to integrate new technologies into existing health care organizations (Textbox 1).

Textbox 1. An ecological approach to the diversity of digital technologies, users, and work.

Types of technology

- Equipment sets (telepresence station, teleconsultation booth, telemedicine trolley, etc)
- Connected medical tools (spirometer, stethoscope, otoscope, ultrasound scanner, electrocardiogram, dermatoscope, etc)
- Mobile apps (crowdsourcing, quantification, gaming, self-help, etc)
- Web-based platforms and software services (networking, forums, videoconference, etc)
- Connected objects (sensors, readers, automatons, robotics, AI, vocal assistants, chatbots, carebots, wearables, etc)

Types of users involved

- Health professionals (specialized or general practitioners, nurses, etc)
- Allied health professionals (paramedics, therapists, assistants, auxiliary personnel, social workers, etc)
- Patients (chronic, nonchronic or acute, emergency, etc)
- Healthy individuals (eg, sportsmen and women)
- Family caregivers (parents, partners, friends, etc)

Types of tasks and work

- Translation work (eg, alignment and sensemaking)
- Coordination work (eg, articulation, framing)
- Patient work (eg, illness work, sentimental work, and information work)
- Users work (concrete efforts such as taking measurements, ticking boxes, or sharing data, but also different reflexivity forms)

To do so, this framework investigates the circumstances under which this work is performed through four dimensions related to the integration of new technologies (ie, organizational, interactional, practical, and experiential). The first dimension, organizational, concerns coordination modalities of health care. The term organization refers to the physical and material environment in which digital health technologies are integrated and whose level of saturation can be an important factor in users' rejection. It also refers to all the additional coordination activities that users must perform, such as articulation work that realigns affected *lines of work*, and framing work that defines rules to normalize uses. This organizational dimension relates to broader changes in the care pathway due to new technologies that define the scope and composition of work groups differently. This is, for example, the case of teleconsultation that allows health care professionals to be brought together with different specialties and sometimes actors who were not participating in traditional consultations, thus contributing to the formation of new micro–work collectives and to the evolution of patient care pathways [60,65].

The second dimension is that of interactions between various actors within health care organizations and with patients. It draws attention to the place of these actors in the whole system of interactions that is mobilized around patients' care [75]. It first includes new modalities in which these actors interact with each other through new technologies that tend to open up the singular colloquium between the physician and patient and change the relationship between the two by adding new actors, both from the medical side and the patients' side. In this regard, Oudshoorn refers to a major transformation in the geography of responsibilities [76] based on a new spatial and temporal distribution of activities related to care delivery. In this *techno-geography*, new proximities may develop between patients and health care professionals [77]. Oudshoorn insists on the way in which the *digital proximity* established through new telemedicine devices highlights "protocol-driven communication, daily surveillance, and self-care" [52] as full-fledged dimensions of the interactions that forge remote care relationships. As it is, this new type of proximity sets aside the psychosocial dimensions of traditional face-to-face care, which requires considering extramedical aspects. These transformations also occur at a more symbolic level. For example, some studies show that hierarchical representations or expert legitimacy can be at stake between professionals who use digital health technologies. Some can associate the use of certain technologies with a lack of professionalism. For example, some mental health professionals tend to hide their teleconsulting practices, which are not well regarded in their professional environment [62]. These symbolic effects also concern patients whose use of these technologies can vary according to the social environment in which they have to make them work. This is the case for diabetic patients who have to use a glucometer that not only discloses their illness but also disrupts social interactions in which they can be engaged [40].

The third dimension of user work is clinical practice, that is, activities directly associated with the diagnosis and medical treatment of patients. It includes new forms of distribution and delegation of tasks between physicians and allied professions [57] and with patients [19] that may enable sharing medical and technical knowledge and increasing expertise. Some users may also end up working twice as much to integrate these devices (ie, patient's double work) [40]. Furthermore, this redistribution of tasks transforms the broader topography and temporality of care activities, both for the professionals and patients. In this

regard, Nicolini showed that the daily exercise of telemedicine is characterized by a *stretching out* of sociomaterial arrangements in space-time and consequently an *expansion* of health care activities [57]. This means that these reconfigurations go far beyond the simple spatiotemporal redistribution of existing activities. They contribute to transforming the social spaces in which these activities are performed. Oudshoorn showed how the homes of older adults who are hospitalized at home with the help of telemonitoring devices becomes a hybrid place in which conflictual logics of care and aesthetics can coexist [76]. This new geography profoundly affects the object and content of these activities. It transforms the relationships between health care professionals by redistributing their work differently, sometimes with artifacts.

The fourth dimension is the subjective experience of these users, which refers to their feelings and representations that they develop within and through their practice. In fact, the integration of new technologies alters not only concrete work activities during the clinical examination but also professional judgments involved in the formulation of a diagnosis. For instance, building trust seems to be a core issue for health professionals who develop an *experimental attitude* [40] toward these devices. As mentioned above in the case of teleconsultations, professionals who engage in such practices with an unclear status question the extent to which previous practices can be transposed into the new framework. For example, they consider the problem of accountability for encountered difficulties. They also consider the costs of this transposition in economic (related to the equipment that needs to be acquired and their compatibility or interoperability with the existing ones), organizational (related to the time and resources needed for preparation), cognitive (related to learning and training needs), and social and symbolic (related to the image conveyed by the device) terms. This is not so different for patients whose subjective experience also plays a key role in how they manage their own health care. Indeed, the experience of illness encompasses the patient's work, but goes far beyond it. It refers to the whole inner experience of the disease, to all that is felt (eg, bodily sensations) and thought (eg, what one would like to do, or, on the contrary, to avoid) subjectively. Overall, the experience of the disease refers to the social definition of oneself (eg, when one tries to hide one's illness and when one talks about it or shows it in some way). New technologies also challenge these reflexive activities. An example is given by Van Hout in his work on a telemonitoring device that has been used with homecare patients who were minimizing their symptoms or even omitting to tell palliative care nurses [37]. However, the device that allowed patients to assess the severity of their various symptoms on a scale of 0 to 5 has not always worked, as patients have criticized the device for reminding them of symptoms they did not yet have or were at risk of having (ie, display effect). Therefore, *forgetting* the device, and thus the disease, can become an important factor in their adoption by patients [78].

This paper proposes to study *users' invisible work* through these four dimensions. Table 1 presents these practice-based criteria in a chart that can be applied as a tool in research protocols. However, there is no single recipe or exclusive way of applying this grid, which is rather a collection of criteria that can be combined as needed, depending on the technologies, contexts of use, and users being studied.

Table 1. An analytical grid to study users works through its four dimensions.

Users' work and criteria	Application examples
Organizational configurations	
Ecology of artifacts	Interoperability between information systems; unforeseen problem-solving; degree of saturation as a factor of rejection
Additional coordination work	Framing work (social, technical, clinical and organizational) to establish the rules of use; intensity of the articulation work as a rejection factor
Recomposition of the care pathway	Scope and composition of new work collectives; forms and conditions of preventative actions
Interactional settings	
System and modalities of interaction	Opening of the singular colloquium of patient-physician to new actors; digital proximity with the patients
Forms of cooperation	Delegation of tasks and sometimes even "real work" to other professionals and artifacts; patients as diagnostic agents
Symbolic effects	Professionals' legitimacy among colleagues; patients' illness in their social environment
Clinical practices	
Topography and temporality	Duplication of the therapeutic space; "expansion" of health care activities; new constraints that organize patients' reflexive work
Learning or cognitive aspects	Knowledge barriers; "increase in expertise"; double work of patients; disciplinarization of patients
Consideration of the psychosocial aspects	Reduced in digital proximity
Subjective experiences	
Commitment and trust in fuzzy practices	Experimental attitude; Transposability issues; economic, organizational cognitive, social and symbolic costs of transposition; Accountability problems
"Forgetting" about the disease or device	New information produced by the device (display effect); representations that affect the experience and the daily management of illnesses

Furthermore, this framework can also be applied as an agenda that calls for further research on the integration phase of various digital health technologies into work systems (eg, connected devices, data collecting and displaying apps, and more infrastructural telemedicine projects, such as teleconsultation cabins). The purpose of this agenda is to redefine some of the *a priori* distinctions (ie, telehealth vs digital health) through variations that can be observed at the level of the different work forms that require users to accomplish in very different configurations. This agenda should include studies of technologies that are used in different spaces, both very localized and spontaneous ones, such as teleconsultations, and mobile and ubiquitous ones, such as self-tracking devices. This agenda should also contain studies on apps in which data can be more or less important to explore the various effects of reflexive technologies on the self-knowledge of patients associated with their illness experience. It must cover devices used in different medical conditions, for example, for rare and common pathologies, to identify how technology adoption modes vary with the rarity of a disease. A preliminary list of such variables is presented in Table 2, which aims to cover a very wide range of configurations, including spatiotemporal, technical, social, and medical variations, to develop this comparative approach between different work forms required in the context of their uses.

Table 2. Variables in the use of digital health technologies.

Variables	Description
Spatial-temporal	
Topography	Single place (eg, fixed teleconsultation cabin), semi mobile (eg, telemedicine trolley), multiple place (eg, mobile apps)
Frequency and punctuality	Frequent (eg, multiple times a day) or rare (eg, once a month), precise (eg, on appointment) or approximate (eg, each morning)
Duration	Continuous (eg, wearable devices and sensors) or punctual (eg, teleconsultations)
Technical	
Autonomy	Automated (eg, parameterization) or triggered actions (eg, synchronization)
Visibility	Visible (eg, reader) or invisible (eg, implants)
Connectivity	Autonomous (eg, pedometer) or connected devices (eg, smart watches)
Artifactuality and agentivity	Cognitive (eg, stocking data) or interactive (eg, following feeds), passive (eg, visual representations) or active (eg, alerts and notifications)
Social	
Context of use	Routine check-up (eg, blood work), emergency (eg, allergy crises) or well-being (eg, sport diet)
Modality of use	Individual (eg, self-help, measurements, etc.) or collective (data sharing applications, dyadic or triadic tele-consultations, etc)
Type of actors	Professional caregivers (interaction with physicians, nurses, etc) or family members (assistance by parents, friends, etc)
Medical	
Pathology	Chronic (eg, diabetes) or acute (eg, heart spasm), rare (eg, cystic fibrosis) or common (eg, kidney disease)
Specialty	Primary care (eg, general medicine), secondary care (eg, specialists), tertiary care and hospitalization (eg, surgery)
Type of treatment	Preventive (eg, dietary programs), curative (eg, physical therapy), palliative or hospice (eg, cancer treatment)

With this agenda, it becomes possible to produce a comparative study of users' work variations in the case of different digital health practices and explain the success or failure of new technologies, according to more or less data-driven, real-time, frequent, or visible nature of activities they require users to do.

Discussion

Principal Findings

This paper draws attention to the plurality of most invisible and unrecognized tasks and activities that need to be performed by professionals and patients to make these devices work in various contexts. As a result, it proposes a theoretical framework that allows the assessment of digital health innovations by studying these work activities under different settings and the transformations they introduce through four main dimensions: organizations, practices, interactions, and experiences. For any given technology, it can be used as a tool in a research protocol to study concrete work activities performed by users to integrate them into their daily lives. It can also be applied as a research agenda that covers a wide range of technological configurations to develop a comparative approach through practice-based criteria.

Main Contributions

This theoretical framework makes three main contributions to the literature. First, it reports on professional practices and patient experiences jointly and in an articulated way. Second, it seeks to guide analytical practices by further operationalizing the theoretical approaches of practice-based studies in a methodological framework to help better understand the successful integration of new technologies into existing health organizations. Third, it redefines traditional categories such as *technology acceptance* or *resistance to change*, through an analysis that remains more faithful to the activity and the concrete reality of the users themselves.

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Conflicts of Interest

None declared.

References

1. Lupton D. Towards critical digital health studies: Reflections on two decades of research in health and the way forward. Health (London) 2016 Jan;20(1):49-61. [doi: 10.1177/1363459315611940] [Medline: 26487686]
2. Mathieu-Fritz A, Gaglio G. In search of the sociotechnical configurations of telemedicine. Réseaux 2018;1(207):27-63. [doi: 10.3917/res.207.0027]
3. May C, Harrison R, Finch T, MacFarlane A, Mair F, Wallace P. Understanding the normalization of telemedicine services through qualitative evaluation. J Am Med Inform Asso 2003;10(6):596-604 [FREE Full text] [doi: 10.1197/jamia.M1145] [Medline: 12925553]
4. Harrison RM, Clayton W, Wallace P. Is there a role for telemedicine in an urban environment? J Telemed Telecare 1997;3 Suppl 1:15-17. [doi: 10.1258/1357633971930832] [Medline: 9218369]
5. May C, Gask L, Atkinson T, Ellis N, Mair F, Esmail A. Resisting and promoting new technologies in clinical practice: The case of telepsychiatry. Soc Sci Med 2001 Jun;52(12):1889-1901. [doi: 10.1016/s0277-9536(00)00305-1] [Medline: 11352414]
6. Bashshur RL, Shannon GW, Smith BR, Woodward MA. The empirical evidence for the telemedicine intervention in diabetes management. Off J Am Telemed Asso 2015 May;21(5):321-354 [FREE Full text] [doi: 10.1089/tmj.2015.0029] [Medline: 25806910]
7. Bashshur RL, Howell JD, Krupinski EA, Harms KM, Bashshur N, Doarn CR. The empirical foundations of telemedicine interventions in primary care. Off J Am Telemed Asso 2016 May;22(5):342-375 [FREE Full text] [doi: 10.1089/tmj.2016.0045] [Medline: 27128779]
8. Williams T, May C, Mair F, Mort M, Gask L. Normative models of health technology assessment and the social production of evidence about telehealth care. Health Policy 2003 Apr;64(1):39-54. [doi: 10.1016/s0168-8510(02)00179-3] [Medline: 12644327]
9. Kidholm K, Clemensen J, Caffery LJ, Smith AC. The Model for Assessment of Telemedicine (MAST): A scoping review of empirical studies. J Telemed Telecare 2017 Oct;23(9):803-813. [doi: 10.1177/1357633X17721815] [Medline: 28758525]
10. Pols J. Care at a Distance: On the Closeness of Technology. Amsterdam: Amsterdam University Press; 2012.
11. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond adoption: A new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. J Med Internet Res 2017 Nov 01;19(11):e367 [FREE Full text] [doi: 10.2196/jmir.8775] [Medline: 29092808]
12. Nicolini D. The work to make telemedicine work: A social and articulative view. Soc Sci Med 2006 Jun;62(11):2754-2767. [doi: 10.1016/j.socscimed.2005.11.001] [Medline: 16343724]
13. Akrich M, Méadel C. Problématiser la question des usages. Sciences Sociales et Santé. 2004. URL: https://www.persee.fr/doc/sosan_0294-0337_2004_num_22_1_1606 [accessed 2021-09-21]
14. Akrich M, Callon M, Latour B. Les utilisateurs, acteurs de l'innovation. In: Sociologie de la Traduction : Textes Fondateurs. Paris: Presses des Mines; 2013:253-265.
15. Callon M. Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of St Brieuc Bay. The Sociological Review 2015 May 29;32(1_suppl):196-233. [doi: 10.1111/j.1467-954x.1984.tb00113.x]
16. Akrich M, Callon M, Latour B. Sociologie de la Traduction. Textes Fondateurs. Paris: Presses des Mines; 2006.
17. Akrich M, Callon M, Latour B. A quoi tient le succès des innovations ? 1 : L'art de l'intéressement; 2 : Le choix des porte-parole. Gérer et Comprendre Annales des Mines 1988:4-17-14-29. [doi: 10.3917/geco]
18. Sicotte C, Lehoux P. La télémédecine et la transformation des formes organisationnelles de l'hôpital. In: L'hôpital en Restructuration : Regards Croisés Sur la France et le Québec. Montréal: Les Presses universitaires de Montréal; 2005:163-184.
19. Oudshoorn N. Diagnosis at a distance: The invisible work of patients and healthcare professionals in cardiac telemonitoring technology. Sociol Health Illness 2008 Mar;30(2):272-288 [FREE Full text] [doi: 10.1111/j.1467-9566.2007.01032.x] [Medline: 18290936]
20. Barlow J, Bayer S, Curry R. Implementing complex innovations in fluid multi-stakeholder environments: Experiences of 'telecare'. Technovation 2006 Mar;26(3):396-406. [doi: 10.1016/j.technovation.2005.06.010]
21. Freidson E. Profession of Medicine: A Study of the Sociology of Applied Knowledge. Chicago: University of Chicago Press; 1988.
22. Lupton D. Beyond techno-utopia: Critical approaches to digital health technologies. Societies 2014 Dec 08;4(4):706-711. [doi: 10.3390/soc4040706]
23. Strauss AL, Fagerhaugh S, Suczek B, Wiener C. The work of hospitalized patients. Soc Sci Med 1982 Jan;16(9):977-986. [doi: 10.1016/0277-9536(82)90366-5]
24. Yin K, Jung J, Coiera E, Laranjo L, Blandford A, Khoja A, et al. Patient work and their contexts: Scoping review. J Med Internet Res 2020 Jun 02;22(6):e16656 [FREE Full text] [doi: 10.2196/16656] [Medline: 32484449]
25. Licoppe C. In the "activity square": International perspectives on labor, work and activity. Sociologie du Travail 2009 Nov;51:155-169. [doi: 10.1016/j.soctra.2009.06.024]
26. Star S. The sociology of the invisible: The primacy of work in the writings of Anselm Strauss. In: Maines D, editor. Social Organization and Social Process: Essays in Honor of Anselm Strauss. Hawthorne, NY: Aldine de Gruyter; 1991:265-283.
27. Star SL, Strauss A. Layers of silence, arenas of voice: The ecology of visible and invisible work. Comput Support Coop Work (CSCW) 1999 Mar;8(1-2):9-30. [doi: 10.1023/a:1008651105359]

28. Dujarier M. The three sociological types of consumer work. J Cons Culture 2014 Apr 08;16(2):555-571. [doi: 10.1177/1469540514528198]
29. Cardon D, Casilli A. Qu'est-ce que le Digital Labor ?. Bry-sur-Marne: INA Éditions; 2015.
30. Corbin J, Strauss A. Managing chronic illness at home: Three lines of work. Qual Sociol 1985;8(3):224-247. [doi: 10.1007/bf00989485]
31. Strauss A. Social Organization of Medical Work. Chicago: University of Chicago Press; 1985.
32. Wiener C. Untrained, unpaid, and unacknowledged: The patient as worker. Arthritis Care Res 1989 Mar;2(1):16-21. [doi: 10.1002/anr.1790020105] [Medline: 2488117]
33. Bury M. Chronic illness as biographical disruption. Sociol Health Illness 1982 Jul;4(2):167-182 [FREE Full text] [Medline: 10260456]
34. Strauss A. La Trame de la Négociation: Sociologie Qualitative et Interactionnisme. Paris: Harmattan; 1992.
35. Pierret J. The illness experience: State of knowledge and perspectives for research. Sociol Health Illness 2003;25:4-22 [FREE Full text] [doi: 10.1111/1467-9566.t01-1-00337] [Medline: 14498927]
36. Strauss AL, Fagerhaugh S, Suczek B, Wiener C. Patients' work in the technologized hospital. Nurs Outlook 1981 Jul;29(7):404-412. [Medline: 6910640]
37. Hout AV, Willems D, Hettinga M, Pols J, Libbrecht E. Why expectations of telecare are often wrong. Réseaux 2018;1(207):95-121. [doi: 10.3917/res.207.0095]
38. Mort M, Finch T, May C. Making and Unmaking Telepatients: Identity and governance in new health technologies. Sci Technol Hum Val 2007 Dec 19;34(1):9-33. [doi: 10.1177/0162243907311274]
39. Pols J. Knowing patients: Turning patient knowledge into science. Sci Technol Hum Val 2013 Sep 13;39(1):73-97. [doi: 10.1177/0162243913504306]
40. Mathieu-Fritz A, Guillot C. Diabetes self-monitoring devices and transformations in "patient work". Revue d'anthropologie des connaissances 2017;11(4):641-675. [doi: 10.3917/rac.037.k]
41. Gilmore JN. Everywear: The quantified self and wearable fitness technologies. New Media Society 2016 Jul 10;18(11):2524-2539. [doi: 10.1177/1461444815588768]
42. Pantzar M, Ruckenstein M. Living the metrics: Self-tracking and situated objectivity. Digital Health 2017;3:1-10 [FREE Full text] [doi: 10.1177/2055207617712590] [Medline: 29942604]
43. Fiske A, Prainsack B, Buyx A. Data Work: Meaning-making in the era of data-rich medicine. J Med Internet Res 2019 Jul 09;21(7):e11672 [FREE Full text] [doi: 10.2196/11672] [Medline: 31290397]
44. Licoppe C. Formes de la présence et circulations de l'expérience. De Jean-Jacques Rousseau au « Quantified Self ». Réseaux 2013;182(6):21-55. [doi: 10.3917/res.182.0021]
45. Lupton D. Self-Tracking Modes: Reflexive self-monitoring and data practices. SSRN Electronic J 2014:e19. [doi: 10.2139/ssrn.2483549]
46. Cahour B, Licoppe C. Confrontations with traces of one's own activity. Revue d'anthropologie des connaissances 2010;4(2):243-253. [doi: 10.3917/rac.010.000a]
47. Lupton D. Critical perspectives on digital health technologies. Sociol Compass 2014 Dec 04;8(12):1344-1359. [doi: 10.1111/soc4.12226]
48. Bruni A, Rizzi C. Looking for Data in Diabetes Healthcare: Patient 2.0 and the re-engineering of clinical encounters. Sci Technol Stud 2013 Jan 01;26(2):29-43. [doi: 10.23987/sts.55297]
49. Piras EM, Miele F. Clinical self-tracking and monitoring technologies: Negotiations in the ICT-mediated patient–provider relationship. Health Sociol Rev 2016 Aug 05;26(1):38-53. [doi: 10.1080/14461242.2016.1212316]
50. Almalki M, Gray K, Martin-Sanchez F. Activity theory as a theoretical framework for health self-quantification: A systematic review of empirical studies. J Med Internet Res 2016 May 27;18(5):e131 [FREE Full text] [doi: 10.2196/jmir.5000] [Medline: 27234343]
51. Lupton D, Pink S, LaBond C, Sumartojo S. Digital traces in context : Personal data contexts, data sense and self-tracking cycling. Int J Commun 2018;12:647-665 [FREE Full text]
52. Oudshoorn N. Physical and digital proximity: Emerging ways of health care in face-to-face and telemonitoring of heart-failure patients. Sociol Health Illness 2009 Apr;31(3):390-405 [FREE Full text] [doi: 10.1111/j.1467-9566.2008.01141.x] [Medline: 19144084]
53. Oudshoorn N. Telecare Technologies and the Transformation of Healthcare. UK: Palgrave Macmillan; 2011.
54. Strauss A, Fagerhaugh S, Suczek B, Wiener C. Sentimental work in the technologized hospital. Sociol Health Illness 1982 Nov;4(3):78-254 [FREE Full text] [doi: 10.1111/1467-9566.ep10487954] [Medline: 10260459]
55. Nicolini D. Zooming In and Out: Studying practices by switching theoretical lenses and trailing connections. Organ Stud 2010 Jan 14;30(12):1391-1418. [doi: 10.1177/0170840609349875]
56. Pappas Y, Seale C. The opening phase of telemedicine consultations: An analysis of interaction. Soc Sci Med 2009 Apr;68(7):1229-1237. [doi: 10.1016/j.socscimed.2009.01.011] [Medline: 19201514]
57. Nicolini D. Stretching out and expanding work practices in time and space: The case of telemedicine. Hum Rel 2016 Apr 22;60(6):889-920. [doi: 10.1177/0018726707080080]

58. Bidet A. Qu'est-ce que le vrai boulot ? Le cas d'un groupe de techniciens. Sociétés Contemporaines 2010;2(78):115-135. [doi: 10.3917/soco.078.0115]
59. Hughes EC. Good people and dirty work. Soc Problem 1962 Jul;10(1):3-11. [doi: 10.1525/sp.1962.10.1.03a00010]
60. Mathieu-Fritz A, Esterle L. Changes in professional practices during medical teleconsultations. Revue Française de Sociologie 2013;54(2):303-329. [doi: 10.3917/rfs.542.0303]
61. Pols J. Wonderful Webcams: About active gazes and invisible technologies. Sci Technol Hum Val 2010 Aug 03;36(4):451-473. [doi: 10.1177/0162243910366134]
62. Mathieu-Fritz A. Teleconsultation in mental health. Réseaux 2018;1(207):123-164. [doi: 10.3917/res.207.0123]
63. Esterle L, Mathieu-Fritz A, Espinoza P. L'impact des consultations à distance sur les pratiques médicales. Vers un nouveau métier de médecin ? Revue Francaise Des Affaires Sociales 2011;1(2):79. [doi: 10.3917/rfas.112.0063]
64. Mathieu-Fritz A, Esterle L. Les transformations des pratiques professionnelles lors des téléconsultations médicales: Coopération interprofessionnelle et délégation des tâches. Revue Française de Sociologie 2013;54(2):303-329. [doi: 10.3917/rfs.542.0303]
65. Esterle L, Mathieu-Fritz A. Teleconsultation in geriatrics: Impact on professional practice. Int J Med Inform 2013 Aug;82(8):684-695. [doi: 10.1016/j.ijmedinf.2013.04.006]
66. Strauss A. The articulation of project work: An organizational process. Sociol Q 1988;29(2):163-178. [doi: 10.1111/j.1533-8525.1988.tb01249.x]
67. Corbin JM, Strauss AL. The articulation of work through interaction. Sociol Q 1993;34(1):71-83. [doi: 10.1111/j.1533-8525.1993.tb00131.x]
68. Strauss A. Negotiations: Varieties, Contexts, Processes and Social Order. San Francisco: Jossey-Bass Inc; 1978.
69. Sicotte C, Lehoux P. Teleconsultation: Rejected and emerging uses. Methods of Information in Medicine 2003;42(4):451-457. [Medline: 14534649]
70. Valdez RS, Holden RJ, Novak LL, Veinot TC. Transforming consumer health informatics through a patient work framework: Connecting patients to context. J Am Med Inform Assoc 2015 Jan;22(1):2-10. [doi: 10.1136/amiajnl-2014-002826] [Medline: 25125685]
71. Valdez RS, Holden RJ, Novak LL, Veinot TC. Technical infrastructure implications of the patient work framework. J Am Med Inform Assoc 2015 Apr;22(e1):213-215 [FREE Full text] [doi: 10.1093/jamia/ocu031] [Medline: 25665705]
72. Schön D. The Reflective Practitioner: How Professionals Think in Action. New York: Basic Books; 1983.
73. Bidet A. L'engagement dans le travail. Qu'est-ce que le vrai boulot ?. Paris: Presses Universitaires de France; Jun 15, 2012.
74. Clot Y. Le Travail à Cœur : Pour en Finir Avec Les Risques Psychosociaux. Paris: Découverte; 2010.
75. Hughes E. The Sociological Eye. New Brunswick, US: Routledge; 1984.
76. Oudshoorn N. How places matter: Telecare technologies and the changing spatial dimensions of healthcare. Soc Stud Sci 2012 Feb;42(1):121-142. [doi: 10.1177/0306312711431817] [Medline: 22530385]
77. Pols J, Willems D. Innovation and evaluation: Taming and unleashing telecare technology. Sociol Health Illness 2011;33(3):484-498 [FREE Full text] [doi: 10.1111/j.1467-9566.2010.01293.x] [Medline: 21241338]
78. Ancker JS, Witteman HO, Hafeez B, Provencher T, Van de Graaf M, Wei E. "You Get Reminded You're a Sick Person": Personal data tracking and patients with multiple chronic conditions. J Med Internet Res 2015;17(8):e202 [FREE Full text] [doi: 10.2196/jmir.4209] [Medline: 26290186]

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Original Paper

Recruiting Participants for Population Health Intervention Research: Effectiveness and Costs of Recruitment Methods for a Cohort Study

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Abstract

Background: Public health research studies often rely on population-based participation and draw on various recruitment methods to establish samples. Increasingly, researchers are turning to web-based recruitment tools. However, few studies detail traditional and web-based recruitment efforts in terms of costs and potential biases.

Objective: This study aims to report on and evaluate the cost-effectiveness, time effectiveness, and sociodemographic representation of diverse recruitment methods used to enroll participants in 3 cities of the Interventions, Research, and Action in Cities Team (INTERACT) study, a cohort study conducted in Canadian cities.

Methods: Over 2017 and 2018 in Vancouver, Saskatoon, and Montreal, the INTERACT study used the following recruitment methods: mailed letters, social media (including sponsored Facebook advertisements), news media, partner communications, snowball recruitment, in-person recruitment, and posters. Participation in the study involved answering web-based questionnaires (at minimum), activating a smartphone app to share sensor data, and wearing a device for mobility and physical activity monitoring. We describe sociodemographic characteristics by the recruitment method and analyze performance indicators, including cost, completion rate, and time effectiveness. Effectiveness included calculating cost per completer (ie, a participant who completed at least one questionnaire), the completion rate of a health questionnaire, and the delay between completion of eligibility and health questionnaires. Cost included producing materials (ie, printing costs), transmitting recruitment messages (ie, mailing list rental, postage, and sponsored Facebook posts charges), and staff time. In Montreal, the largest INTERACT sample, we modeled the number of daily recruits through generalized linear models accounting for the distributed lagged effects of recruitment campaigns.

Results: Overall, 1791 participants were recruited from 3 cities and completed at least one questionnaire: 318 in Vancouver, 315 in Saskatoon, and 1158 in Montreal. In all cities, most participants chose to participate fully (questionnaires, apps, and devices). The costs associated with a completed participant varied across recruitment methods and by city. Facebook advertisements generated the most recruits (n=687), at a cost of CAD $15.04 (US $11.57; including staff time) per completer. Mailed letters were the costliest, at CAD $108.30 (US $83.3) per completer but served to reach older participants. All methods resulted in a gender imbalance, with women participating more, specifically with social media. Partner newsletters resulted in the participation of younger adults and were cost-efficient (CAD $5.16 [US $3.97] per completer). A generalized linear model for daily Montreal

recruitment identified 2-day lag effects on most recruitment methods, except for the snowball campaign (4 days), letters (15 days), and reminder cards (5 days).

Conclusions: This study presents comprehensive data on the costs, effectiveness, and bias of population recruitment in a cohort study in 3 Canadian cities. More comprehensive documentation and reporting of recruitment efforts across studies are needed to improve our capacity to conduct inclusive intervention research.

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KEYWORDS

recruitment methods; Facebook recruitment; cost-effectiveness; built environment; intervention research; natural experiment; mobile phone

Introduction

Background

Urban interventions have the power to shape how people move, feel, and interact in cities, with the potential to improve health outcomes for all [1]. To understand the impacts of urban change on populations over time, researchers are using existing panel data sets [2-4] or collecting primary data [5,6]. Although representative population-based cohorts are key to successful population health intervention research [7], recruitment remains challenging [8,9]. Web-based recruitment strategies are increasingly used [10] because of their potential for wide reach over a short period and relatively low cost. Web-based technologies and related tools, such as smartphone apps or wearables, open new opportunities for data collection with lower participation burden. However, challenges to recruitment remain, including concerns over data privacy [11], time commitment for longitudinal studies [12], and limited reach toward marginalized populations [8,9]. All these can lead to biased samples, study delays, and increased costs [13].

Currently, few large-scale population health cohort studies have provided detailed reports on recruitment methods and effectiveness [6,14]. In a recent systematic review of studies that used Facebook to recruit participants in health, medical, or psychosocial research [10], only 19 out of 110 studies published between 2012 and 2017 reported details on cost and number of recruited participants by method. On average, the cost per completed participation through Facebook was CAD $6.79 (US $5.23; excluding staff time), although this varied widely (range CAD $1.36-$110 [US $1.05-$84.6]). Most of these studies were cross-sectional, with the exception of 2 cohort studies that focused on specific populations [15,16]. In a recent longitudinal web-based study examining physical activity through sustainable transport approaches in European cities, collaborations with local organizations, Facebook, mailing lists, and direct street recruitment were the most effective approaches to recruit participants, and Facebook was the most time-efficient method [6].

Objective

The overarching aim of this paper is to report and evaluate the effect of different recruitment methods used to enroll participants in a cohort study in 3 Canadian cities, led by the Interventions, Research, and Action in Cities Team (INTERACT) [5].

Methods

Study Design and Procedures

INTERACT uses a longitudinal design that is currently applied to 4 Canadian cities: Montreal, Saskatoon, Vancouver, and Victoria [5]. Local teams aimed to recruit approximately 300-person samples, except for Montreal, where the initial goal was 3000 participants across the Montreal region, where we aimed to evaluate a larger set of built environment interventions.

In our analyses, we only concentrated on 3 of the 4 INTERACT cities: Montreal, Saskatoon, and Vancouver, where we asked participants to report on how they had heard about the study. Interested participants were invited to complete a web-based eligibility questionnaire after consenting to the study. Participants could identify how they had heard about the study, either through a letter in the mail, referral from a friend or family member, social media (eg, Facebook and Twitter), met with study team, website, or other. In Saskatoon, they could choose from a few additional specific options (eg, posters on buses). This information was used to run the analyses by the recruitment method.

Eligible participants could choose from different levels of participation. The participants were asked to complete two web-based questionnaires: a health questionnaire and the Visualization, Evaluation, and Recording of Itineraries and Activity Spaces (VERITAS), a map-based activity space and social network questionnaire [17,18]. In addition, participants could choose to download and activate a smartphone app collecting GPS and accelerometer data for 30 days and answer Ecologic Momentary Assessment of well-being for 7 days. They could also choose to wear a hip-worn multi-sensor device (SenseDoc; Mobysens Technologies) for 10 days.

Target Sampling and Eligibility Criteria

Generally, participants were recruited through convenience sampling, with additional recruitment efforts aimed at reaching priority populations. Priority populations are those who are vulnerable or marginalized and need to be prioritized in research on healthy cities to ensure that every person has a fair and just opportunity to be as healthy as possible. Priority populations represent communities defined based on their age, gender, race, income, or ability. These priority populations include women, Black and Indigenous people, people with disabilities, people with low incomes, and older adults. For example, some social media campaigns specifically targeted underrepresented or

low-income neighborhoods. The choice of inclusion criteria and survey questions was shaped by conversations with our knowledge user partners. Therefore, our recruitment approaches varied based on each site's target sample and context. The specific recruitment tactics deployed in each city are described in the *Interventions and Participants by City* section. Inclusion criteria across all sites were as follows: being aged ≥18 years, being able to read or write English (or French in Montreal) well enough to answer a web-based questionnaire, and not planning to move out of the region in the next 2 years.

Interventions and Participants by City

In Vancouver, INTERACT evaluates the impact of the Arbutus Greenway, a 9-km former railway being redeveloped into a continuous walking and cycling corridor. Recruitment was conducted from April 20 to September 20, 2018 (123 days). The initial inclusion criteria required participants to live in one of the 8 forward sortation areas (FSAs) within 2 km of Greenway and be aged ≥45 years. To boost recruitment and to be consistent with age limits used in other sites, recruitment was then extended from June 18 to 12 FSAs within 3 km of the Arbutus Greenway and to adults aged ≥18 years. Participants were entered into a lottery to win one of 5 CAD $50 (US $39.5) Visa gift cards and a CAD $600 (US $461.5) gift certificate for a stay at a resort hotel.

In Saskatoon, INTERACT is studying the impact of a Bus Rapid Transit (BRT) system. Inclusion criteria included riding the bus at least once in a typical month or living within 800 m of the proposed BRT lines as determined by their postal codes. Recruitment ran from September 19, 2018, to January 4, 2019 (108 days). The participants received a CAD $10 (US $7.69) gift certificate upon completion of the health questionnaire. To encourage participants to contribute more data, participants were entered into a prize draw and received an additional chance of winning for each additional level of participation (VERITAS Questionnaire, app, or SenseDoc). Prizes included transit passes, a Bluetooth speaker, and headphones.

In Montreal, INTERACT evaluated the impacts of built environment interventions related to the Montreal Sustainability Plan (Plan Montréal durable 2016-2020). Interventions of interest include traffic calming measures, new transportation infrastructure, place-making, and greening programs. Target areas for recruitment included the Island of Montreal, Longueuil, Brossard, Saint-Lambert, and Laval. Participants were recruited between June 6 and December 21, 2018 (199 days). Participants were entered into a prize draw, with 20 CAD $100 (US $76.9) Visa gift cards and 1 prize with a value of CAD $500 (US $384.6): a choice of an iPad, a bicycle, or a stay at a resort hotel. Similar to Saskatoon, participants' chances of winning increased with their level of participation.

Recruitment Methods

Recruitment methods deployed at all sites included social media, news media, partner communications, snowball recruitment, and other methods, including in-person recruitment activities. Specific efforts and opportunities were tailored to each city.

Mailed Letters

Mailed letters were sent to Vancouver and Montreal. Mailing lists were rented from Canada Post. For the initial recruitment in Vancouver, 8614 personalized letters with an accompanying bookmark were sent to all homes in the 8 FSAs within 2 km of the Greenway where an individual aged ≥45 years lived. In Montreal, a mailed letter campaign with 3 types of options was sent to 15,000 people: a personalized letter with a postcard followed by a reminder postcard 2 weeks later (n=5000; group A), a personalized letter with a color card without a reminder (n=5000; group B), or a nonpersonalized postcard only (n=5000; group C). Letters were sent out by a third-party mail provider from the Canada Post Marketing program. Mailings were stratified by postal code to enable group identification based on the participants' postal code.

Social Media

All 3 cities used the INTERACT Twitter account (@teaminteract) and Facebook page [19] for promotion. In Montreal, the Centre de recherche du CHUM Facebook account also posted INTERACT content. In an effort to recruit underrepresented groups, messaging was adapted to younger people, and Facebook advertising was boosted in low-income postal codes in Montreal and Saskatoon. Facebook group administrators of community groups and nonprofit organizations in Montreal were contacted to post an invitation to the study.

News Media

Across all sites, the study was advertised through unpaid media coverage, through press releases to local media outlets, and by contact with journalists. In Montreal, the study was featured on news outlets such as *La Presse* and *Le Devoir*, CBC Montreal, *Montreal Gazette*, and TVA Nouvelles. In Saskatoon, the study was featured on CTV local news and CBC Saskatoon. In Vancouver, local CBC radio shows covered the study.

Newspaper Advertisement

In Montreal, information about the study was published in the Société de transport de Montréal section of the *Journal Métro*, free of charge.

Partner Communications

The research staff leveraged partner mailing lists, newsletters, and web-based spaces to promote the study. Efforts were made to reach community organizations working closely with citizens. Local teams also took advantage of institutional networks to share information, such as using listservs and university portals to advertise the study.

Snowball Recruitment

In Vancouver and Montreal, *Refer a friend* campaigns were launched using MailChimp. The participants were sent an email to share with a friend. Participants received a CAD $10 (US $7.69) gift card for every 2 referred friends who had signed up. In Saskatoon, participants were encouraged to share information about the study in their network, although no incentive was provided.

Other

We participated in a variety of community events to promote this study. In Saskatoon, research staff distributed flyers at bus terminals. In Vancouver, research staff attended farmers' markets, street parties, and seniors' activities around Arbutus Greenway. In Montreal, the team participated in city and community events, distributed flyers at the Centre hospitalier de l'Université de Montréal, and visited local food banks. At these events, we collected email addresses for follow-up with interested people. All 3 cities designed and distributed posters to advertise the study. In Vancouver, posters were placed in cafés, local shops, and community spaces. In Saskatoon, posters were placed on buses. In Montreal, posters were placed in universities, community centers, and municipal buildings.

Recruitment Effectiveness Metrics

Cost

To calculate the cost of each recruitment method, we added the cost of producing materials (ie, printing costs), transmitting recruitment messages (ie, mailing list rental, postage, and sponsored Facebook post charges), and staff time. Staff time was assessed as 0.5 hours per Facebook post, 4 hours per in-person event, 2 hours per media publication, 2 hours per partner post, 50 hours for the mailed letters, and 35 hours for the snowball campaign. Compensation and expenses for prizes were excluded from the cost, as they were not consistent across sites.

Sociodemographic Profiles

We provide descriptive statistics on recruited populations for each method for age (4 categories: 18-34 years, 35-54 years, 55-64 years, and 65-88 years); gender (man, woman, and other); household income (CAD $0-49,999 [US $0-38,460]; CAD $50,000-99,999 [US $38,461-$76,922]; and CAD $100,000 [US $76,923] or more); education (less than a university degree, university degree, and graduate degree); and ethnicity (White; Indigenous or Aboriginal; and visible minorities, including South Asian, Chinese, Black, Filipino, Latin American, Arab, Southeast Asian, West Asian, Korean, and Japanese).

Effectiveness

Recruitment method–specific effectiveness was determined by calculating the cost per completer, completion rate of the health questionnaire, and completion delay. The completion rate was calculated as the number of people who completed the health questionnaire divided by the number of eligible participants. Completion delay is defined as the time between the completion of eligibility and the health questionnaires.

Statistical Analyses

City differences in completion rate and completion delay were tested using the Kruskal–Wallis rank-based nonparametric method. A pairwise Wilcoxon test was used for multiple pairwise comparisons. Cost and compliance analyses per recruitment method were calculated for each city.

Modeling of daily recruitment by method and intensity was conducted for Montreal, where recruitment activities were recorded daily, and the sample size was larger. We modeled the number of participants recruited each day from the start to the end of the recruitment period (n=199 days). A recruited person was defined as someone who had completed the eligibility questionnaire and was deemed eligible and accepted to participate. Recruited participants were chosen over those who had completed the health surveys (eg, *completers*, above) to identify how different recruitment methods were able to reach participants and obtain their willingness to participate.

We fitted a distributed lag model using generalized linear regression to estimate the number of participants recruited on any given day. Predictive variables for each day were the type and intensity of recruitment campaigns, which included the following: (1) mailed letters, (2) people reached through paid Facebook posts and advertisements, (3) unpaid Facebook posts, (4) mailed reminders, (5) partner communications, (6) snowball recruitment campaigns, (7) wide-reach news media coverage (articles published in *La Presse* and *Le Devoir*, the 2 major francophone newspapers in Montreal), (8) smaller-reach news media coverage, and (9) other means of recruitment, including person events, posters, advertisements on web-based venues such as university websites, and classified advertisements. To consider the potential lag effect in recruitment for each method, we built different finite distributed lag weights ranging from 1 to 15 days [20]. Semilog transformations of the distributed lagged variables were used for Facebook reach:

$$y_d = \alpha + \beta_1 \times [x1(d\text{-}s)] + \beta_2 \times [\log x2(d\text{-}s)] + \beta_3 \times [x3(d\text{-}s)] + \beta_4 [x4(d\text{-}s)] + \beta_5 [x5(d\text{-}s)] + \beta_6 [x6(d\text{-}s)] + \beta_7 [x7(d\text{-}s)] + \beta_8 [x8(d\text{-}s)] + \beta_9 [x9(d\text{-}s)] + \mu_t$$

where y_d=number of participants recruited on a given day, lag length (s)=1, 2, 3....q, *x*1=mailed letters, *x*2=paid Facebook reach/1000, *x*3=unpaid Facebook posts, *x*4=mailed reminders, *x*5=partner communications, *x*6=snowball recruitment campaigns, *x*7=wide-reach news media coverage, *x*8=smaller-reach news media coverage, and *x*9=other means.

We retained the most efficient lag length (number of days) for each campaign type based on statistical significance, model fit (Akaike Information Criteria and Bayesian Information Criteria), and R-squared. We also visually examined the distribution of the residuals by plotting the observed and predicted estimates. Full details on the construction of the lagged variables and results of all combinations of different lag lengths (summarized in a CSV file) are provided on INTERACT's GitHub account [21]. Multimedia Appendix 1, Table S1 provides an example of 2- and 4-day lagged intensity variables. RStudio (version 3.6.1) was used to conduct all statistical analyses.

Results

The recruitment flowchart (Figure 1) provides details of recruitment, dropouts, eligibility, and completion of the health questionnaire. Participation choices by city are presented in Table 1.

Figure 1. Flowchart of recruitment numbers in the 3 Interventions, Research, and Action in Cities Team (INTERACT) cities.

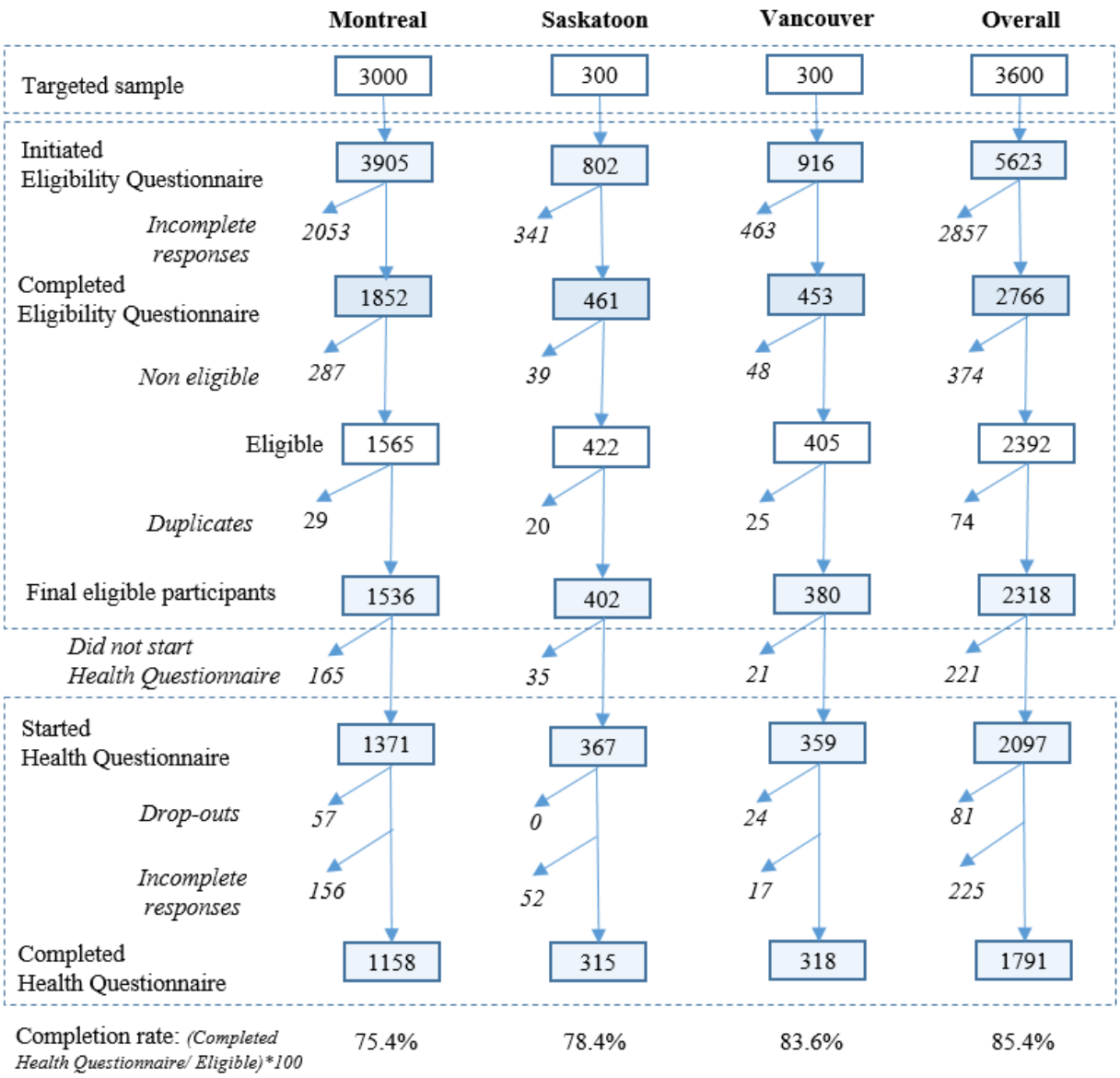

Table 1. Overall recruitment: participation option and health questionnaire completion by city[a].

	Montreal	Saskatoon	Vancouver
Total number of recruited participants per city, N (%)	1536 (100)	402 (100)	380 (100)
Total number of recruited participants who completed the health questionnaire per city, n/N (%)	1158/1536 (75.4)	315/402 (78.4)	318/380 (83.7)
Participation option			
1. Full participation (with a smartphone app and multi-sensor device)			
Number of recruited participants, N_1/N (%)	937/1536 (61)	225/402 (56)	161/380 (42.4)
Participants who completed a health questionnaire, n/N_1 (%)	744/937 (79.4)	179/225 (79.6)	134/161 (83.2)
2. Intermediate participation (with a smartphone app)			
Number of recruited participants, N_2/N (%)	277/1536 (18)	67/402 (16.7)	68/380 (17.9)
Participants who completed health questionnaire, n/N_2 (%)	201/277 (72.6)	56/67 (84)	51/68 (75)
3. Intermediate participation (with multi-sensor device)			
Number of recruited participants, N_3/N (%)	N/A[b]	13/402 (3.2)	72/380 (18.9)
Participants who completed health questionnaire, n/N_3 (%)	N/A	9/13 (69)	68/72 (94)
4. Basic participation (only questionnaires)			
Number of recruited participants, N_4/N (%)	322/1536 (20.9)	97/402 (24.1)	79/380 (20.8)
Participants who completed health questionnaire, n/N_4 (%)	213/322 (66.1)	71/97 (73.2)	65/79 (82.3)

[a]The percentage of participants who completed the health questionnaire is provided per participation option.

[b]N/A: not applicable.

Recruitment Methods and Corresponding Sociodemographic Profiles

Table 2 provides sociodemographic information using the recruitment method. City-specific numbers are provided in Multimedia Appendices 2 and 3. Most participants were recruited through social media (n=687). The participants were younger (mean age 41.8 years, SD 14.1, years) than those recruited through most other means, especially traditional media (mean age 58.5 years, SD 12.6, years). Other methods were more effective in recruiting younger participants, such as partner communications (mean 35.2 years, SD 16.1, years) or snowball sampling (mean 39.5 years, SD 15.1, years), compared with social media. Gender imbalance was strong across all methods, with 69% of all recruits identifying as women, 30% as men, and less than 1% as other genders. Social media recruitment was the most gendered (78% women vs 21% men vs 0.4% other) and letters the least (57% women vs 43% men). Recruits were distributed across income categories, with the highest share of lower-income participants (less than CAD $50,000 per year [US $38,461 per year]) recruited through partner communications (40%), *other* methods (32%), and social media (29%). All methods managed to recruit higher-income brackets (15.2% of the sample had household incomes equal to or above CAD $150,000 per year (US $115,384 per year), but this was particularly strong for mailed letters (22% of recruits by that category). Finally, most of the people in the sample identified as White (83.6%), followed by visible minorities (South Asian, Chinese, Black, Filipino, Latin American, Arab, Southeast Asian, West Asian, Korean, and Japanese: 13.6%), and Indigenous (1.6%). There were differences in proportions among the cities: in Montreal and Vancouver, only 10.1% and 15.1% were visible minorities and 0.4% and 1.3% were Indigenous, whereas Saskatoon's sample consisted of 24.8% of visible minorities and 6.3% of Indigenous participants. Interestingly, in Saskatoon, 38.9% of the visible minority participants were recruited through partner communication.

Table 2. Demographic characteristics by recruitment method[a].

Demographics	Mailed letters (n=282)	Social media (n=687)	News media (n=230)	Partner communications (n=218)	Snowball recruitment (n=121)	Other (n=253)	Total (n=1791)
Age category (years), n (%)							
18-34	10 (3.5)	238 (34.6)	44 (19.1)	108 (49.5)	58 (47.9)	56 (22.1)	514 (28.7)
35-54	91 (32.3)	273 (39.7)	74 (32.2)	47 (21.6)	34 (28.1)	75 (29.6)	594 (33.2)
55-64	89 (31.6)	95 (13.8)	62 (27)	17 (7.8)	11 (9.1)	29 (11.5)	303 (16.9)
65-88	92 (32.6)	48 (7)	46 (20)	13 (6)	12 (9.9)	39 (15.4)	250 (13.9)
Education, n (%)							
Less than university degree	94 (33.3)	142 (20.7)	26 (11.3)	63 (28.9)	21 (17.4)	74 (29.2)	420 (23. 5)
University degree	85 (30.1)	259 (37.7)	90 (39.1)	79 (36.2)	51 (42.1)	82 (32.4)	646 (36.1)
Graduate degree	100 (35.5)	282 (41)	113 (49.1)	70 (32.1)	49 (40.5)	94 (37.2)	708 (39.5)
Gender, n (%)							
Male	120 (42.6)	144 (21)	84 (36.5)	67 (30.7)	45 (37.2)	81 (32)	541 (30.2)
Female	161 (57.1)	537 (78.2)	144 (62.6)	149 (68.3)	75 (62)	170 (67.2)	1236 (69)
Other	0 (0)	3 (0.4)	2 (0.9)	2 (0.9)	0 (0)	2 (0.8)	9 (0.5)
Income category, n (%)							
CAD $0- $49,999 (US $0- $38,460)	50 (17.7)	200 (29.1)	36 (15.7)	87 (39.9)	31 (25.6)	82 (32.4)	486 (27.1)
CAD $50,000- $99,999 (US $38,461-$76,922)	79 (28.0)	212 (30.9)	91 (39.6)	38 (17.4)	41 (33.9)	56 (22.1)	517 (28.9)
CAD $100,000-$149,999 (US $76,923-$115,383)	49 (17.4)	122 (17.8)	49 (21.3)	33 (15.1)	20 (16.5)	45 (17.8)	318 (17.8)
CAD $150,000-$199,999 (US $115,384-$153,845)	29 (10.3)	53 (7.7)	19 (8.3)	14 (6.4)	9 (7.4)	22 (8.7)	146 (8.2)
≥CAD $200,000 (US $153,846)	33 (11.7)	40 (5.8)	15 (6.5)	15 (6.9)	10 (8.3)	13 (5.1)	126 (7)
Ethnicity, n (%)							
White	246 (87.2)	591 (86.0)	217 (94.3)	155 (71.1)	93 (76.9)	195 (77.1)	1497 (83.6)
Indigenous or Aboriginal	<5 (0.7)	10 (1.5)	0	5 (2.3)	<5 (0.8)	11 (4.3)	29 (1.6)
Visible minorities	31 (11)	81 (11.8)	11 (4.8)	55 (25.2)	23 (19)	42 (16.6)	243 (13.6)

[a]Missing responses: age: 7.25% (130/1791); education: 0.95% (17/1791); gender: 0.28% (5/1791); income: 11.05% (198/1791); and ethnicity: 1.23% (22/1791).

Questionnaire Completion

Completion rate, calculated as the proportion of eligible recruits who completed the health questionnaire, varied by city and by recruitment method (Table 3). The completion rate was highest for Vancouver (83.6%) and lowest for Montreal (75.4%; Figure 1). The completion rate by recruitment method varied from 88.4% (mailed letters) to 72.5% (snowball recruitment), yet between-city variations were also observed. For example, Vancouver's completion rate for those recruited through letters was 97.1%, compared with 87.1% in Montreal. The time elapsed between eligibility and health questionnaire completion varied widely across participants and recruitment methods but did not differ between cities. Those recruited through letters were quickest to complete the questionnaires (mean 9.1 days, SD 29.9, days), whereas the slowest were those recruited through social media (mean 14.3 days, SD 37.7, days), followed by partner communications (mean 13.8 days, SD 31.4, days), media (mean 11.8 days, SD 34.6, days), and other means (mean 10.6 days, SD 25.8, days).

Table 3. Completion of eligibility and health questionnaires and time taken by recruitment method for baseline INTERACT[a] in Montreal, Saskatoon, and Vancouver.

	Recruitment method						
	Mailed letters	Social media	News media	Partner communications	Snowball recruitment	Other	Total
Number of participants who completed eligibility questionnaire (recruited), n (%)	319 (13.76)	944 (40.73)	284 (12.25)	264 (11.39)	167 (7.20)	340 (14.67)	2318 (100)
Number of participants who completed health questionnaire (completer), n (%)	282 (15.74)	687 (38.36)	230 (12.84)	218 (12.17)	121 (6.75)	253 (14.13)	1791 (100)
Average days from eligibility to completion of health questionnaire, mean (SD)	9.1 (29.9)	14.3 (37.7)	11.8 (34.6)	13.8 (31.4)	9.6 (28.6)	10.6 (25.8)	12.3 (10.4)
Completion rate, %	88.4	72.8	81.0	82.6	72.5	74.4	77.3

[a]INTERACT: Interventions, Research, and Action in Cities Team.

Cost-effectiveness

Cost per completer by recruitment method varied by city (Table 4). The average cost per completer for the 3 cities (Montreal, Saskatoon, and Vancouver) was CAD $23.28 (US $17.91). City-specific costs per completion were CAD $26.52 (US $20.4) in Montreal, CAD $23.80 (US $18.3) in Vancouver, and CAD $10.85 (US $8.35) in Saskatoon. Cost per completer by recruitment method varied by city. Partner communications was the most cost-effective recruitment method across cities, with an average cost of CAD $5.16 (US $3.97) per completer. They were particularly efficient in Saskatoon, costing <CAD $1(US $1.3) per completer. News media cost on average CAD $7.35 (US $5.65) per completer and generated a considerable number of participants in Montreal.

Social media, which generated the most recruits, came third in terms of cost-effectiveness across cities, at an average cost of CAD $15.04 (US $11.57) per completer. The highest recruitment cost resulted from mailed letters, at an average of CAD $108.30 (US $83.3) per completer (CAD $130.80 (US $100.6) in Montreal; CAD $83.56 (US $ 64.27) in Vancouver). Comparing different mailed options showed that personalized letters were much more cost-effective than postcards only, and reminder cards did not help recruitment. The cost per completer for group B (personalized letter and color card only; n=88) was CAD $60.11 (US $46.23), followed by group A (personalized letter, color card, and a reminder postcard; n=75) at CAD $106.68 (US $82.06), and group C (nonpersonalized postcard only) was the costliest at CAD $796.34 (US $612.57) per completer (n=8 recruitment).

Table 4. Cost per completer by city and recruitment method.

Reported recruitment method	Montreal (n=1158)	Saskatoon (n=315)	Vancouver (n=318)	Total (n=1791)
Mailed letters, n (%)[a]	148 (12.8)	0 (0)	134 (42.1)	282 (15.7)
Cost per completer, CAD$ (US$)[b]	130.80 (100.61)	N/A	83.56 (64.27)	108.30 (83.31)
Social media, n (%)	503 (43.4)	88 (27.9)	96 (30.2)	687 (38.4)
Cost per completer, CAD$ (US$)	13.35 (10.27)	16.13 (12.4)	22.91 (17.62)	15.04 (11.56)
News media, n (%)	226 (19.5)	4 (1.3)	0 (US 0)	230 (12.8)
Cost per completer, CAD$ (US$)	6.17 (4.75)	74.04 (56.95)	N/A	7.35 (5.65)
Other, n (%)	109 (9.4)	79 (25.1)	65 (20.4)	253 (14.1)
Cost per completer, CAD$ (US$)	18.05 (13.88)	21.60 (16.62)	72.70 (55.92)	33.20 (25.54)
Partner communications, n (%)	91 (7.9)	126 (40)	1 (0.3)	218 (12.2)
Cost per completer, CAD$ (US$)	7.32 (5.63)	0.88 (0.68)	347.10 (267)	5.16 (3.97)
Snowball recruitment, n (%)	81(7)	18 (5.7)	22 (6.9)	121 (6.8)
Cost per completer, CAD$ (US$)	16.40 (12.6)	0 (0)	59.80 (46)	21.85 (16.8)
Average cost per completer, CAD$ (US$)	26.52 (20.4)	10.85 (8.35)	23.80 (18.3)	23.28 (17.9)

[a]Number of participants who completed the health questionnaire Percentages indicate the proportion of city participants recruited through this specific method.

[b]Cost per completer includes the cost of all materials, expenses, and staff time and is expressed in Canadian dollars. Additional costs of participant compensation in Saskatoon (CAD $10 [US $7.69]) for questionnaire completion) are not included in this table.

Recruitment Modeling in Montreal

We modeled the number of people recruited per day over the 199-day recruitment period, which included 1536 participants from the Montreal cohort who completed the eligibility questionnaire and were willing to participate. The predictor variables included campaign events by recruitment type. Within the 199-day recruitment period, there were 227 campaign events, including (1) 151 days of paid Facebook posts and advertisements with an average reach of 2770 (SD 3558) potential participants (minimum=144, maximum=20,156); (2) 44 unpaid Facebook posts posted over 34 days; (3) a mailed letter campaign reaching 15,000 people; (4) a mailed reminder campaign reaching 5000 people; (5) 18 communications with partners who sent out newsletters or shared information on their web-based spaces; (6) 2 wide-reach media coverage events; (7) 6 smaller-reach media coverage events; (8) 1 snowball recruitment campaign; and (9) 16 other events, including 2 in-person community events.

The model performed relatively well overall, with an adjusted R-square of 0.78. The model parameters are listed in Table 5. Each coefficient should be interpreted as the effect of a campaign event or the number of participants recruited. The weights for each campaign are distributed over several days (specific lag per campaign type), and the sum of weights per campaign event equals 1. The model estimates 107 recruits that occur over 15 days for the letter campaign sent to 15,000 participants. Every 1% increase in Facebook reach per 1000 participants resulted in a 0.014 increase in recruitment. For example, an increase of 10% (277 participants) from the average Facebook reach of 2770 participants per day recruited an estimated 3.8 participants over 2 days. Unpaid Facebook posts recruited an estimated 3.2 participants over 2 days. On average, every wide-reach news article was associated with the recruitment of 164 participants over the course of 2 days. Finally, on average, each smaller-reach news media campaign was associated with an estimated recruitment of 10 participants. The best model fit and residual distribution indicated 2-day lag effects for all recruitment methods, except for 4 days for snowball recruitment, 15 days for the mailed letter campaign, and 5 days for the mailed reminder campaigns. Figure 2 shows the predicted and observed daily recruitment during the 199-day recruitment period.

Figure 2. Predicted and observed daily recruitment of Montreal's Interventions, Research, and Action in Cities Team (INTERACT) cohort.

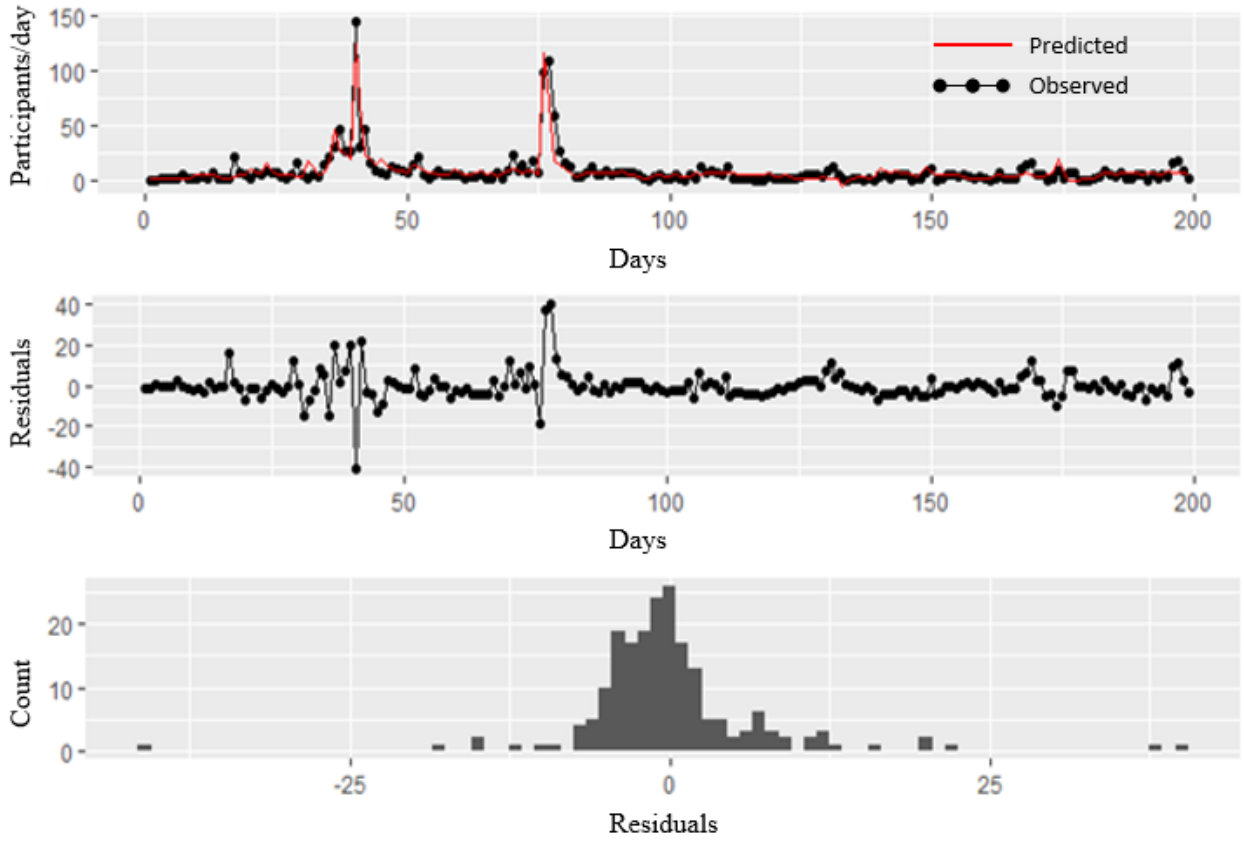

Table 5. Results of the regression model estimating the number of participants recruited per campaign event (number of observations=199)[a].

Predictors (lag in days)	Estimated number of recruited participants per campaign event	*P* value	95% CI
Mailed letters (15 days)	106.5[b]	.002	39.6 to 173.4
Mailed reminders (5 days)	16.9	.28	−13.5 to 47.2
Log paid Facebook reach per 1000 (2 days)	1.4[b]	<.001	0.6 to 2.1
Facebook unpaid posts (>2 days)	3.2[b]	.002	1.5 to 5.0
Wide-reach news media coverage (>2 days)	163.6[b]	<.001	149.0 to 178.2
Other recruitment means (>4 days)	−1.3	.05	−2.7 to 0.0
Partner communications (>2 days)	3.5	.16	−1.4 to 8.4
Snowball recruitment (>4 days)	2.5	.85	−24.4 to 29.3
Smaller-reach news media coverage (>2 days)	10.4[b]	.001	4.1 to 16.8
Intercept	4.3[b]	<.001	2.9 to 5.7

[a]R^2/R^2 adjusted=0.79/0.78.

[b]$P<.05$.

Discussion

Study Significance

This study documents the procedures and effectiveness of recruitment efforts to constitute baseline population-based samples in 3 Canadian cities as part of the INTERACT study. We further propose a daily recruitment modeling strategy that provides estimates of effectiveness for various recruitment campaigns, which we applied to the 199-day Montreal recruitment period. The existing literature generally lacks detailed reporting on recruitment performance [8,22]. To our knowledge, this is the first Canadian study to provide detailed performance indicators, including the time- and cost-effectiveness of different population-based recruitment methods.

Recruitment Method and Cost-effectiveness

Social media is a powerful and relatively cost-effective way to recruit participants. Approximately one-third of our participants were recruited through social media (687/1791, 38.4%), at an average cost of CAD $15.04 (US $11.56) per participant. However, these participants also took the longest to complete the questionnaires and had the lowest completion rates. This is possibly because social media users have direct access to the web-based recruitment material and therefore are more inclined to start the process, even with medium levels of motivation.

In contrast, letters had the highest and fastest completion rates (Table 6). Even if few of those receiving a letter were engaged, those who did were committed. Researchers recruiting samples for longitudinal studies or for studies requiring substantial time commitments from participants may want to consider such trade-offs and plan for potentially different follow-up rates by recruitment strategy. Previous studies found that follow-up rates were generally lower when participants were recruited on the web [23,24]. Although this study reports only baseline recruitment, future work should also consider differential attrition rates linked to the different recruiting methods.

The effectiveness of social media for recruitment has increased over the years. Montreal's (CAD $10.18 [US $7.83]) and Saskatoon's (CAD $14.45 [US $11.11]) social media costs (excluding staff time to facilitate comparisons with the literature) are in line with previously reported median costs of CAD $11.60 (US $8.92) for Facebook recruitment across 18 studies [10]. In Vancouver, where we initially targeted older adults living in a small geographic area, social media costs were higher (CAD $21.30 [US $16.38]) but in line with a recent Canadian study that recruited a hard-to-reach population through Facebook (CAD $19.27 [US $14.82]) [25].

Facebook posts were reported as an efficient recruitment method for a cohort study across 7 European cities (recruitment period: 2014-2016), although the cost per completer was not documented [6]. Earlier reports on one of the largest prospective cohort studies in the United Kingdom (recruitment period: 2009-2012) showed that Facebook posts are less efficient than mailed letters, SMS text messages sent on mobile phones, and emails [12]. However, since 2009, the share of the population with a social media account has grown, and Facebook has considerably refined its advertisement program, facilitating reach and recruitment [26]. Facebook advertisement features now make it possible to specifically target local areas or population segments based on individual profiles. These tools allow research teams to react to potential biases during the recruitment process, for example, by adjusting campaigns by targeting underrepresented geographic areas or population groups. Concomitantly, physical mail use has diminished, at least for letter correspondence. A previous study on smoking targeting young adults in Montreal (recruitment: 2011-2012) reported a 25% participation rate through letter recruitment [27], a much higher number than was achieved here (<1%). This difference might be linked to the presence of compensation and the age of the participants because CAD $10 (US $7.69) gift

certificates were given to those completing the survey. Transformations in communication habits and lower receptivity for mailed communication may also partly explain this difference. Finally, letters recruited older men than other methods, whereas social media recruited younger women, meaning these methods may be complementary.

Garnering attention for the study through newspaper articles was the second most effective strategy in Montreal, recruiting a high share of participants (226/1158, 19.5%) at a low cost (CAD $6.17 [US $4.75] per participant including staff time). Opportunities to publicize public health research in mainstream news outlets should be seized not only as a way to reach future participants, but also as a means to highlight existing research on the topic.

We recommend that researchers use multiple recruitment methods to amplify the impact of messaging and reach a greater diversity of participants. In Montreal, social media recruits were younger (mean age 41.8 years, SD 14.1, years) than those recruited through letters (mean age 58.8 years, SD 12.6, years) and media campaigns (mean age 51.4 years, SD 14.8, years). However, our social media recruitment profiles echo Canada's Facebook users: 38.2% (192/503) of our social media recruits were aged 18-34 years (42% of Facebook users in Canada), 40.2% (202/503) were aged 35-54 years (34% of Facebook users in Canada), 14.5% (73/503) were aged 55-64 years (12% of Facebook users in Canada), and 7.2% (36/503) were aged ≥65 years (10% of Facebook users in Canada) [28]. Gender imbalance was present across all recruitment methods but especially so among social media recruits: in Montreal, 77.1% (388/503) of the social media recruits were women compared with an average of 68% (788/1158) recruited through all other means of recruitment; in Saskatoon, 76.1% (67/88) were women compared with 73.7% (232/315); and in Vancouver, 85.4% (82/96) were women compared with 67.9% (216/318). Our gender imbalance is in the higher range of the 22 studies reporting a gender split in a 2016 systematic review, for which the median proportion of women was 61.1% [10]. We did not anticipate such a gender imbalance, although research has shown that women tend to join [29] web surveys and volunteer their time more than men [30], which may explain why more women completed the surveys.

INTERACT engaged with community organizations and institutions that had already established communication with citizens to promote the study. Low-income populations were best recruited through partner newsletters, consistent with previous research that supports working with community partners to reach priority populations [8,22]. Contacting citizens through such partners may improve the receptivity and trust of the participants [8]. This requires that the research team develop relationships with community partners who work directly with marginalized groups. Building relationships with both advocacy organizations as knowledge users and service delivery organizations as recruitment partners requires early and ongoing engagement from the research staff throughout the project.

When evaluating the extent of bias by sociodemographic factors in recruitment methods, one should consider the sociodemographic characteristics of each recruitment method. For example, because there is a higher share of female Facebook users, a nonbiased recruitment among Facebook users would result in more women participating. Similarly, mailing lists tend to have more up-to-date information on homeowners than tenants. This means that mail campaigns may be more effective in recruiting homeowners. Certain community organizations may have relationships with priority populations, facilitating recruitment. It is important to be aware of the sociodemographic population characteristics that these methods do reach before drawing conclusions about recruitment bias. Furthermore, although it is useful to assess bias for each specific method, using a variety of recruitment methods will tend to increase reach across sociodemographic groups. Table 6 presents a summary of the results and lessons learned from the INTERACT recruitment campaigns.

Table 6. Summary of strengths and weaknesses of each recruitment method, as seen in the INTERACT[a] study (lessons learned from INTERACT results).

Recruitment method	Strengths	Weaknesses
Mailed letters	• Highest and quickest completion rates • Effective at recruiting older populations • Higher share of older men than other methods	• Most expensive cost-per-completer rate
Social media	• Generally cost-effective for recruiting a large cohort • Effective in recruiting women and younger participants	• Had the lowest and slowest completion rates
News media	• Low cost-per-completer rate • Effective at recruiting older participants	• Low effectiveness for recruiting participants without a university degree • Little control from research team to garner attention from media
Partner communications	• High completion rate • Effective in reaching priority population participants • Effective for recruiting participants without a university degree • Least expensive cost-per-completer rate	• Slow completion rate • Important investments in time for building trust with partners
Snowball recruitment	• Ease of implementation through automated email campaigns	• Tends to reinforce trends within sample composition, because referred participants resemble their peers

[a]INTERACT: Interventions, Research, and Action in Cities Team.

Recruitment Method and Time Efficiency

One of the contributions of this study is that it provides a novel method to predict the number of daily recruits in a population-based recruitment effort, testing finite distributed lag weights for each recruitment approach. These results can inform the timing of different recruitment campaigns, including indications of their expected reach through time. We provide a detailed methodology, R syntax, and sample data on GitHub to facilitate the reproduction of this approach in other contexts. A systematic review [31] of modeling techniques used to predict recruitment to randomized clinical trials revealed a variety of modeling approaches, including Poisson and negative binomial models or Bayesian, time series, and Markov chain models. Using Poisson and negative binomial models does not capture the immediate rise in recruitment after special campaigns (eg, the peaks of recruited participants after wide-reach news media coverage). Bayesian, time series, and Markov chain analyses are less simple to reproduce [31]. With distributed lag weights as proposed in our study, ordinary least square models can be used [32]. Our model performed well in predicting daily recruitment, and recruitment-specific lags provided useful indications about temporal reach.

Limitations

The INTERACT study requires considerable time and effort from the participants. Beyond recruitment methods, the messaging used can affect diversity in recruitment. We used a variety of hooks and angles to capture the participants' attention. The impact of these factors was not assessed in this study. Moreover, differences in protocol in each city, notably compensation and prizes, may explain some of the variation in questionnaire completion rates among the cities. Future research may want to explore the impact of different types of messaging and visuals, including levels of participation and the impact of incentives on completion rates. It is possible that participants could have heard about the study from several sources, suggesting over- and underestimations and possible correction effects among methods. However, the model performs well in terms of cumulative recruitment; lag effects per method provide useful indications of the temporal dimensions of different recruitment approaches. Lower recruitment rates among priority populations are due to barriers such as distrust of participants and lack of knowledge in research, cultural beliefs and language issues [9], fear of stigmatization among those who may have engaged in high-risk behavior [8], issues related to low (technology) literacy, limited knowledge on the benefits the research might provide [33], privacy concerns, competing interests among busy participants [34], and lack of trust in web-based recruitment strategies [35]. The research team addressed these barriers in part by dedicating efforts to presenting the goals of the research and recruiting participants in person, connecting with community organizations that could promote the study among their clients and members, and providing phone or in-person assistance to participants answering questionnaires. Recruitment methods are only part of the equation for making participation more appealing and safer for all. Consequently, research teams should decide on the protocol at the outset and budget accordingly. Building trust and addressing logistical hurdles with priority populations are key goals for our next waves and should be considered at the forefront of any population health research.

Another limitation of the recruitment model is the inability to determine the sociodemographic profiles of the (unknown) exposed populations. Although Facebook Analytics provides profile statistics on the people reached through advertisements, such as sex, age, and geography, equivalent data for other recruitment methods were not available. For example, the number of people who are exposed to news media, snowball campaigns, or partner newsletters is unknown. Our model did not control for the demographic characteristics of those who were exposed to our campaigns.

Conclusions

Our study provides detailed documentation of recruitment efforts and the costs of population baseline samples across 3 Canadian cities. We also provide a novel lag-based modeling approach to evaluate the effectiveness of different recruitment strategies, illustrated using data from Montreal. Different recruitment methods had different costs, returns, and possible biases, suggesting that diversifying recruitment methods are useful to increase reach and sample diversity. Local contexts should not be ignored, as shown by the differences among the cities. Research teams should keep detailed logs of recruitment activities and ask participants to report how they were recruited to improve reporting of recruitment efficiency and costs. With increasing opportunities to collect large-scale citizen science data stemming from web-based platforms, smartphones, or wearables, setting up comprehensive recruitment strategies and better understanding how and why citizens choose to participate or not is important for the future of population-based research.

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Conflicts of Interest

YK, the nominated principal investigator holds shares in Mobysens Technologies Inc, a spin-off company that markets SenseDoc 2.0. SenseDoc is a multi-sensor device used for mobility (GPS) and physical activity (accelerometer) tracking in the Interventions, Research, and Action in Cities Team study. SenseDoc was filed as an invention in 2013 at Univalor, a valorization company affiliated with Université de Montréal and Centre de Recherche du CHUM. YK (nominated principal investigator) holds shares in Polygon Co, which markets the Visualization, Evaluation, and Recording of Itineraries and Activity Spaces tool referenced in this paper. the Visualization, Evaluation, and Recording of Itineraries and Activity Spaces was filed as an invention in 2012 at Univalor, a valorization company affiliated with Université de Montréal.

Multimedia Appendix 1

A hypothetical example to calculate the lagged intensity measure.
[DOCX File , 19 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Number of recruited participants, rate, and time of completion by city and recruitment method.
[DOCX File , 21 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Demographic characteristics by recruitment method and city.
[DOCX File , 26 KB-Multimedia Appendix 3]

References

1. Rydin Y, Bleahu A, Davies M, Dávila JD, Friel S, De Grandis G, et al. Shaping cities for health: complexity and the planning of urban environments in the 21st century. Lancet 2012 Jun;379(9831):2079-2108. [doi: 10.1016/s0140-6736(12)60435-8]
2. Wasfi R, Steinmetz-Wood M, Kestens Y. Place matters: a longitudinal analysis measuring the association between neighbourhood walkability and walking by age group and population center size in Canada. PLoS One 2017 Dec 19;12(12):e0189472 [FREE Full text] [doi: 10.1371/journal.pone.0189472] [Medline: 29261706]

3. Wasfi RA, Dasgupta K, Orpana H, Ross NA. Neighborhood walkability and body mass index trajectories: longitudinal study of Canadians. Am J Public Health 2016 May;106(5):934-940. [doi: 10.2105/ajph.2016.303096]
4. Fuller D, Pabayo R. The relationship between utilitarian walking, utilitarian cycling, and body mass index in a population based cohort study of adults: comparing random intercepts and fixed effects models. Prev Med 2014 Dec;69:261-266. [doi: 10.1016/j.ypmed.2014.10.022] [Medline: 25450496]
5. Kestens Y, Winters M, Fuller D, Bell S, Berscheid J, Brondeel R, et al. INTERACT: a comprehensive approach to assess urban form interventions through natural experiments. BMC Public Health 2019 Jan 10;19(1):51 [FREE Full text] [doi: 10.1186/s12889-018-6339-z] [Medline: 30630441]
6. Gaupp-Berghausen M, Raser E, Anaya-Boig E, Avila-Palencia I, de Nazelle A, Dons E, et al. Evaluation of different recruitment methods: longitudinal, web-based, pan-european physical activity through sustainable transport approaches (PASTA) project. J Med Internet Res 2019 Mar 09;21(5):e11492 [FREE Full text] [doi: 10.2196/11492] [Medline: 31066715]
7. Lavrakas PJ. Encyclopedia of Survey Research Methods. Thousand Oaks, CA: SAGE Publications; 2008.
8. Bonevski B, Randell M, Paul C, Chapman K, Twyman L, Bryant J, et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. BMC Med Res Methodol 2014 Mar 25;14:42 [FREE Full text] [doi: 10.1186/1471-2288-14-42] [Medline: 24669751]
9. UyBico SJ, Pavel S, Gross CP. Recruiting vulnerable populations into research: a systematic review of recruitment interventions. J Gen Intern Med 2007 Jun 21;22(6):852-863 [FREE Full text] [doi: 10.1007/s11606-007-0126-3] [Medline: 17375358]
10. Thornton L, Batterham PJ, Fassnacht DB, Kay-Lambkin F, Calear AL, Hunt S. Recruiting for health, medical or psychosocial research using Facebook: systematic review. Internet Interv 2016 May;4:72-81 [FREE Full text] [doi: 10.1016/j.invent.2016.02.001] [Medline: 30135792]
11. Roberts L, Sipes J. Ethical issues in online research. In: The Cambridge Handbook of Applied Psychological Ethics. New York, United States: Cambridge University Press; 2018:474-492.
12. Toledano MB, Smith RB, Brook JP, Douglass M, Elliott P. How to establish and follow up a large prospective Cohort study in the 21st century--lessons from UK COSMOS. PLoS One 2015 Jul 6;10(7):e0131521 [FREE Full text] [doi: 10.1371/journal.pone.0131521] [Medline: 26147611]
13. Allsworth JE. Invited commentary: recruiting for epidemiologic studies using social media. Am J Epidemiol 2015 May 15;181(10):747-749. [doi: 10.1093/aje/kwv007] [Medline: 25883156]
14. Nolte MT, Shauver MJ, Chung KC. Analysis of four recruitment methods for obtaining normative data through a Web-based questionnaire: a pilot study. Hand (N Y) 2015 Sep 14;10(3):529-534 [FREE Full text] [doi: 10.1007/s11552-014-9730-y] [Medline: 26330790]
15. King DB, O'Rourke N, DeLongis A. Social media recruitment and online data collection: a beginner's guide and best practices for accessing low-prevalence and hard-to-reach populations. Can Psychol/Psychologie Canadienne 2014;55(4):240-249. [doi: 10.1037/a0038087]
16. Hernandez-Romieu AC, Sullivan PS, Sanchez TH, Kelley CF, Peterson JL, Rio CD, et al. The comparability of men who have sex with men recruited from venue-time-space sampling and facebook: a Cohort study. JMIR Res Protoc 2014 Jul 17;3(3):e37 [FREE Full text] [doi: 10.2196/resprot.3342] [Medline: 25048694]
17. Kestens Y, Chaix B, Gerber P, Desprès M, Gauvin L, Klein O, et al. Understanding the role of contrasting urban contexts in healthy aging: an international cohort study using wearable sensor devices (the CURHA study protocol). BMC Geriatr 2016 May 05;16(1):96 [FREE Full text] [doi: 10.1186/s12877-016-0273-7] [Medline: 27151297]
18. Naud A, Sueur C, Chaix B, Kestens Y. Combining social network and activity space data for health research: tools and methods. Health Place 2020 Nov;66:102454 [FREE Full text] [doi: 10.1016/j.healthplace.2020.102454] [Medline: 33032243]
19. Team Interact. URL: https://www.facebook.com/interact.ca [accessed 2021-10-29]
20. Franses PH. Distributed lags. In: The New Palgrave Dictionary of Economics. London, U.K: Palgrave Macmillan; 2018:1-5.
21. TeamINTERACT / Recruitment_Wave1_Paper. GitHub. URL: https://github.com/TeamINTERACT/Recruitment_Wave1_Paper [accessed 2021-10-29]
22. Galli L, Knight R, Robertson S, Hoile E, Oladapo O, Francis D, et al. Using marketing theory to inform strategies for recruitment: a recruitment optimisation model and the txt2stop experience. Trials 2014 May 22;15(1):182 [FREE Full text] [doi: 10.1186/1745-6215-15-182] [Medline: 24886627]
23. Bajardi P, Paolotti D, Vespignani A, Eames K, Funk S, Edmunds WJ, et al. Association between recruitment methods and attrition in internet-based studies. PLoS One 2014 Dec 9;9(12):e114925 [FREE Full text] [doi: 10.1371/journal.pone.0114925] [Medline: 25490045]
24. Peels DA, Bolman C, Golsteijn RH, De Vries H, Mudde AN, van Stralen MM, et al. Differences in reach and attrition between web-based and print-delivered tailored interventions among adults over 50 years of age: clustered randomized trial. J Med Internet Res 2012 Dec 17;14(6):e179 [FREE Full text] [doi: 10.2196/jmir.2229] [Medline: 23246790]
25. Wozney L, Turner K, Rose-Davis B, McGrath PJ. Facebook ads to the rescue? Recruiting a hard to reach population into an Internet-based behavioral health intervention trial. Internet Interv 2019 Sep;17:100246 [FREE Full text] [doi: 10.1016/j.invent.2019.100246] [Medline: 31080751]

26. Dodds L. Exclusive: Britons abandon Facebook as usage plummets by more than a third. The Telegraph. 2019. URL: https://www.telegraph.co.uk/technology/2019/07/06/exclusive-britons-abandon-facebook-usage-plummets-third/ [accessed 2021-10-16]
27. Frohlich K, Shareck M, Vallée J, Abel T, Agouri R, Cantinotti M, et al. Cohort profile: the Interdisciplinary Study of Inequalities in Smoking (ISIS). Int J Epidemiol 2017 Apr 01;46(2):e4. [doi: 10.1093/ije/dyv036] [Medline: 25948662]
28. Number of Facebook users in Canada from 2017 to 2026. Statista. 2021. URL: https://www.statista.com/statistics/282364/number-of-facebook-users-in-canada/ [accessed 2021-10-26]
29. Keusch F. Why do people participate in web surveys? Applying survey participation theory to internet survey data collection. Manag Rev Q 2015 Jan 9;65(3):183-216. [doi: 10.1007/s11301-014-0111-y]
30. Simmons WO, Emanuele R. Male‐female giving differentials: are women more altruistic? J Econ Stud 2007 Nov 06;34(6):534-550. [doi: 10.1108/01443580710830989]
31. Barnard KD, Dent L, Cook A. A systematic review of models to predict recruitment to multicentre clinical trials. BMC Med Res Methodol 2010 Jul 06;10(1):63 [FREE Full text] [doi: 10.1186/1471-2288-10-63] [Medline: 20604946]
32. Parker J. Linear distributed lag models. Reed College, Portland, Oregon. 2019. URL: https://www.reed.edu/economics/parker/312/online_slides/312_4-1.pdf [accessed 2021-10-16]
33. Mendoza-Vasconez AS, Linke S, Muñoz M, Pekmezi D, Ainsworth C, Cano M, et al. Promoting physical activity among underserved populations. Curr Sports Med Rep 2016;15(4):290-297. [doi: 10.1249/jsr.0000000000000276]
34. O'Connor S, Hanlon P, O'Donnell CA, Garcia S, Glanville J, Mair FS. Barriers and facilitators to patient and public engagement and recruitment to digital health interventions: protocol of a systematic review of qualitative studies. BMJ Open 2016 Sep 02;6(9):e010895 [FREE Full text] [doi: 10.1136/bmjopen-2015-010895] [Medline: 27591017]
35. Staffileno BA, Zschunke J, Weber M, Gross LE, Fogg L, Tangney CC. The feasibility of using Facebook, Craigslist, and other online strategies to recruit young African American women for a web-based healthy lifestyle behavior change intervention. J Cardiovasc Nurs 2017;32(4):365-371. [doi: 10.1097/jcn.0000000000000360]

Abbreviations

BRT: Bus Rapid Transit
FSA: forward sortation area
INTERACT: Interventions, Research, and Action in Cities Team
VERITAS: Visualization, Evaluation, and Recording of Itineraries and Activity Spaces

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Review

Blockchain Integration With Digital Technology and the Future of Health Care Ecosystems: Systematic Review

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Abstract

Background: In the era of big data, artificial intelligence (AI), and the Internet of Things (IoT), digital data have become essential for our everyday functioning and in health care services. The sensitive nature of health care data presents several crucial issues such as privacy, security, interoperability, and reliability that must be addressed in any health care data management system. However, most of the current health care systems are still facing major obstacles and are lacking in some of these areas. This is where decentralized, secure, and scalable databases, most notably blockchains, play critical roles in addressing these requirements without compromising security, thereby attracting considerable interest within the health care community. A blockchain can be maintained and widely distributed using a large network of nodes, mostly computers, each of which stores a full replica of the data. A blockchain protocol is a set of predefined rules or procedures that govern how the nodes interact with the network, view, verify, and add data to the ledger.

Objective: In this article, we aim to explore blockchain technology, its framework, current applications, and integration with other innovations, as well as opportunities in diverse areas of health care and clinical research, in addition to clarifying its future impact on the health care ecosystem. We also elucidate 2 case studies to instantiate the potential role of blockchains in health care.

Methods: To identify related existing work, terms based on Medical Subject Headings were used. We included studies focusing mainly on health care and clinical research and developed a functional framework for implementation and testing with data. The literature sources for this systematic review were PubMed, Medline, and the Cochrane library, in addition to a preliminary search of IEEE Xplore.

Results: The included studies demonstrated multiple framework designs and various implementations in health care including chronic disease diagnosis, management, monitoring, and evaluation. We found that blockchains exhibit many promising applications in clinical trial management such as smart-contract application, participant-controlled data access, trustless protocols, and data validity. Electronic health records (EHRs), patient-centered interoperability, remote patient monitoring, and clinical trial data management were found to be major areas for blockchain usage, which can become a key catalyst for health care innovations.

Conclusions: The potential benefits of blockchains are limitless; however, concrete data on long-term clinical outcomes based on blockchains powered and supplemented by AI and IoT are yet to be obtained. Nonetheless, implementing blockchains as a novel way to integrate EHRs nationwide and manage common clinical problems in an algorithmic fashion has the potential for improving patient outcomes, health care experiences, as well as the overall health and well-being of individuals.

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KEYWORDS

blockchain, Internet of Things; digital; artificial intelligence; machine learning; eHealth; ledger; distributed ledger technology

Introduction

The blockchain concept was first described 3 decades ago and was meant to be used as a digital timestamp for documents to prevent tampering, functioning somewhat like a notary. However, it did not develop significantly and went largely unnoticed until the global financial crisis. In 2008, the blockchain revolution began when Nakamoto pioneered and crystallized it by releasing his whitepaper [1] followed by his cryptocurrency called Bitcoin, offered as an open-access protocol to the public.

Blockchain is considered one of today's important ground-breaking technologies. The question is what makes blockchain so unique and useful.

In simple words, it provides digital trust and transparency, something that has not only been seriously lacking in the digital world but is also posing major challenges in an era of increased dependence on electronic data, along with viewing the shift toward digitization and substituting other traditional methods of data storage as a glorified goal. A caveat that needs to be considered is that many digital health start-ups have failed, given their inability to convince the investors and users or because of using older technologies that become outdated by the time a completely digital health system is established.

The security of digital data, and the fact that it can be manipulated, tampered with, and purposefully hidden to suit the parties of interest, can be quite an alarming thought. Security concerns have led to resistance toward the use of electronic cloud-based data. However, using blockchain technology can potentially provide a breakthrough.

We will evaluate cases involving 2 patients in typical yet different clinical scenarios and then analyze the role of blockchains in the management of these patients.

Chenoa is an 8-year-old girl from Cheyenne, Wyoming, who was recently diagnosed with acute lymphoblastic leukemia. Her parents were farmers and there was no large tertiary care center in town that could provide treatment for life-threatening cancers with aggressive chemotherapy. They traveled to Colorado to obtain specialized care as recommended by their local hematologist. She received all her initial treatments in Denver, followed by a stem cell transplant from her elder brother as the donor after receiving massive radiation and chemotherapy for the transplant. Moreover, 4 months posttransplant, there was no evidence of leukemia or rejection (graft-versus-host disease), and they return to Cheyenne to celebrate their cancer conquest with the rest of the Cherokee tribe. A month after returning, Chenoa develops high-grade fever and is diagnosed with an extremely low white blood cell count along with a relapse of her leukemia at the local hospital. Immediate transfer to the transplant center in Colorado is recommended.

Khaled is a 58-year-old retired banker and an ex-smoker who lives in Dearborn, Michigan, with hypertension, coronary heart disease, and chronic kidney disease for which he undergoes hemodialysis thrice a week and is on the renal transplant list for a transplant. He is divorced and single; however, his daughter, who lives in Cleveland (Ohio), frequently visits him. He was recently diagnosed with heart failure; given the precarious health system and lack of caretakers in Dearborn, he is temporarily planning to move to his daughter's house.

The above 2 examples characterize the real-world scenarios within the United States, a developed country; despite incurring some of the highest health care costs, the United States has a disjointed health care system as far as digital health is concerned. Given the impediments and complexities in the US health care system, errors and wastage within the health ecosystem can directly affect patient outcomes like those of Chenoa and Khaled.

Chenoa's transfer was delayed given that she became increasingly unstable, as her infection led to septic shock. Though intensive care unit (ICU) management was optimum, and she was receiving multiple antibiotics and vasopressors, hopes for her stabilization and transfer to Denver were diminishing. A couple of days prior to hospital admission, Chenoa was taken to another local hospital because of fever and flu-like symptoms, where she was given an outpatient prescription of antihistamines. Though her transplant team had instructed the parents to telephone them for any issues, this was a very minor issue, and not entirely unexpectedly, the local physician in the community did not realize the depth of the immunosuppressive state that Chenoa exhibited. A week after highly aggressive treatment in the ICU, Chenoa died of multiple organ failure due to sepsis.

Khaled's story had a different twist; his daughter made a hasty decision to take him to Ohio, but he deteriorated quickly. She had to take him directly to a large tertiary care center in Cleveland where the emergency room doctors evaluated and triaged him appropriately and were relentlessly trying to obtain medical records from Detroit where Khaled's doctors were located. He went into cardiac arrest twice within a few hours of arrival and cardiopulmonary resuscitation was stopped after a prolonged effort following discussions with his daughter, as it seemed futile.

Fortunately, most of the patients in the United States do not exemplify the above cases; however, similar issues routinely occur given the lack of trustworthy and secure digital infrastructure for health care. Many questions arise after the death of Chenoa and Khaled, the most essential of which is whether there was a medical error on the side of the individuals or the health care ecosystem, which led to their fatal demise (eg, were these deaths preventable?).

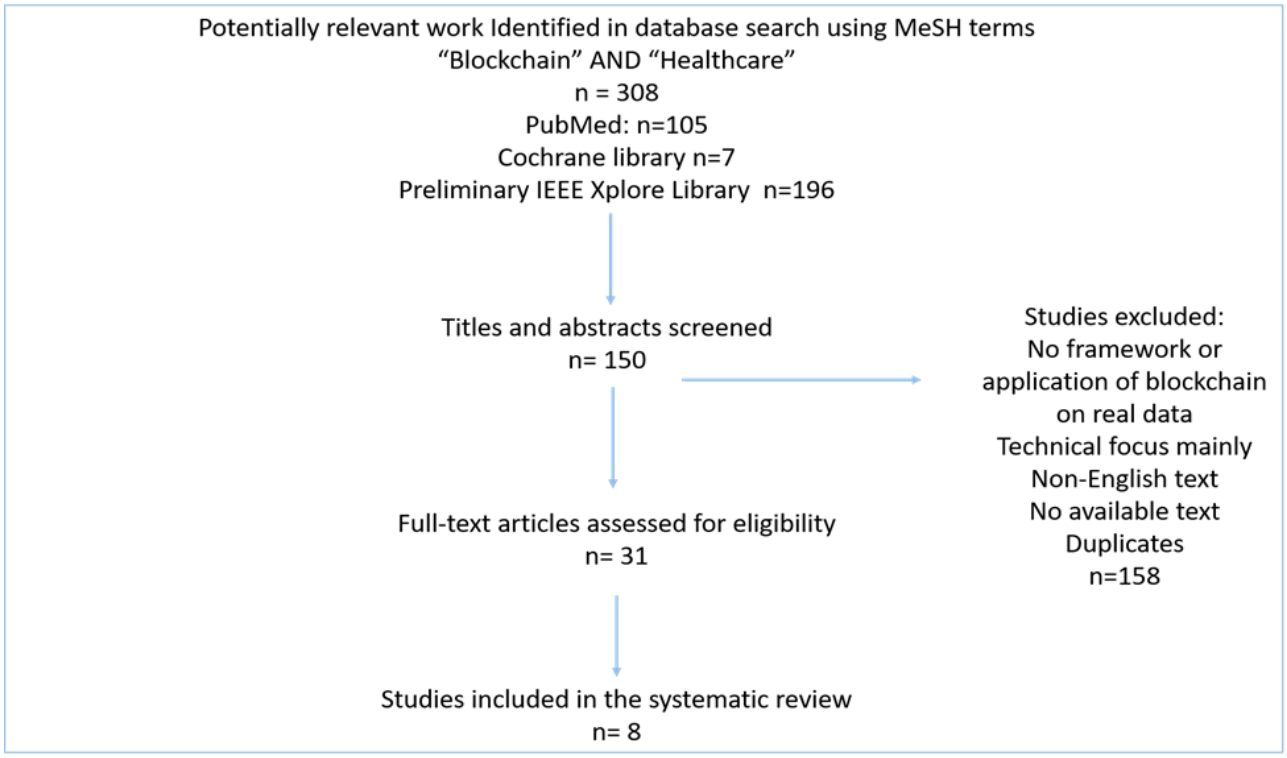
We provide a systematic review of literature on the novel health care ecosystem focusing on blockchains and then consider the cases of Chenoa and Khaled based on the current data.

Methods

Literature Search

The authors searched through the literature using the terms "blockchain" and "healthcare" based on Medical Subject Headings to identify related existing work. The inclusion criteria were focused on studies related to health care and clinical research; a working framework was proposed as well as implementation and testing with data. Exclusion criteria are presented in Figure 1.

Figure 1. Systematic review outcome. MeSH: Medical Subject Headings, IEEE: Institute of Electrical and Electronics Engineers.



The literature sources for this systematic review were PubMed, Medline, and the Cochrane library in addition to a preliminary search of IEEE Xplore, which had works with a technical focus rather than a health care outcome focus.

Reviewers created a data extraction sheet and identified the required data, and 31 full-text studies were critically evaluated; among these, 9 studies were finally selected, and they are summarized in Table 1.

First, we provide an overview of the essential elements of blockchains for readers and then explain the specific methodology in detail.

Overview of Blockchain Technology

The 3 pillars of blockchain technology that make it a revolutionary technology are decentralization, transparency, and immutability. A block is a virtual data storage unit that holds records, transactions, or other means of data. Each block is chronologically linked to the previous blocks using cryptography; once a block is created, it is permanently stored on the blockchain and cannot be modified or removed, thus becoming immutable. If one wishes to update a network node, make another transaction, or add new data, a new block must be added to the chain; all the previous blocks will still be unchanged and visible. Another aspect of a blockchain is that it is a decentralized database using the distributed ledger technology, which simultaneously stores a full replica of the data on multiple nodes, unlike most other data management technologies where data storage is centralized, meaning that it is stored at a single location, mostly on a single server or mainframe computer [2].

The immutability of a blockchain is attributed to different factors; each block has an autogenerated header, which has a unique identification and a timestamp. The block also has a hash key, which is the header of the previous block. Therefore, all blocks are interlocked within their respective blockchains.

Once a verified permissioned node (node C) wants to add new data or make a transaction, a request is sent to all associated blockchain nodes to verify that the content of node C's blockchain matches the content of all the other nodes (nodes A, B, etc). In addition to ensuring a complete match of all the block headers, a unique signature header will be generated for the new block. The new block is added to the blockchain only after the approval of the node.

Blockchains may be permissionless (public), permissioned (private), or sometimes hybrid, as described below. Public

blockchains allow any user to join, view, and add data to the ledger, which offers maximal transparency. However, private blockchains allow only those with access to interact with the network and are usually controlled and maintained by a single organization offering superior privacy and scalability compared to public blockchains. Finally, in consortium-based blockchains, which are hybrids of the other 2 types, the configuration for viewing and writing access is determined by a group of organizations or entities.

Based on this general overview of blockchain technology, we present the salient features of blockchains, which include cybersecurity, applications, and various domains associated with them.

Results

The results of this systematic review alluded to a wide variety of applications for blockchains and various technical differences in the methods used to establish a blockchain [3-10]; a summary is provided in Table 1.

All the studies pertained to electronic health records (EHRs), clinical trials [6-8], or device integration using Internet of Things (IoT) [3,5,9,10].

Researchers at the Chinese Institute of Physical Science have proposed a model called Med-PPPHIS, which combines permissionless and permissioned blockchains, aiming at a closed-loop method for chronic disease management; the authors used Med-PPPHIS for national physique monitoring and scientific exercise guidance using various self-invented IoT medical devices such as health parameter assessment tools, athletic and functional performance assessment devices, wearable heart rate monitors, and intelligent fitness equipment. The blockchain was tested by 25 virtual machine simulations over 500 nodes, with results revealing superior security, higher data transmission rates, and low latency [3]. Another method was used by Hylock and Zeng et al, in which they used a proof-of-concept tool to extensively test all the 16 configurations of their proposed framework in a variety of scenarios, and they demonstrated results similar to the above study [4].

The blockchain was integrated with IoT devices for evaluating and monitoring essential tremor disease; herein, patients were able to use their smartphones to report their location and activity, self-evaluate their disease activity, and log aggravating and relieving factors, in addition to the data from their smartwatches and multiple air systems, providing a holistic view of their disease status. The authors concluded that blockchains resulted in increased efficiency, scalability, decreased cost, and flexibility in data access management [5]. Other studies have employed IoT devices and blockchains for patient monitoring [9,10]. They have created systems that can analyze and manage medical sensor data as well as send alerts based on patient-customized threshold values and abnormal patterns using smart contracts while simultaneously integrating the data into the patients' EHRs.

The last 3 studies [6-8] focused more on the application of blockchains in biomedical research and clinical trials providing proof-of-concept frameworks featuring customized smart contracts, which allowed for more control over data access depending on researcher privilege levels and patient-controlled authorization. Researchers have also incorporated additional security measures such as biometric verification for physician access. Additionally, blockchains have been used as a solution for continuous trial monitoring by clinics, financial sponsors, and participants.

Blockchains are instrumental in many clinical and research domains. Therefore, some governments are exploring the option of having a nationwide blockchain for the EHRs of all their citizens. Estonia is the first country in the world with a digital health care ecosystem for EHRs based on blockchain technology and has provided the world with a model for data integrity and efficiency. Some other countries are in the process of adopting blockchains at the macroscopic level to reduce health care waste, increase efficiency, and ultimately improve outcomes. However, besides the conventional risks of technological failure, scalability remains a challenge; for instance, conducting 800 transactions per second for hyperledgers using blockchains to store continuous telemetry data is not yet practical. Nonetheless, researchers hope that with the current advances in technology, specific solutions for storage optimization and redesigning of blockchain will be available soon [11]. One additional study [12] evaluated the performance of a blockchain-based online machine learning tool available on the internet called ExplorerChain, which uses 3 separate and different data sets (myocardial infarction, cancer biomarkers, and length of hospitalization). The study concluded that the performance of ExplorerChain was as good as the central server–based algorithm while providing the benefits of a distributed model. Nevertheless, the tradeoff with some of those benefits was the cost of efficiency. However, with the rise of supercomputers, the costs associated with running a blockchain are likely to decrease over time.

Let us return to the unfortunate cases of Khaled and Chenoa. Imagine that they lived in a digitalized nation (ie, a smart country as opposed to a smart city), where all the EHRs were on a private or a consortium-based blockchain.

Table 1. Summary of data extraction results.

Reference	Title	Platform or model	Implementation	Features	Method (blockchain interface and IoT[a] device)
Zhou et al [3]	Med-PPPHIS: blockchain-based personal healthcare information system for national physique monitoring and scientific exercise guiding	Med-PPPHIS and Med-DLattice blockchain	Chronic disease management: physique monitoring	Chronic disease management target; scientific and personalized exercise prescriptions (electronic prescriptions), providing users with safe, effective, and private scientific health guidance for the management of chronic diseases	Web portal and mostly self-developed medical IoT devices such as health sign monitoring equipment, heart rate monitor, and intelligent fitness equipment
Hylock and Zeng [4]	A blockchain framework for patient-centered health records and exchange (HealthChain): evaluation and proof-of-concept study	HealthChain	Patient-centered blockchain framework	Smart contracts, proxy re-encryption, revocable access, and patient-centered framework	Web portal
Zheng et al [5]	Accelerating health data sharing: a solution based on the Internet of Things and distributed ledger technologies	IOTA tangle	Remote diagnosis of essential tremor disease	App allowing users to report their location, activity, and tremor level; self-evaluation of the disease and other factors related to the disease, such as medication and alcohol consumption	App; wearable devices (Pebble smartwatch) and stationary air quality sensors
Zhuang et al [6]	Applying blockchain technology for health information exchange and persistent monitoring for clinical trials		Patient-reported outcomes for trials; EHR[b] sharing	Private blockchain, smart contracts, biometric verification of physicians, and patient-controlled data access	Web portal
Johnson et al [7]	Building a secure biomedical data sharing decentralized app (DApp): tutorial	Oasis Devnet/Ethereum	Biomedical research	Smart contracts, public code for app recreation, and geolocation sharing	iPhone (iOS) app
Maslove et al [8]	Using blockchain technology to manage clinical trials data: a proof-of-concept study	BlockTrial/ Ethereum protocol	Clinical trials	Smart contracts and mediated data access based on patient-granted permissions	Web app
Satamraju and Malarkodi [9]	Proof of concept of scalable integration of Internet of Things and blockchain in healthcare	DApp/Ethereum protocol	Remote patient monitoring	Smart contracts, off-chain storage, and Ethereum-based system users including patients, doctors, pharmacists, and insurance companies	App; pulse oximetry device, body temperature sensor, and room temperature sensor
Griggs et al [10]	Healthcare blockchain system using smart contracts for secure automated remote patient monitoring	DApp /Ethereum protocol	Automated patient monitoring	Smart contracts, custom threshold values for alerts, Oracle (master device to control smart contacts), and integration with EHRs	App; medical IoT devices
Kuo et al [11]	Expectation propagation logistic regression on permissioned blockchain (ExplorerChain): decentralized online healthcare/genomics predictive model learning	ExplorerChain	Blockchain combined with artificial intelligence for health care and genomics; predictive model training	iDASH private HIPAA[c]-compliant computing environment network; applied on 3 different data sets including myocardial infarction, cancer biomarkers, and length of hospitalization	Distributed servers using internet-based machine learning

[a]IoT: Internet of Things.

[b]EHR: electronic health record.

[c]HIPAA: The Health Insurance Portability and Accountability Act of 1996.

Discussion

Cybersecurity

EHRs play a vital role in providing smooth, safe, and efficient health care delivery. As many countries do not currently possess a unified health care system, data sharing and interoperability (in a secure manner) become essential for providing patients with the best care. However, this has been a major issue in current health care management systems. Data are one of the most valuable commodities; since the increased reliance on digital systems, cybercriminals have adjusted their methods owing to huge financial incentives, especially through selling the identifying data of people. Thus, medical records are currently worth more than social security numbers on the black market, as they include the date of birth, home addresses, contact data, health data, and other sensitive data. EHR data can be employed for various criminal activities like identity frauds, insurance frauds, phishing, and ransomware, leaving the patients compromised and susceptible to harm [13]. Cyberattacks on hospital systems have increased worldwide in the past decade; such attacks not only impede health care delivery and cause financial losses but also affect patients' trust in medical providers [13,14].

In 2018, a cyberattack on SingHealth (Singapore Health Services) compromised the records of 1.5 million patients [15]; it is considered one of the biggest data breaches in Singapore and worldwide. It has stirred considerable controversy about the security of patients' data and the reasons behind not implementing any significant measures for changing the EHR data systems. Compared to the conventional methods of EHR storage, a blockchain is a potentially secure and an immutable method for data storage and management owing to its decentralized nature. This means that the latest version of the chain is replicated, sent, and widely distributed in a huge network of nodes; there are no weak links for hackers to breach. Each block has a key of its own, in addition to having the hash key of the previous block. Once a transaction request has been made by a user, the blockchain protocol requests the network nodes to verify the validity of the entire blockchain content. This in turn means that unless the networks nodes verify that the current version of the chain is identical to theirs and approve the transaction, it cannot be added to the chain [16,17].

Furthermore, the transaction validation uses cryptominers, which are nodes that possess specialized hardware and software capable of solving energy-intensive cryptographic puzzles. It would be extremely difficult for someone to gather enough computing power to hack the blockchain database by altering the ledgers. The larger the blockchain, the more distributed it is, the more enormous is the computing power required for hacking, and the more secure it becomes [16,17].

Finally, digital signatures are employed to verify the identity of those who wish to access or add data to the blockchain. Additional features such as hardware security modules (HSMs) can be added as an additional layer to further enhance the protection of the patients' data. HSMs are specialized hardware devices that are used to guard highly sensitive data. An HSM acts as a trusted network node that performs several cryptographic processes such as key generation and management, as well as encryption and decryption of digital signatures. HSMs are usually placed in a secure physical location and cannot be accessed, thereby making them highly tamper-resistant systems [18].

Applications and Domains of Use in Health Care

Blockchain technology has thrived in many industries ranging from banking to supply chain management. It is predicted to have a major impact on the health care industry. According to the forecast report for 2018 to 2023 provided by Market Research Future, the global blockchain market is predicted to expand exponentially.

Fundamentally, from a patient's perspective, the potential role of a blockchain in developing a patient's personal health record could be significant. The patient-facing applications of this technology would benefit from one window and one operating system for the personal health records, out-of-pocket costs, covered versus uncovered services, clinical trial searches, consenting for clinical trials, and "omics" data interpretation.

The review focuses on 5 main areas in which most health care–related implementations fall under remote patient monitoring (including IoT devices), EHRs, patient-centered interoperability, clinical trial data management, and monetization, as shown in Table 2 and Figure 2. The potential application areas of blockchain technology in health care are depicted in Figure 3.

Table 2. Areas of blockchain implementation.

Application area	Blockchain technology features
Electronic health record management	• Patient-reported outcomes • Consent
Patient-centered interoperability	• DNR[a] orders • Instantaneous data access and interoperability
Remote patient monitoring	• Patient-mediated and controlled record access • IOT[b]-enabled monitoring of vital signs, glucose, and other parameters • Disease surveillance and outbreak management
Clinical trial data management	• Increased RCT[c] data transparency and quality • IOT-generated clinical research data • Smart contracts applying data specifications and incentives
Monetization	• Revenue cycle management • Clinical trial budgets

[a]DNR: do not resuscitate.

[b]IoT: Internet of Things.

[c]RCT: randomized control trial.

Figure 2. Illustration of blockchain usage in health care.

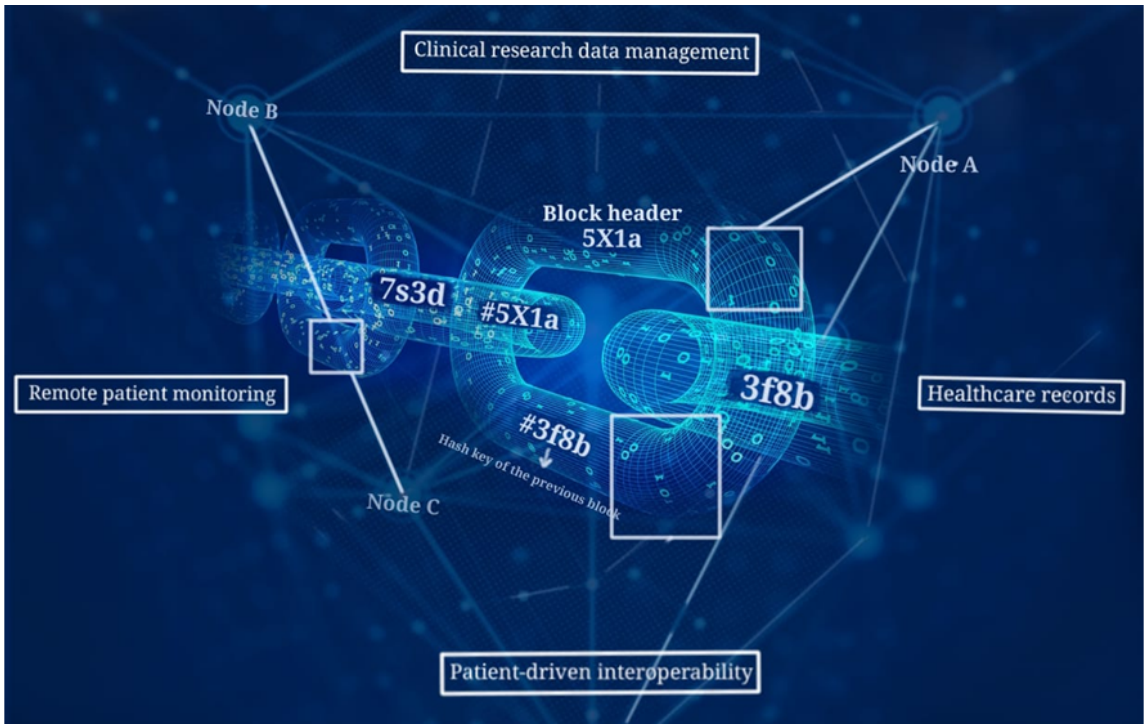
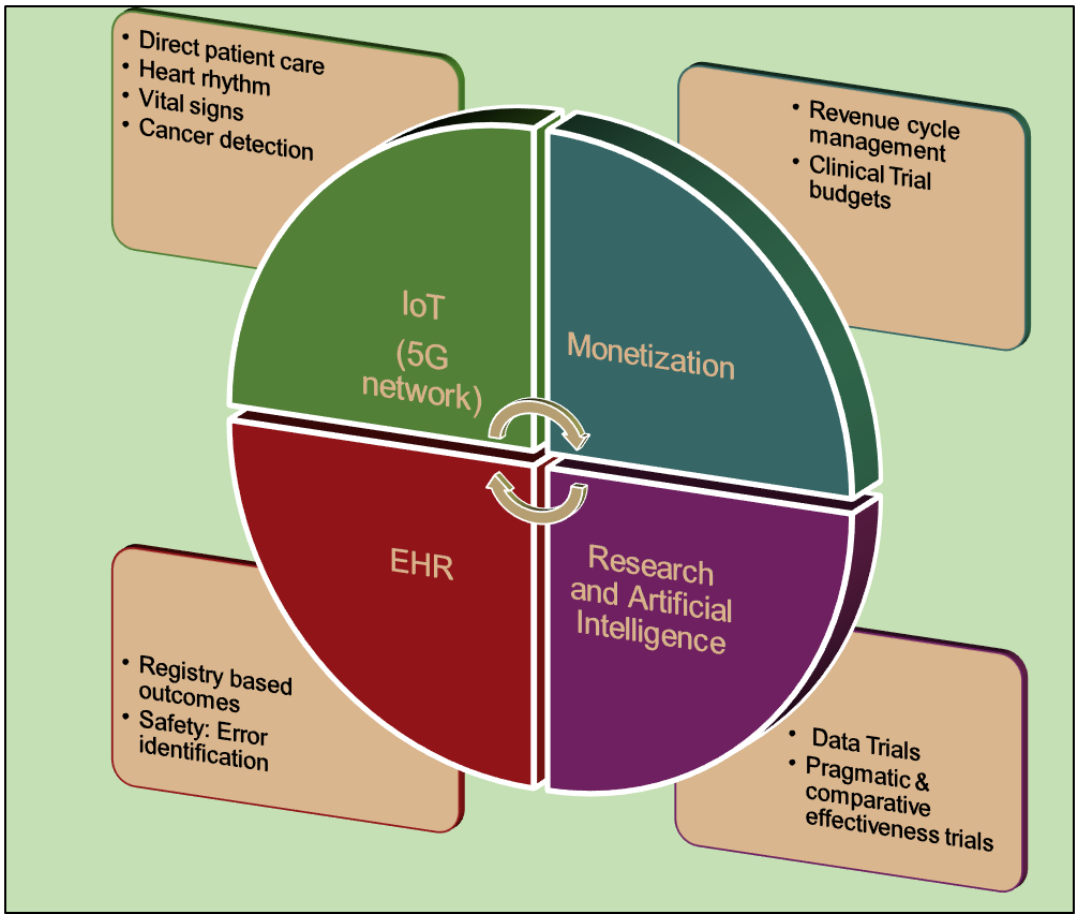


Figure 3. Areas of Blockchain utilization in healthcare.



The IoT Concept, Blockchain, and Clinical Trials

The integration of blockchains with other technologies such as artificial intelligence (AI), IoT, and big data management can be highly effective and act as a catalyst for innovation and increased efficiency, which is invaluable for the interpretation and management of data.

IoT refers to a world where people, things, and devices are all connected through the internet, allowing them to collect and exchange data seamlessly over the network. From coffee machines, wearable devices, and sensors to home security systems, IoT will likely change the way people live because 5G wireless technology (with high bandwidth and low latency) is becoming readily available. All the data streamed over the network can interlock without the need for human interactions. Future smart cities are based on IoT devices and applications. Additionally, it has been gaining considerable attention from stakeholders, investors, and various organizations owing to its unlimited application possibilities [19-21].

Data from sensors and wearable devices can revolutionize the way health care is viewed and delivered, especially in an era of patient-centered care, precision medicine, and individualized health care delivery. IoT can transform the approach to health care and take patient-centered care to a new level, where people can take charge of their health, providing patients and physicians with invaluable continuous real-time data about the physiological state and well-being of patients, ranging from data such as the heart rate, temperature, or sleeping habits to biochemical marker measurements in biofluids through various biosensor technologies, as well as sending alerts when certain thresholds are crossed or abnormal patterns are detected [22-27].

Using IoT technology in conjunction with blockchain technology can maximize its efficacy and potential uses. The massive amounts of various data streamed through different IoT devices can be used to collect large amounts of invaluable data for researchers to analyze and interpret. It could also be useful for data-hungry AI technology companies, public health surveillance, monitoring of disease outbreaks (eg, for monitoring COVID-19), epidemiology, and patient-oriented outcomes [28-33].

AI has been one of the key catalysts in health care innovation; for instance, researchers at the Massachusetts Institute of Technology made a ground-breaking discovery of a new antibiotic using AI technology through a trained deep learning model that was able to produce a powerful wide-spectrum antibiotic called Halicin [34]. However, one of the most critical shortcomings of AI and a crucial component for achieving revolutionary benefits is the requirement of tons of data for training its models to produce accurate and useful outputs. The combination of AI, IoT, and blockchain technologies can be powerful, where IoT devices provide the data (input), blockchains facilitate their transmission to various machine learning, and deep learning models can translate these data into extremely useful outputs. Some of the newer developments in machine learning are significantly driving blockchains to be better integrated with AI in the health care field. This enables

improvements in the security, privacy, functionality, and operational aspects of blockchain technology for health care applications [12,35,36].

Clinical Scenarios, Potential Applications, and Conclusions

If Chenoa had IoT devices that could monitor her vital signs (particularly temperature) 24/7 and the information was transmitted live via a blockchain to live monitors powered by machine learning algorithms, then her temperature fluctuations and trends would have prompted a return to the transplant center much sooner. Although research on nanotechnology and IoT-based sensors for detecting cancers (or relapses) is in its infancy, IoT devices for monitoring vital signs have already proved their effectiveness in monitoring patient physiology. Moreover, if Chenoa's EHR was available to all the treating clinicians across the country via a blockchain, it may have triggered a sense of urgency in the local physician treating her.

For Khaled, having his EHR not readily available to a treating emergency room physician is perhaps a classic example of a disjointed medical ecosystem. If there are IoT devices detecting potassium, oxygen, and vital signs in a heart failure patient, they could be instrumental in saving the lives of many patients with heart and kidney diseases. Moreover, having a living will and information on the power of attorney on a blockchain could be very helpful in certain end-of-life cases as well. Finally, for the hundreds of thousands of patients participating in clinical trials, informed consent on a blockchain could be very beneficial for the trial sponsors, ethics boards (eg, institutional review boards), and patient care providers.

Thus, the potential benefits of blockchains are limitless; however, concrete data on long-term clinical outcomes based on blockchains powered and supplemented by AI and IoT are yet to be achieved. Nonetheless, the implementation of blockchains as a novel way to integrate EHRs nationwide and manage common clinical problems in an algorithmic fashion has the potential of saving thousands of lives like those of Chenoa and Khaled.

Conflicts of Interest

None declared.

References

1. Nakamoto S. Bitcoin: a peer-to-peer electronic cash system. Decentralized Business Review. 2008. URL: http://bitcoin.org/bitcoin.pdf [accessed 2020-03-03]
2. Hoy MB. An introduction to the blockchain and its implications for libraries and medicine. Med Ref Serv Q 2017 Jul;36(3):273-279. [doi: 10.1080/02763869.2017.1332261] [Medline: 28714815]
3. Zhou T, Li X, Zhao H. Med-PPPHIS: blockchain-based personal healthcare information system for national physique monitoring and Scientific Exercise Guiding. J Med Syst 2019 Aug;43(9):305. [doi: 10.1007/s10916-019-1430-2] [Medline: 31410583]
4. Hylock RH, Zeng X. A blockchain framework for patient-centered health records and exchange (HealthChain): evaluation and proof-of-concept study. J Med Internet Res 2019 Aug;21(8):e13592 [FREE Full text] [doi: 10.2196/13592] [Medline: 31471959]
5. Zheng X, Sun S, Mukkamala RR, Vatrapu R, Ordieres-Meré J. Accelerating health Data sharing: a solution based on the Internet of Things and distributed ledger technologies. J Med Internet Res 2019 Jun;21(6):e13583 [FREE Full text] [doi: 10.2196/13583] [Medline: 31172963]
6. Zhuang Y, Sheets L, Shae Z, Tsai JJP, Shyu C. Applying blockchain technology for health information exchange and persistent monitoring for clinical trials. In: AMIA Annu Symp Proc. 2018 Presented at: AMIA Annual Symposium; November 3-7, 2018; San Jose, CA, United States p. 1167-1175.
7. Johnson M, Jones M, Shervey M, Dudley JT, Zimmerman N. Building a secure biomedical data sharing decentralized app (DApp): tutorial. J Med Internet Res 2019 Oct;21(10):e13601 [FREE Full text] [doi: 10.2196/13601] [Medline: 31647475]
8. Maslove DM, Klein J, Brohman K, Martin P. Using blockchain technology to manage clinical trials data: a proof-of-concept study. JMIR Med Inform 2018 Dec;6(4):e11949 [FREE Full text] [doi: 10.2196/11949] [Medline: 30578196]
9. Satamraju KP, Malarkodi B. Proof of concept of scalable integration of Internet of Things and blockchain in healthcare. Sensors (Basel) 2020 Mar;20(5):1389 [FREE Full text] [doi: 10.3390/s20051389] [Medline: 32138380]
10. Griggs KN, Ossipova O, Kohlios CP, Baccarini AN, Howson EA, Hayajneh T. Healthcare blockchain system using smart contracts for secure automated remote patient monitoring. J Med Syst 2018 Jun;42(7):130. [doi: 10.1007/s10916-018-0982-x] [Medline: 29876661]
11. Kuo T, Kim H, Ohno-Machado L. Blockchain distributed ledger technologies for biomedical and health care applications. J Am Med Inform Assoc 2017 Nov;24(6):1211-1220 [FREE Full text] [doi: 10.1093/jamia/ocx068] [Medline: 29016974]
12. Kuo T, Gabriel R, Cidambi K, Ohno-Machado L. Expectation propagation logistic regression on permissioned blockchain (ExplorerChain): decentralized online healthcare/genomics predictive model learning. J Am Med Inform Assoc 2020 May;27(5):747-756 [FREE Full text] [doi: 10.1093/jamia/ocaa023] [Medline: 32364235]
13. Luna R, Rhine E, Myhra M, Sullivan R, Kruse CS. Cyber threats to health information systems: a systematic review. Technol Health Care 2016 Jan;24(1):1-9 [FREE Full text] [doi: 10.3233/THC-151102] [Medline: 26578272]

14. Argaw ST, Bempong N, Eshaya-Chauvin B, Flahault A. The state of research on cyberattacks against hospitals and available best practice recommendations: a scoping review. BMC Med Inform Decis Mak 2019 Jan 11;19(1):10 [FREE Full text] [doi: 10.1186/s12911-018-0724-5] [Medline: 30634962]
15. Tham I. Personal info of 1.5m SingHealth patients, including PM Lee, stolen in Singapore's worst cyber attack. The Straits Times. 2018. URL: https://www.straitstimes.com/singapore/personal-info-of-15m-singhealth-patients-including-pm-lee-stolen-in-singapores-most [accessed 2018-07-20]
16. Alam Khan F, Asif M, Ahmad A, Alharbi M, Aljuaid H. Blockchain technology, improvement suggestions, security challenges on smart grid and its application in healthcare for sustainable development. Sustain Cities Soc 2020 Apr;55:102018. [doi: 10.1016/j.scs.2020.102018]
17. Sultana M, Hossain A, Laila F, Taher KA, Islam MN. Towards developing a secure medical image sharing system based on zero trust principles and blockchain technology. BMC Med Inform Decis Mak 2020 Oct;20(1):256 [FREE Full text] [doi: 10.1186/s12911-020-01275-y] [Medline: 33028318]
18. Boireau O. Securing the blockchain against hackers. Network Security 2018 Jan;2018(1):8-11. [doi: 10.1016/s1353-4858(18)30006-0]
19. Kamel BMN, Al-Shorbaji NM. On the Internet of Things, smart cities and the WHO healthy cities. Int J Health Geogr 2014 Mar;13:10 [FREE Full text] [doi: 10.1186/1476-072X-13-10] [Medline: 24669838]
20. Lynggaard P, Skouby KE. Complex IoT systems as enablers for smart homes in a smart city vision. Sensors (Basel) 2016 Nov;16(11):1840 [FREE Full text] [doi: 10.3390/s16111840] [Medline: 27827851]
21. Cirillo F, Wu F, Solmaz G, Kovacs E. Embracing the future Internet of Things. Sensors (Basel) 2019 Jan;19(2):351 [FREE Full text] [doi: 10.3390/s19020351] [Medline: 30654571]
22. Dimitrov DV. Medical Internet of Things and big data in healthcare. Healthc Inform Res 2016 Jul;22(3):156-163 [FREE Full text] [doi: 10.4258/hir.2016.22.3.156] [Medline: 27525156]
23. Chen HS, Jarrell JT, Carpenter KA, Cohen DS, Huang X. Blockchain in healthcare: a patient-centered model. Biomed J Sci Tech Res 2019 Aug;20(3):15017-15022 [FREE Full text] [Medline: 31565696]
24. Kamel Boulos MN, Wilson JT, Clauson KA. Geospatial blockchain: promises, challenges, and scenarios in health and healthcare. Int J Health Geogr 2018 Jul;17(1):25 [FREE Full text] [doi: 10.1186/s12942-018-0144-x] [Medline: 29973196]
25. Kang M, Park E, Cho BH, Lee K. Recent patient health monitoring platforms incorporating Internet of Things-enabled smart devices. Int Neurourol J 2018 Jul;22(Suppl 2):S76-S82 [FREE Full text] [doi: 10.5213/inj.1836144.072] [Medline: 30068069]
26. Yang Z, Zhou Q, Lei L, Zheng K, Xiang W. An IoT-cloud based wearable ECG monitoring system for smart healthcare. J Med Syst 2016 Dec;40(12):286. [doi: 10.1007/s10916-016-0644-9] [Medline: 27796840]
27. Coulby G, Clear A, Jones O, Young F, Stuart S, Godfrey A. Towards remote healthcare monitoring using accessible IoT technology: state-of-the-art, insights and experimental design. Biomed Eng Online 2020 Oct;19(1):80 [FREE Full text] [doi: 10.1186/s12938-020-00825-9] [Medline: 33126878]
28. Bhattacharya S, Singh A, Hossain MM. Strengthening public health surveillance through blockchain technology. AIMS Public Health 2019 Sep;6(3):326-333 [FREE Full text] [doi: 10.3934/publichealth.2019.3.326] [Medline: 31637281]
29. Singh RP, Javaid M, Haleem A, Suman R. Internet of things (IoT) applications to fight against COVID-19 pandemic. Diabetes Metab Syndr 2020 Jul;14(4):521-524 [FREE Full text] [doi: 10.1016/j.dsx.2020.04.041] [Medline: 32388333]
30. Panarello A, Tapas N, Merlino G, Longo F, Puliafito A. Blockchain and IoT integration: a systematic survey. Sensors (Basel) 2018 Aug;18(8):2575 [FREE Full text] [doi: 10.3390/s18082575] [Medline: 30082633]
31. Dwivedi AD, Srivastava G, Dhar S, Singh R. A decentralized privacy-preserving healthcare blockchain for IoT. Sensors (Basel) 2019 Jan;19(2):326 [FREE Full text] [doi: 10.3390/s19020326] [Medline: 30650612]
32. Madanian S, Parry D. IoT, cloud computing and big data: integrated framework for healthcare in disasters. Stud Health Technol Inform 2019 Aug;264:998-1002. [doi: 10.3233/SHTI190374] [Medline: 31438074]
33. Catherwood PA, Steele D, Little M, Mccomb S, Mclaughlin J. A community-based IoT personalized wireless healthcare solution trial. IEEE J Transl Eng Health Med 2018 May;6:1-13 [FREE Full text] [doi: 10.1109/JTEHM.2018.2822302] [Medline: 29888145]
34. Stokes J, Yang K, Swanson K, Jin W, Cubillos-Ruiz A, Donghia NM, et al. A deep Learning approach to antibiotic discovery. Cell 2020 Feb;180(4):688-702.e13 [FREE Full text] [doi: 10.1016/j.cell.2020.01.021] [Medline: 32084340]
35. Chen X, Ji J, Luo C, Liao W, Li P. When machine learning meets blockchain: decentralized, privacy-preserving secure design. United States: IEEE; 2018 Presented at: IEEE International Conference on Big Data (Big Data); Decembe 10-13, 2018; Seattle, WA, United States p. 1178-1187. [doi: 10.1109/bigdata.2018.8622598]
36. Li Z, Liu J, Hao J, Wang H, Xian M. CrowdSFL: a secure crowd computing framework based on blockchain and federated learning. Electronics 2020 May;9(5):773. [doi: 10.3390/electronics9050773]

Abbreviations

AI: artificial intelligence
EHR: electronic health record

HSMs: hardware security modules
IoT: Internet of Things

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