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Original Paper

Extraction and Standardization of Patient Complaints from Electronic Medication Histories for Pharmacovigilance: Natural Language Processing Analysis in Japanese

Misa Usui[1], BA; Eiji Aramaki[2], PhD; Tomohide Iwao[2], MS; Shoko Wakamiya[2], PhD; Tohru Sakamoto[3], BA; Mayumi Mochizuki[4,5], PhD

[1]Division of Hospital Pharmacy Science, Graduate School of Pharmaceutical Sciences, Keio University, Tokyo, Japan

[2]Social Computing Lab, Graduate School of Information Science, Nara Institute of Science and Technology, Nara, Japan

[3]Holon Co, Ltd., Hiroshima, Japan

[4]Division of Hospital Pharmacy Science, Faculty of Pharmacy, Keio University, Tokyo, Japan

[5]Department of Pharmacy, Keio University Hospital, Tokyo, Japan

Abstract

Background: Despite the growing number of studies using natural language processing for pharmacovigilance, there are few reports on manipulating free text patient information in Japanese.

Objective: This study aimed to establish a method of extracting and standardizing patient complaints from electronic medication histories accumulated in a Japanese community pharmacy for the detection of possible adverse drug event (ADE) signals.

Methods: Subjective information included in electronic medication history data provided by a Japanese pharmacy operating in Hiroshima, Japan from September 1, 2015 to August 31, 2016, was used as patients' complaints. We formulated search rules based on morphological analysis and daily (nonmedical) speech and developed a system that automatically executes the search rules and annotates free text data with *International Classification of Diseases, Tenth Revision* (ICD-10) codes. The performance of the system was evaluated through comparisons with data manually annotated by health care workers for a data set of 5000 complaints.

Results: Of 5000 complaints, the system annotated 2236 complaints with ICD-10 codes, whereas health care workers annotated 2348 statements. There was a match in the annotation of 1480 complaints between the system and manual work. System performance was .66 regarding precision, .63 in recall, and .65 for the F-measure.

Conclusions: Our results suggest that the system may be helpful in extracting and standardizing patients' speech related to symptoms from massive amounts of free text data, replacing manual work. After improving the extraction accuracy, we expect to utilize this system to detect signals of possible ADEs from patients' complaints in the future.

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KEYWORDS

adverse drug events; natural language processing; medical informatics; medication history; pharmacovigilance

Introduction

Background

Adverse drug events (ADEs) are any untoward injuries resulting from the use of a drug [1]. They occur in around 18% of inpatients [1-4] and are a significant burden on health care and society. The ADEs are a cause of morbidity, and mortality and their economic loss is estimated at US $177.4 billion annually in the US [5]. In the field of pharmacovigilance, postmarketing surveillance such as spontaneous reporting is important for the detection of ADEs because clinical trials have limitations including patient sample size, population, and administration period [6].

The need to understand patients' subjective complaints and to use other sources in pharmacovigilance has increased. Unlike health care providers, patients use various expressions and terminology to describe their situations. Direct reporting from patients is helpful in understanding their detailed symptoms and impacts on quality of life, which medical professionals tend to overlook [7-9]. For example, analysis of the content of comments posted on patients' online community pages revealed unknown long-term symptoms of antidepressant withdrawal [10]. The Maintenance and Support Services Organization developed the Patient-Friendly Term List [11] based on the most frequent ADEs reported by patients and consumers to facilitate direct patient reporting of ADEs to regulators and the pharmaceutical industry. Despite its importance, little work has

been done on exploring patient records until recently due to their unstructured, time-consuming data format.

Natural language processing (NLP) is the automatic manipulation of natural language such as narrative text and speech for extraction and structuring [12]. Numerous attempts have been made to use NLP in electronic health records (EHRs), social media, medical literature, or existing reporting systems [13-29]. Those studies found that NLP could identify various points for the assessment of medications (eg, inactive medication, nonadherence, patients' mentions of ADEs).

In Japan, text analysis and automated detection of medical events from EHRs have been reported [30], and a tool for disease entity encoding was developed [31]. However, these 2 studies intended only to manipulate clinical text provided by health care professionals using medical terminology. No previous study dealt with patients' complaints in their own words in Japanese.

Prior Work

Nikfarjam et al [25] introduced a machine learning-based extraction system using conditional random fields (CRFs) for user posts on DailyStrength (precision: .86, recall: .78, F-measure: .82) and Twitter (precision: .76, recall: .68, F-measure: .72) to detect adverse drug reaction (ADR) signals. Freifeld et al [28] classified Twitter posts (precision: .72, recall: .72) to compare product-event pairs with the US Food and Drug Administration Adverse Event Reporting System (FAERS) data.

In the mining of patients' reports, Topaz et al [26] used a linguistic-based approach comparing EHRs (clinicians' reports) and social media (patients' mentions) for 2 common drugs. White et al [27] used search log data for the identification of ADE signals and a comparison with FAERS data resulted in high concordance as determined by the Area Under the Curve Receiver Operating Characteristics curve of .82. Denecke et al [29] collected data from multiple media sites with keyword lists and classified texts as relevant/irrelevant using support vector machines.

Although no previous studies have been completed in Japanese, Aramaki et al [30] reported on a system to extract medical event information from Japanese EHRs based on CRFs (precision: .85, recall: .77, F-measure: .81). The text source in their study was written in medical terminology, mainly by physicians. No lexicon to standardize patients' informal expressions such as the Patient-Free Term List [11] and the work of Freifeld et al [28] has been published in Japanese.

Study Aim

This study aimed to develop techniques to establish a method for extracting and standardizing patient complaints from electronic medication history data (EMHD) accumulated in a Japanese community pharmacy for the detection of possible ADE signals.

Methods

Concept of the System

We propose a system that automatically extracts and standardizes patient complaints (Figure 1). In this system, subjective information included in the medication histories collected from a pharmacy is input data, and data in which *International Classification of Diseases, Tenth Revision* (ICD-10) codes are attached to patient expressions are outputs. A dictionary-based method was adopted for extraction and standardization. The processing steps in the system are as follows. First, morphological analysis is performed on input data. Next, the search rules are applied to split data. In the search rules, morpheme combinations in general expressions and the corresponding ICD-10 codes are described for each line, and exclusion rules are set for some ICD-10 codes. When a patient expression satisfies the search rules, a corresponding ICD-10 code is given. Procedures for creating the search and exclusion rules and system development procedures are detailed in "Search Rules" and "System Development."

Data Sources

The EMHD stored in a community pharmacy were used as the source of patients' comments. When pharmacists dispense prescription drugs to patients, they are required to record the results of medication instructions and patients' queries/responses. A medication history in Japan is typically written in the "SOAP" format, which consists of 4 sections: "Subjective information" (complaints of the patient), "Objective information" (objective indicators such as laboratory findings or names of drugs prescribed), "Assessment" (the pharmacist's findings on the occurrence of ADRs, interactions, or doubt about prescription instructions), and "Plan" (action plan of the pharmacist derived from the assessment).

Although patients do not write the medication history, of those 4 sections the "Subjective information" appeared to be the most appropriate text source, because pharmacists complete that section in the patients' own words.

Patients' comments were extracted from the EMHD of a community pharmacy operated by Holon Co, Ltd, Hiroshima, Japan. This company operates a chain of 14 pharmacies, and the data used in this study mainly came from a single one. The study period was from September 1, 2015 to August 31, 2016. Personal information such as patients' names and birth dates were anonymized before analysis.

Information on the hospitals or clinics that issued prescriptions for which the subjective information used in this study was derived is shown in Table 1. The pharmacy filled a total of 42,120 prescriptions during the study period for the top 9 prescribing hospitals or clinics. The number of prescriptions from medical institution A was the highest (18,273/42,120, 43.5%). Clinic A specializes in otolaryngology, and the patients are older adults who often complain of dizziness or hearing loss.

Table 2 shows the items recorded in the EMHD, while Figure 2 is an example of a recording object.

Figure 1. Concept of the system. ICD-10: *International Classification of Diseases, Tenth Revision.*.

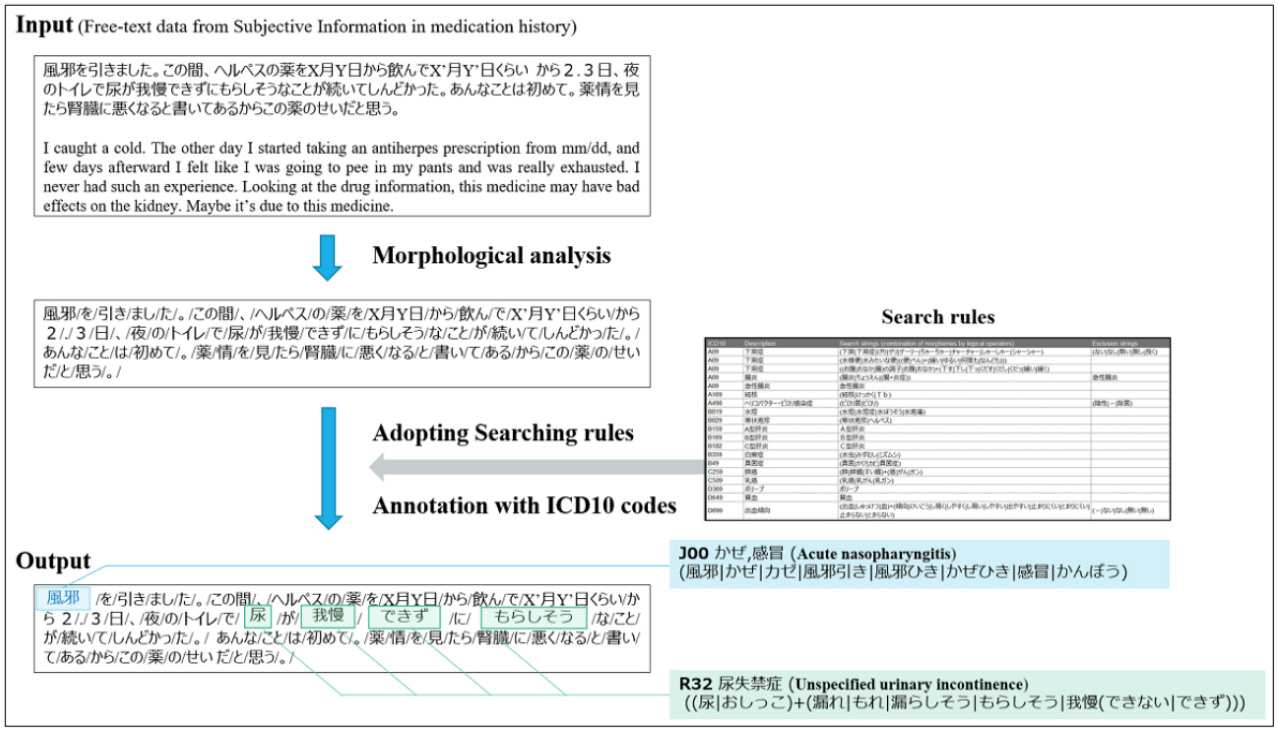


Table 1. Backgrounds of the prescriptions used in this study (N=42,120).

Hospital/ clinic	Specialty	Main patient characteristics	Prescriptions, n (%)
A	Otolaryngology	• Elderly • Dizziness • Tinnitus • Hearing loss	18,273 (43.38)
B	General medicine; cardiology	• Elderly • Heart disease • Hypertension	5356 (12.72)
C	General medicine; gastroenterology; cardiology	• Elderly • Digestive tract diseases • Circulatory diseases	537 (1.27)
D	General medicine; Kampo[a] medicine	• Elderly • Kampo[a] medicines (for >half of the patients)	989 (2.35)
E	Neuropsychiatry	• Wide range of age-groups	377 (0.90)
F	Neuropsychiatry	• Wide range of age-groups	563 (1.34)
G	Obstetrics and gynecology	• Gynecological conditions	649 (1.54)
H	Obstetrics and gynecology	• Infertility treatment	4206 (9.99)
I	Breast surgery	• Breast cancer patients visiting for diagnosis and postoperative care	2608 (6.19)
Other[b]	Various	• Various	8562 (20.33)

[a]The word "Kampo" means herbal medicine in Japanese. The term "Kampo Shoseiryuto" is commonly used to treat watery nasal discharge, nasal congestion, watery sputum, and sneezing.

[b]These are medical institutions that are not the major clinics "A" to "I" from which this pharmacy receives prescriptions.

Table 2. Items recorded in the electronic medication history data.

Category	Content
Identification	Identification of patient
Name	Name of patient
Sex	Male/female
Birth[a]	Year/month/day
Special instructions	Notes as required (eg, disease entity)
Concomitant drugs	
Drug name	YJ-code[b] or product name
Dosing period	Year/month/start date/end date
Prescription data	
Dispensing date	Year/month/day
Drug name	YJ-code or product name
Dosage/administration[c]	Free text
Medication counseling	
Counseling date	Year/month/day
Subjective information[d]	Free text
Objective information[e]	Free text
Assessment[f]	Free text
Plan[g]	Free text

[a]Only the year of birth data was used.

[b]YJ-codes identify prescription drugs covered by insurance in Japan.

[c]Not used in this study.

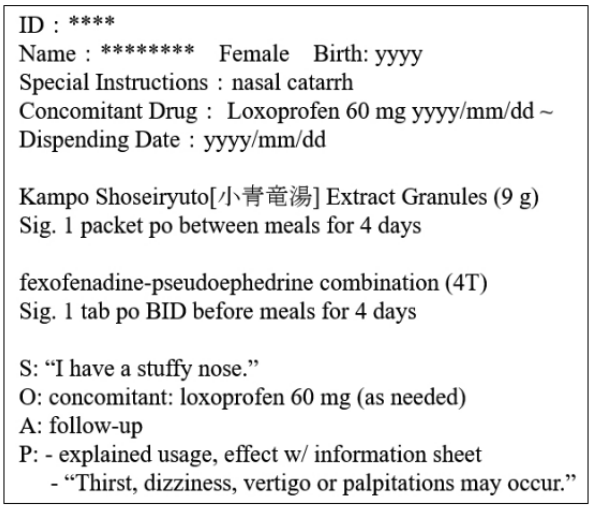
[d]Includes patient complaints.

[e]Includes laboratory data.

[f]Includes pharmacists' assessments of patient conditions.

[g]Includes pharmacists' plans for prescription questions, patient education, and follow-up.

Figure 2. Example of a medication history.



Search Rules

We created search rules to identify the appropriate ICD-10 code from the free text in the "Subjective information" section and developed a coding system that annotates the ICD-10 codes within patient complaints. The ICD-10 was originally an English-based system but is also used in Japan. It was translated into Japanese by the World Health Organization, and a coding rulebook was published. For example, in Medis [32] the ICD-10 is given as the basic classification code, and coding matched as closely as possible to clinical interpretation is undertaken. Although it may be possible to use the Medical Dictionary for Regulatory Activities (MedDRA) or the International Classification of Primary Care as a medical code system, we adopted ICD-10 in this study because it is used for insurance claims in Japan and because many coders are familiar with ICD-10.

In developing the system, a nurse with 10 years of experience in the field of terminal care and a medical coder with 20 years of experience created the search rules based on the expressions in the "Subjective information" section. A programmer read the search rules and developed a program to accommodate new expressions. Search rules were created by a combination of morphological analysis and common expressions.

The search rules govern the pattern for analyzing comments included in the subjective information. The rules were saved in Microsoft Excel format with the corresponding disease entity category and ICD-10 codes. For example, to search for "D69.9: Hemorrhagic condition, unspecified," the search strings are "(出血|しゅっけつ|血)+(傾向|けいこう|し易く|しやすく|し易い|しやすい|出やすい|止まりにくい|とまりにくい|止まらない|とまらない)." In English, this would translate to "(bleeding|blood)+(tendency|easy to|hard to stop|won't stop|not stop)." Written Japanese utilizes 3 orthographic systems: Chinese characters, *hiragana*, and *katakana*. Therefore, the actual search strings are longer than in English. All rules are shown in Multimedia Appendix 1. The rule-making steps are shown in Textbox 1. We repeated this process 5 times over 1 month in order to refine the search rules.

The nurse first checked the free text recorded in the "Subjective information" section and selected complaints referring to patients' symptoms. Then words related to ICD-10 codes were manually extracted from the complaints. Finally, the extracted words were added sequentially to the search string for each ICD-10 code. The search strings consist of patterns of word combinations using "|" (logical sum) or "+" (logical product). At present, a maximum of 3 words/terms can be combined in a string separated by "+" signs. For example, from the text "blood pressure today was a little high," the terms "blood pressure" and "a little high" were extracted, and the system annotated the text with the ICD-10 code "I10: hypertension."

However, some text found in the "Subjective information" section could not be annotated with an ICD-10 code even though it followed the search rules. Therefore, we set exclusion rules for some codes, which were created following the same procedure as for the search rules but were only applied when a health care worker could visually confirm the keyword for exclusion. For the previous example of "D69.9: Hemorrhagic condition, unspecified," terms with "(-|ない|なし|無い|無し)," in English, "(-|no|none|negative|never|don't)" were excluded even if they included search strings. For example, "(血がとまりにくい)," in English, "(the bleeding won't stop)," was annotated as D69.9, but "(血がとまりにくいことはない)," in English, "(I never felt the bleeding wouldn't stop)," was excluded.

System Development

The system developed extracts complaints related to patients' symptoms from the "Subjective information" section of EMHD automatically and annotated each complaint with the ICD-10 code using the search rules above. During system development, we used Perl as the programming language and MeCab [33] as a morphological analyzer. The Microsoft Excel format was used for subsequent analysis.

The development procedure can be summarized as follows:

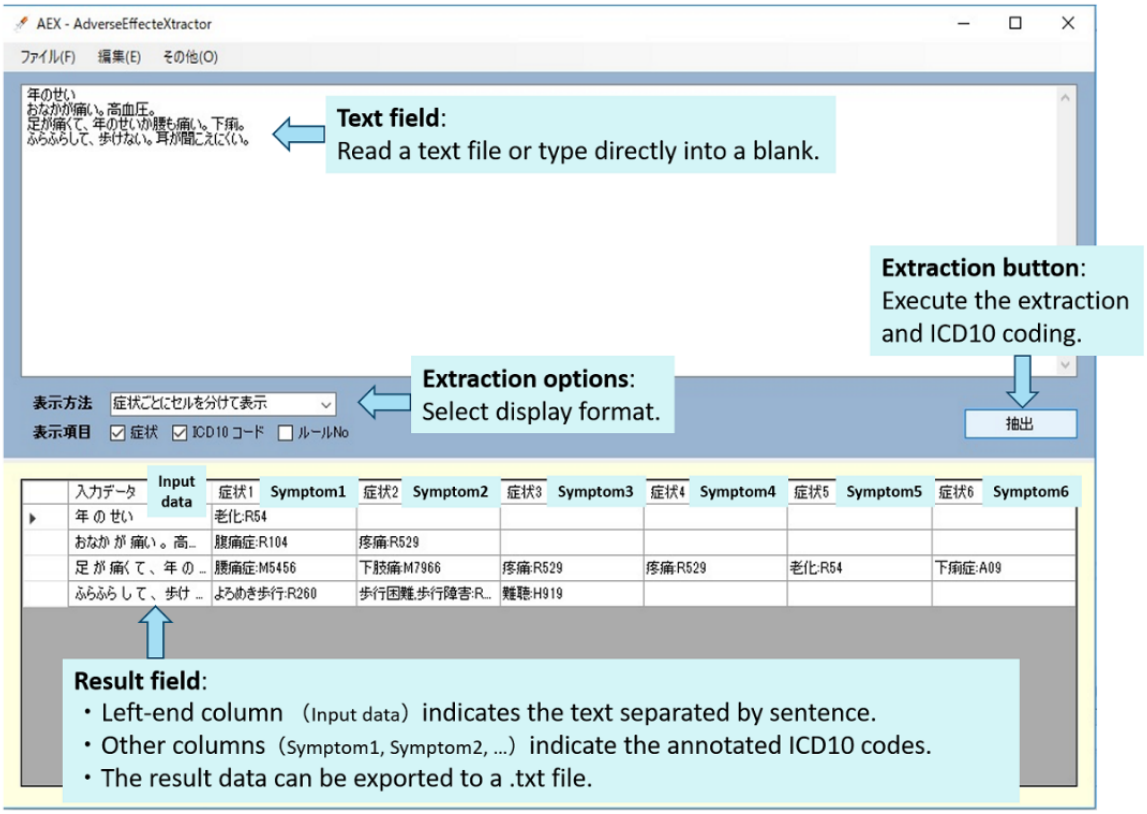
1. Subjective information was extracted from each saved Microsoft Excel file
2. Morphological analysis was performed to extract subjective information, separating the text with spaces into minimum meaningful units of words/terms
3. After the processes above were performed, the subjective information was copied back into a Microsoft Excel file. Search rules and exclusion rules were applied to the subjective information by analyzing each complaint and searching for the ICD-10 code
4. If an appropriately matching ICD-10 code was found, the complaint was annotated with the ICD-10 code and the corresponding disease entity

The coding system adapts the search rules (shown in Multimedia Appendix 1) in order from the top. If an adaptable rule is found, the result of ICD-10 coding is output. If multiple rules are matched, all of them are output in the results.

Textbox 1. Rule-making steps.

1. Make seed rules
2. Apply seed rules to development set
3. Error analysis performed by two rule curators (the nurse and medical coder)
4. New rules added by the programmer, who converts the error analysis to general expressions
5. Repeat steps 3 and 4

Figure 3. System interface screenshot. ICD-10: *International Classification of Diseases, Tenth Revision*.



Optimization of System Performance

For optimal performance of the system, the system-annotated disease entities should ideally match the entities manually annotated by health care professionals. As mentioned above, the more thoroughly the search rules are satisfied, the more accurate the system. Therefore, we reviewed the search rules multiple times to determine the most appropriate ones to improve the accuracy of the system.

In this study, we did not attempt machine learning for the detection of relevant terms to match ICD-10 codes. By adding search rules as appropriate, free text can be automatically associated with ICD-10 codes via the system.

Experiment

An evaluation experiment was conducted to confirm the performance of the system. Five thousand complaints from the subjective information were processed, and 323 search rules were created. In the experiment, health care workers (1 nurse and 1 pharmacist) first independently annotated the 5000 complaints manually with the ICD-10 codes. Second, 108 mismatched annotations were excluded, and the data from the remaining 2348 were used as correct answers for the subsequent step. Finally, the system with 323 search rules was applied to the 5000 complaints.

The subjective information used in this study consisted of multiple sentences, and thus several patient expressions were obtained from one "Subjective information" section. Since each patient expression is linked to the ICD-10 code, multiple ICD-10 codes are assigned to a single "Subjective information" section.

In evaluating the system in this study, if one of the plural ICD-10 codes differed from the manual result, it was judged that all other coding for that entry was incorrect (unmatched). Figure 3 shows an actual system execution screen.

Based on the results of this experiment, the precision, recall, and F-measure of the system were calculated [34,35]. Precision was calculated by dividing the matched number (the number of "Subjective information" sections for which manual coding and system coding had the same result) by the searched number (the number of "Subjective information" sections that the system annotated with ICD-10 codes). Recall was calculated by dividing the matched number by the correct answers (the number of "Subjective information" sections manually coded). The F-measure was calculated by taking the harmonic mean between precision and recall.

Ethical Considerations

This study was approved by the Ethics Committees on Human Research of the Faculty of Pharmacy, Keio University and Nara Institute of Science and Technology.

Results

Examples of correct answer data and system execution results are shown in Table 3. From 5000 complaints, 2348 ICD-10 codes were extracted by health care workers. The system extracted 2236 codes, 1480 of which matched the manual results. The system performed .662 for precision, .630 for recall and .646 for F-measure. Table 4 shows precision and recall for the 10 most frequent symptoms extracted by health care workers.

Table 3. Comparison between manual and system extraction of ICD-10 codes for patient complaints from typical examples.

Patient complaints (Original text of Japanese is attached)	Manual results	System results	Matching
めまいは起こっていないです。暑さでフラーっとすることがある。 No vertigo/dizziness. Sometimes I feel unsteady due to the heat.	R42: Dizziness and giddiness; R26.0: Ataxic gait	R42: Dizziness and giddiness	Not matched
昨日の夜から頭の後ろが重いような感じがする。風邪かと思って受診。 From the night before last, the back of my head felt heavy. I probably caught cold, so I saw a doctor.	J00: Acute nasopharyngitis (common cold); R51: Headache	J00: Acute nasopharyngitis (common cold); R51: Headache	Matched
私よく走っちゃうんだけど坂で躓いてね。ちょっとなのに大きなアザガできた。整形外科の先生は血流の薬があるからって。でも飲まないとだめだといわれた。 I was in a hurry, stumbled, and fell. A big bruise came up. My orthopedist said it may be caused by my blood thinner, though I have to continue that medicine.	Q82.5: Congenital nonneoplastic nevus	Q82.5: Congenital nonneoplastic nevus	Matched
血圧はちょっと高かったの。１４０後半。家だったら１３０くらいなんだけど。整形外科でもらったパップはかぶれてしまった。 My blood pressure was a bit high, in the upper 140s, although it's around 130 when I'm at home. I got a rash from plasters prescribed by orthopedics.	I10: Essential (primary) hypertension; L259: Unspecified contact dermatitis, unspecified cause	I10: Essential (primary) hypertension; L259: Unspecified contact dermatitis, unspecified cause	Matched
風邪を引きました。この間、ヘルペスの薬をX月Y日から飲んでX'月Y'日くらいから２．３日、夜のトイレで尿が我慢できずにもらしそうなことが続いてしんどかった。あんなことは初めて。薬情を見たら腎臓に悪くなると書いてあるからこの薬のせいだと思う。 I caught a cold. The other day I started taking an antiherpes prescription from mm/dd, and few days afterward I felt like I was going to pee in my pants and was really exhausted. I never had such an experience. Looking at the drug information, this medicine may have bad effects on the kidney. Maybe it's due to this medicine.	J00: Acute nasopharyngitis; R32: Unspecified urinary incontinence	J00: Acute nasopharyngitis; B02.9: Zoster without complication; R32: Unspecified urinary incontinence; R53: Malaise and fatigue; N28.9: Disorder of kidney and ureter, unspecified; R94.4: Abnormal results of kidney function studies	Not matched

Table 4. Precision and recall for the 10 most frequent symptoms.

Rank	ICD-10[a]	Matched, n (%)	Correct answer, n (%)	Searched, n (%)	Precision	Recall
1	R42 (Dizziness and giddiness)	146 (9.86)	173 (7.37)	254 (11.36)	.575	.844
2	J00 (Acute nasopharyngitis[b])	189 (12.77)	208 (8.86)	226 (10.11)	.836	.909
3	R52.9 (Pain, unspecified)	108 (7.29)	146 (6.22)	199 (8.90)	.543	.740
4	F19.6 (Mental and behavioral disorders[c])	142 (9.59)	168 (7.16)	197 (8.81)	.721	.845
5	R05 (Cough)	114 (7.70)	134 (5.71)	143 (6.40)	.797	.851
6	H931 (Tinnitus)	99 (6.68)	131 (5.58)	134 (6.00)	.739	.756
7	R26.0 (Ataxic gait)	41 (2.77)	59 (2.51)	120 (5.37)	.341	.695
8	I10 (Essential [primary] hypertension)	51 (3.44)	89 (3.79)	87 (3.89)	.586	.573
9	F51.1 (Nonorganic hypersomnia)	39 (2.63)	46 (1.96)	85 (3.80)	.459	.848
10	R53 (Malaise and fatigue)	40 (2.70)	59 (2.51)	81 (3.62)	.494	.678

[a]ICD-10: *International Classification of Diseases, Tenth Revision*.

[b]Common cold.

[c]Due to multiple drug use and use of other psychoactive substances.

Textbox 2. Six reasons for unmatched results. ICD-10: International Classification of Diseases, Tenth Revision.

1. Misdetection of negation or possible event

System misread an expression including negation or possible event as a symptom that actually occurred (eg, “dizziness has not occurred,” “If I feel dizzy”)

2. Misdetection of a clinical test item

System mistook a clinical test term as a patient symptom (eg, “test for dizziness”)

3. Misdetection of drug class name

System mistook the name of the drug class as a patient symptom (eg, “painkiller” mistaken for “R529: Pain, unspecified”)

4. Misdetection of unrelated words

System mistook unrelated words as a patient symptom (eg, “I’m getting old” mistaken for “R54: Senility”)

5. False negative

System missed a word that indicates a patient symptom

6. Inappropriate ICD-10 code

System failed to choose the appropriate ICD-10 code even if it extracted words related to a patient symptom

The results indicated that the average performance of the system was .66 for precision, .63 for recall, and .65 for the F-measure. Comparing the performance for each symptom, the precision of “dizziness and giddiness,” “pain, unspecified,” and “ataxic gait” was especially low. We identified 6 reasons for the unmatched results for these 3 symptoms, as shown in Textbox 2.

Table 5 details the unmatched results and typical examples for 3 symptoms. The main reason for discordance between manual and system coding was misdetection of negation or possible event in “R42: dizziness and giddiness” (79/108 results, 73.1%) and “R26.0: ataxic gait” (71/79 results, 90%), whereas misdetection of drug class name was the most common in “R52.9: pain, unspecified” (28/91 results, 31%).

Table 5. Details of unmatched results and typical examples for 3 symptoms.

Symptom and category	n (%)	Example of Patient complaints (Original text of Japanese is attached)	Manual results	System results
R42: Dizziness and giddiness (N=108)				
1 (Misdetection of negation or possible event)	79 (73.1)	眩暈は起きていないが、２回くらいふらつきがあった。今日Ｄｒに診てもらったら大丈夫だと言われた。 I didn‘t feel dizzy but staggered about twice. Today I saw a doctor and be said there was no problem.	R26.0: Ataxic gait	R42: Dizziness and giddiness; R26.0: Ataxic gait
2 (Misdetection of clinical test item)	5 (4.6)	なぜかニセルゴリンだけ１０錠余ってる。調子はなんともない。眩暈も検査したけど問題ないと言われたし、聞こえも悪くなってないと言われた。 I don’t know why, but I have 10 leftover Nicergoline pills. I feel fine. I was examined for dizziness and no problem was found. I was also told that there was no problem with my hearing.	—	R42: Dizziness and giddiness; H91.9: Unspecified hearing loss
3 (Misdetection of drug class name)	8 (7.4)	めまいの薬は昼飲めないことが多くて残りがあるの。ずっと仕事だから飲むのが難しくて。 I have leftover motion sickness medicine because I often don’t take it in the daytime. I work all day and it’s hard to take it.	—	R42: Dizziness and giddiness; R13:Dysphagia
4 (Misdetection of unrelated words)	4 (3.7)	母の介護で忙しかったけど秋に亡くなって、葬式とかでまた忙しくてあまり薬が飲めてなかったので残りはあります。めまいもそんなにひどくなってなかったです。 I was busy taking care of my mother. She passed away this autumn and I got busy with the funeral arrangements, etc. I didn’t have time, so there are still some pills. The dizziness didn’t get much worse.	R42: Dizziness and giddiness	R42: Dizziness and giddiness; R99: Other ill-defined and unspecified causes of mortality
5 (False negative)	11 (10.2)	めまいは起こっていないです。暑さでフラーっとすることがある。 No vertigo/dizziness. Sometimes I feel unsteady due to the heat.	R42: Dizziness and giddiness; R26.0: Ataxic gait	R42: Dizziness and giddiness
6 (Inappropriate ICD10 code)	1 (0.9)	ふらふらするのは最近落ち着いてる。Ｄｒに言われて、起き上がるときもゆっくり起きるようにしたら眩暈あまり起きなくなった。 The dizziness is getting better. My doctor told me to stand up slowly and when I tried that I didn’t feel dizzy.	R42: Dizziness and giddiness; H81.1: Benign paroxysmal vertigo	R42: Dizziness and giddiness; R26.0: Ataxic gait
R52.9: Pain, unspecified (N=91)				
1 (Misdetection of negation or possible event)	20 (22.0)	血圧１１０くらい。ふらつくことはないです。筋肉痛もないです。気になったことはないが、言われてみれば、たまにだるくなることがあります。 BP is around 110. No dizziness and no muscle pain. But now that you ask, I sometimes feel malaise.	R53: Malaise and fatigue	M79.1: Myalgia; R52.9: Pain, unspecified; R53: Malaise and fatigue
3 (Misdetection of drug class name)	28 (30.8)	痛くないから神経痛の薬はもういらない。納豆が本当は大好きなんだけど、ワーファリン錠飲んでるから止めてる。納豆関係ない薬もあるらしいけど、値段が高いらしいね。 II don’t feel pain, so I don’t need the nerve medicine any longer. I really love natto (fermented soybeans), but have to avoid it because I take warfarin. I think there is some kind of medicine that is not affected by eating natto, but I hear it’s really expensive.	—	R52.9: Pain, unspecified; M79.2: Neuralgia and neuritis, unspecified
4 (Misdetection of unrelated words)	8 (8.8)	耳鳴りとのどが痛い。 My ears are ringing and I have a sore throat.	H93.1: Tinnitus; J02.9: Acute pharyngitis, unspecified	H92.0: Otalgia; H92.1: Otorrhea; R52.9: Pain, unspecified

Symptom and category	n (%)	Example of Patient complaints (Original text of Japanese is attached)	Manual results	System results
5 (False negative)	9 (9.9)	胃が痛い、のんでも治らんから先生に相談した。腰もいたいんよね。ロキソニンは手持ち無くなった。今回でてない？あら。ボラザＧ軟膏は２１本持ってるけどちょっと足りないかもね。 My stomach hurts. I took some medicine but didn't feel better so I saw a doctor. My lower back also hurts. I'm out of Loxoprofen, so did the doctor give me a new prescription? I have 21 tubes of ointment but that may not be enough.	R10.1: Pain localized to upper abdomen; R52.9: Pain, unspecified; M54.5: Low back pain	R101: Pain localized to upper abdomen; R52.9: Pain, unspecified
6 (Inappropriate ICD10 code)	26 (28.6)	前の粉薬を止めたら尿の出は治ったんだけど、他の薬を続けていたら手の甲と関節がピリピリ痛み始めて驚いた。飲むのを辞めたら治ったよ。 After I stopped taking the powdered medicine, my urine flow improved but I'm still taking the other medicine. I suddenly felt a sharp pain on the back of my hand and in the joints, but that stopped after I quit taking the medicine.	M25.5: Pain in joint; M79.6: Pain in limb	M25.5: Pain in joint; 52.9: Pain, unspecified
R26.0: Ataxic gait (N=79)				
1 (Misdetection of negation or possible event)	71 (89.9)	カルデナリン錠が中止になって、フラツキはあれっきりよくなった。血圧の薬は内科でかるいのが追加になりました。眼科は今はかかってなく、内科で目薬出してもらってます。 After I stopped taking Doxazosin, the light-headedness got better. A new mild blood pressure medicine was prescribed by the doctor. I don't go to the eye doctor anymore, so I have my regular doctor prescribe eyedrops.	—	R26.0: Ataxic gait
4 (Misdetection of unrelated words)	2 (2.5)	かるいフラツキあるんだけど大丈夫。内科はいってない。先生行けって言わないから大丈夫なんだと思う。セロクラールとパルトックス錠はわかるから赤線はひかなくていいよ。 I stagger a little bit, but that's OK. I didn't go to the Internal Medicine Department because my doctor didn't tell me to, so it probably isn't a problem. I know which pills are Cerocral and Pantethine, so you don't have to draw a red line on the bottles for me.	R26.0: Ataxic gait	R26.0: Ataxic gait; R21: Rash and other nonspecific skin eruption
5 (False negative)	5 (6.3)	血圧はいつもより良かった。病院で血糖が６８だったから飴玉食べた。ブドウ糖も持ってる。ふわっとする症状もあった。 My blood pressure was better than usual. My blood glucose was 68, so I ate some candy. I carry glucose tablets with me, too. I felt weightless.	E16.2: Hypoglycaemia, unspecified; R26.0: Ataxic gait	R26.0: Ataxic gait
6 (Inappropriate ICD10 code)	1 (1.3)	頭がフラフラするので医師に相談した。リリカが効き過ぎているのではないかとのこと。 I felt woozy and went to the doctor. He thought that the Pregabalin was too strong.	R42: Dizziness and giddiness	R26.0: Ataxic gait

Discussion

Principal Results

Nikfarjam et al [25] and Aramaki et al [30] used CRFs, and Freifeld et al [28] used a tree-based dictionary matching algorithm for extracting the terms. Our approach involved rule-based searching, which is much simpler but less tolerant of orthographic variants. Additionally, differences in linguistic features might have contributed to the gap between the results of the present study and nonJapanese ones [25,28]. In written Japanese, words are not separated by spaces, and therefore the accuracy of extraction is affected by the quality of morphological analysis. Considering these points, the results are at least adequate as the first step in possible ADE signal detection.

This was the first attempt to standardize patients' expressions with the Japanese version of ICD-10 and to use the "Subjective Information" section in the medication history as a source. The advantage of using the medication history is its structured format and data storability. The medication history is recorded for patient monitoring including side effects. Its features provide more specialized information relevant to possible ADEs than social media like Twitter or EHRs in hospitals. Moreover, the number of pharmacies in Japan is increasing [36,37], and pharmacists are required to record patient medication histories for health insurance claims. Thus, huge amounts of data on

patients' medication are available, making medication histories an appropriate source for ADE signal detection.

It is not necessary for ADEs to have causal relationships with drugs, whereas ADRs must have a reasonable association with drug use. Using patient records to detect ADRs is a major challenge because causality cannot be readily assessed; however, it is also important to detect potential ADE signals.

In this study, some text could not be annotated with ICD-10 codes. As compared with the performance of health care professionals, our newly developed system performed at levels of .66 for precision, .63 for recall, and .65 for the F-measure. These values are relatively lower than in previous studies [25,28,30], likely due to differences in methodology. As explained in the Experiment section, if one of the many ICD-10 codes was different from the manual result, all other coding was regarded as incorrect (unmatched) for that entry. This is one reason why the F-measure was lower than in previous research.

There was also insufficient specific information about the condition of each patient. Because the majority of patients are not medical experts, they describe their symptoms in everyday language, which is more equivocal and more inflected than medical terminology. Nikfarjam et al [25] reported similar aspects of ambiguity and lack of context in patients' wording.

The dialect spoken can affect the subjective information, although, of 5,000 complaints analyzed in this study, only 7 were recorded in a regional dialect. This is probably related to the nature of the text. Although it is recommended that pharmacists record patients' statements exactly, it is possible that they replace dialect expressions with standard wording to make the information easier to understand by others later.

Regarding standardization across languages, the present system could be applied to other languages to some extent by translating the morphemes used for the search rules or by adding or refining the search rules later.

Limitations

There were some limitations of this study. First, qualitative differences in the text data could have occurred. The "Subjective information" section is filled in by pharmacists, and therefore they may interpret and summarize patients' comments when they record them. To ensure that the medication histories of all patients are recorded during the daily business hours of community pharmacies, in some cases fixed-form complaint set phrases and excerpts of comments may be relied on to decrease the time needed to complete the "Subjective information" section. It is therefore possible that the finer nuances patients hope to convey are altered or lost during the process. Qualitative differences were also noted among pharmacists for the contents of the "Subjective information" section. Some wrote about symptoms using explicit medical terminology (eg, "back pain and knee pain were unabated"). Others included general information unrelated to symptoms (eg, greetings and general conversation transcribed word for word).

Second, it was difficult for the system to determine whether the extracted keyword was related to patients' symptoms or those of others. For example, from the sentence "My friend had hypertension," the system may extract "hypertension," although it is unrelated to the speaker's condition. This point should be improved by revising the search rules after consultation with regulatory experts or using machine learning to deal with ambiguity.

Also, since only 1 of 14 pharmacies in a single chain participated in this study, there is a possibility that the search rules were optimized for patients receiving prescriptions from specific medical departments. In the experimental results, the most frequent ICD-10 code was "dizziness and giddiness." As shown in Table 1, the target pharmacy frequently dispenses prescriptions from otolaryngologists, and the results may reflect this potential bias. Before the practical application of the system, it is necessary to improve the search rules by considering a wider range of medication histories including data from other community pharmacies.

ICD-10 codes were used as normalization terms for patients' complaints regarding their symptoms because they are widely available and understood, but MedDRA is thought to be more suitable for extracting information on ADRs and for signal detection. We are currently enhancing the system to accommodate MedDRA terms.

Conclusions

In this study, we developed an automated system to extract terms related to symptoms from the verbal complaints of Japanese patients. As a result of an evaluation experiment comparing automated with manual extraction, the system performed at the level of .66 in precision, .63 in recall, and .65 for the F-measure. Although the accuracy of the system was not satisfactory, our results suggest that it might be useful in extracting and standardizing patients' expressions related to symptoms from massive amounts of free text data instead of performing those procedures manually. After improving the extraction accuracy, we expect to utilize this system to detect the signals of ADRs from patients' complaints in the future.

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Conflicts of Interest

One of the authors (TS) is an employee of Holon Co, Ltd.

Multimedia Appendix 1

Search rules for the program.

[XLSX File (Microsoft Excel File), 40KB - medinform_v6i3e11021_app1.xlsx]

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Abbreviations

ADE: adverse drug event
ADR: adverse drug reaction
AMED: Japan Agency for Medical Research and Development
CRF: conditional random fields
EHR: electronic health record
EMHD: electronic medication history data
FAERS: US Food and Drug Administration Adverse Event Reporting System
ICD-10: International Classification of Diseases, Tenth Revision
MedDRA: Medical Dictionary for Regulatory Activities
NLP: natural language processing

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Original Paper

Uncovering a Role for Electronic Personal Health Records in Reducing Disparities in Sexually Transmitted Infection Rates Among Students at a Predominantly African American University: Mixed-Methods Study

Kevon-Mark Jackman[1], DrPH, MPH; Stefan David Baral[1], MD, MPH; Lisa Hightow-Weidman[2], MD, MPH; Tonia Poteat[1], PhD, MPH

[1]Center for Public Health and Human Rights, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

[2]Institute for Global Health and Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States

Corresponding Author:
Kevon-Mark Jackman, DrPH, MPH
Center for Public Health and Human Rights
Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
E7143
615 N Wolfe Street
Baltimore, MD, 21205
United States
Phone: 1 352 871 1286
Email: kjackma2@jhmi.edu

Abstract

Background: Black youth continue to bear an overwhelming proportion of the United States sexually transmitted infection (STI) burden, including HIV. Several studies on web-based and mobile health (mHealth) STI interventions have focused on characterizing strategies to improve HIV-related prevention and treatment interventions, risk communication, and stigma among men who have sex with men (MSM), people who use substances, and adolescent populations. The Electronic Sexual Health Information Notification and Education (eSHINE) Study was an exploratory mixed-methods study among students at a historically black university exploring perceptions on facilitating STI testing conversations with partners using electronic personal health records (PHRs).

Objective: The purpose of this paper is to use eSHINE Study results to describe perceived impacts of electronic PHRs on facilitating STI testing discussions between sexual partners.

Methods: Semistructured focus groups and individual in-depth interviews were conducted on a heterogeneous sample of students (n=35) between May and July 2014. Qualitative phase findings guided development of an online survey instrument for quantitative phase data collection. Online surveys were conducted using a convenience sample of students (n=354) between January and May 2015. Online survey items collected demographic information, sexual behaviors, beliefs and practices surrounding STI testing communication between partners, and beliefs about the impact of electronic PHR access on facilitating these discussions with partners. Chi-square analysis was performed to assess gender differences across quantitative measures. A Wilcoxon signed rank sum test was used to test the null hypothesis that electronic PHRs are believed to have no effect on the timing of dyadic STI health communication.

Results: Participants described multiple individual and dyadic-level factors that inhibit initiating discussions about STI testing and test results with partners. Electronic PHRs were believed to improve ability to initiate conversations and confidence in STI screening information shared by partners. Among online survey participants, men were more likely to believe electronic PHRs make it easier to facilitate STI talks with potential partners (59.9% vs 51.9%; χ^2=3.93, *P*=.05). The Wilcoxon signed-rank test results indicate significant increases in perceived discussion timing before sex with electronic PHR access (61.0% vs 40.4%; *P*<.001).

Conclusions: Findings suggest that electronic PHR access in STI screening settings among similar populations of Black youth may improve both motivation and personal agency for initiating dyadic STI health communication. Results from this study will likely inform novel interventions that use access to electronic PHRs to stimulate important health-related discussions between sexual partners. Moving forward requires studying strategies for implementing interventions that leverage electronic PHRs to create new sexual health communication channels with providers, peers, and family among black youth.

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KEYWORDS

PHR; STI; HIV; mHealth; intervention; prevention; young people; black; health disparities

Introduction

The High Burden of Sexually Transmitted Infections Among Black Youth and Dyadic Sexually Transmitted Infection Testing Talks

Young black people in the United States (US) are largely overrepresented in cases of sexually transmitted infections (STIs), including HIV. While black people constitute approximately 15.4% of US youth ages 15 to 24 years, they accounted for 29.9% of chlamydia cases, 47.7% of gonorrhea cases, 43.3% of early syphilis, and 54.7% of HIV cases diagnosed in this age group in 2016 [1-3]. Getting young people to talk about STI testing, including HIV, with partners prior to sex is a critical challenge to disease prevention and control [4]. These preventative conversations support testing, disease status disclosure, condom use, and the use of medicines to prevent and treat STIs [5]. The "Get Yourself Tested" campaign launched nationally in 2009 in effort to reduce STIs in young people by targeting four key behaviors: STI testing, HIV testing, talking to partners about testing, and talking to providers about testing. Formative research used to inform the campaign design found that STIs remain highly stigmatized and as a result, few young people discuss testing with partners prior to sex [4,6].

In young people, conversations on STI testing are more likely to be facilitated by those that routinely screen for STIs [7]. In studies of students at historically black colleges and universities, women reported higher screening rates and asked partners about HIV status more than their male counterparts [8,9]. Additionally, individuals are more likely to discuss STI status and risk behaviors with a main partner compared to a casual partner [10]. Expected partner reactions of suspicion, accusation, or insult (from inadvertently implying partner distrust) are sometimes barriers to discussing STI testing [4]. Barriers that inhibit partner communication regarding STI risk restricts the ability to make well-informed decisions about the level of risk assumed and employable methods to prevent disease transmission [11,12].

Digital Prevention Tools

The US National HIV Strategy calls for federal agencies to encourage the development and implementation of highly accessible digital tools to educate and inform the American people with scientifically accurate information on disease risk, prevention, transmission, and treatment [13]. Several studies on Web-based and mobile health (mHealth) HIV/STI interventions have been conducted and are currently ongoing that focus on improving outcomes related to testing, risk communication, reducing stigma, increasing condom use, and improving adherence to biomedical prevention and treatment among men who have sex with men (MSM), substance using, and adolescent populations [14-19]. Although mHealth intervention studies focused on improving partner communication on STI testing are promising, most studies do not account for the role of remote access to STI screening records in dyadic STI health communication. Electronic personal health records (PHRs) or patient portal services (eg, Epic MyChart, Cerner Patient Portal, Kaiser Permanente My Health Manager, Quest Diagnostics Care360) provide patients with remote access to their laboratory test results, including STI results. Electronic PHRs differ from most mHealth platforms in STI intervention studies since electronic PHRs contain protected health information managed by covered entities, therefore, federal regulations require electronic PHR vendors to adhere to data security and integrity measures outlined by the Secretary of the Department of Health and Human Services [20]. Nevertheless, electronic PHRs can provide several services in addition to medical record access, like educational resources and tools for communicating with healthcare providers.

Study Purpose

The Electronic Sexual Health Information Notification and Education (eSHINE) Study was a mixed-methods study among students 18 to 25 years old attending a historically black university. The project was completed using a dissertation research funding grant from the Agency for Healthcare Research and Quality, and explores perceptions of using electronic PHRs to share electronic STI screening information between sexual partners. The current study is an analysis of eSHINE Study qualitative and quantitative data to explore attitudes and practices surrounding STI testing talks between partners, barriers to talking about STI testing with partners, and perceived impacts of electronic PHRs on risk discussion facilitation. Thus, the purpose of our study is to provide a rich contextual understanding of how diffusing electronic PHR access in our study population may impact health-related communication between sexual partners.

Methods

Study Design

Exploratory mixed methods are a two-phase sequential study design that is particularly useful for exploring new research questions [21]. It calls for an initial qualitative exploration phase (ie, focus-groups and individual interviews), an intermediate survey development phase, and a second quantitative research phase (ie, an online survey) [22]. A constructivist approach of

incorporating multiple theoretical frameworks structured our study protocol. The Integrative Model of Behavioral Prediction (IMBP), often used for designing health messages, posits that behavioral intentions are a function of attitude, normative, and self-efficacy beliefs [23]. IMBP also considers the impact of demographic variables, culture, and environmental constraints on behavior. If electronic PHR–facilitated STI talks is a novel concept to the study population, constructs of the Diffusion of Innovation Theory (DOI), such as innovation attributes and communication channels, were incorporated into our exploration [24]. Finally, the Disclosure Processes Model provide considerations for individuals with a history of STI diagnosis or exposure; here, disclosing risk is a function of antecedent goals (ie, approach goals vs avoidance goals) [25].

Recruitment

Eligible study participants were students, ages 18 to 25 years, enrolled at a southern historically black college and university at the time of study. Qualitative phase participants were recruited between May and July 2014 and quantitative phase participants between January and May 2015. Recruitment flyers were posted on campus along with multiple announcements sent through the university's student, faculty, and staff email list. Targeted recruitment efforts were conducted in collaboration with University Health Services, the Student Counseling Center, the Office for Residence Life to post study materials and conduct tabling events. Study flyers were posted to a university affiliated Facebook page for lesbian, gay, bisexual, transgendered, and questioning students. Participants were also recruited at student organizational meetings, including theatre, peer educator, and football. Study enrollment included providing eligible students with a detailed description of the project, participation requirements, and terms for receiving incentives. To complete enrollment, prospective participants signed an informed consent form in person or online using Adobe Echosign. Qualitative and quantitative phase research protocols, including focus-group, interview guides and online survey instruments were separately reviewed and approved by the university's Institutional Review Board.

Qualitative phase participants received US $25 cash for each session (limited to one focus group or one interview per participant). Quantitative phase participants received US $20 cash for completing the online survey; and if eligible, qualitative phase participants could participate in the quantitative phase. Online survey participants were not asked to provide their name or email address on the survey. To receive incentives, participants provided a unique code generated at survey completion. Participants were additionally entered to win prizes in one of three raffle drawings (eg, textbook vouchers, US $25 up to US $100 gift cards, Samsung Galaxy tablets). eSHINE Study data collection and analyses was conducted by KJ as part of his dissertation research, with guidance from project mentors and dissertation committee members. Prior to the study, KJ completed training in qualitative and quantitative research methods, including academic coursework and work as an STD prevention and control program disease intervention specialist.

Qualitative Methods

A total of 35 students participated in the qualitative research phase (19 male; 16 female). Audio-recorded focus group and individual interview sessions were conducted by KJ inside private conference rooms located on the university's campus. In May 2014, 33 students participated in one of three separate focus group sessions (n=6; n=10; n=17). Semistructured sessions averaging 70 minutes in length were divided into three discussion sections: (1) electronic PHR perceptions, (2) experiences and perceptions related to dyadic STI health communication, and (3) perceptions related to using electronic PHRs in dyadic STI health communication. At the end of each focus group, participants were invited to schedule an in-depth individual interview session. Focus group and interview recordings were played back after sessions by KJ to construct field notes and inform any modifications to main questions in subsequent sessions.

Semistructured interviews were important to explore in depth the statements made by participants during focus groups in a setting isolated from peers. On average, interviews lasted 45 minutes. An oral questionnaire was administered during interviews to collect demographic information, orientation, and sexual risk behavior, such as number of recent sex partners, condom usage, and sex under the influence of alcohol or drugs practices. Considering the sensitivity of sexual topics and to support higher levels of comfort among participants, this information was not collected during focus groups. Sixteen of eighteen individual in-depth interviewees were recruited from a focus group session. Transcripts and field notes were uploaded to ATLAS.ti to facilitate the qualitative analysis [26]. The analysis included reading through transcripts and field notes while identifying useful quotes or sentences, creating memos, coding segments of information, assigning labels to codes, and the grouping of codes into broad themes [21].

Survey Development

A Qualtrics online survey was developed during the intermediate survey development phase between July and December 2014 [27]. Qualitative codes were operationalized into IMBP behavioral construct variables, such as attitudinal, self-efficacy, and intentional beliefs within broad emergent themes. The operationalization process included using individual codes within themes as variables as well as using specific quotes from participants within items on the survey [21]. Behavioral construct variables, for example, attitudes on the importance of discussing STI testing with partners, were measured using 7-point Likert scale items, scored –3 to 3 [28]. Data was also collected on several demographic and sexual behavior variables, such as gender, screening practices, and risky sex behaviors. The survey was piloted with eight students and revisions made based upon participant feedback and researcher observations. The final survey had 116 items and a completion time of approximately 30-45 minutes.

Quantitative Methods

To access the online survey, a secured and unique Web-link was sent to the enrolled participant's student email account

using the university's email database. Between January and May 2015, 1093 participants registered for the online survey and were emailed secured survey links; 501 surveys were started, 380 completed, and 354 completed without missing data.

Survey data were uploaded into STATA 14 for statistical analyses [29]. Chi-squared analyses were conducted by gender to describe distributions of demographic information, risk behaviors, STI testing talk attitudes and practices, and perceptions of electronic PHR–facilitated discussions by gender. Effect size (Cohen *d*) was calculated for variables demonstrating significant differences by gender related to electronic PHR impacts on discussions. A Wilcoxon signed rank sum test was performed to determine differences in perceived discussion timing with electronic PHR access compared to without electronic PHR access. To test the null hypothesis that electronic PHRs are believed to have no effect on the timing of STI conversations, we compared responses on two survey items: (1) "When do discussions about STD testing typically occur between you and your partner(s)?" and (2) "When would discussions about STD testing likely occur if you and your partner(s) had electronic PHRs?" Reponses were ranked from 1 to 4; (1) never (2) after sex (3) inconsistently before or after sex, and (4) before sex.

Results

Qualitative Phase Results

Qualitative phase participants were heterogeneous in academic classification, degree major, sexual behaviors, sexual orientation, including for example, student athletes, peer educators, and members of Greek lettered social organizations. Table 1 presents interview and focus group quotations from our qualitative phase study. For this study, quotations were categorized under two major themes: attitudes and practices surrounding dyadic STI health communication and expected impacts of electronic PHRs on dyadic STI health communication. Table 1 also indicates online survey measures derived from qualitative codes.

Sexually Transmitted Infection Testing Talks: Qualitative Attitudes and Practices

STI testing talks or risk discussion events were described as verbal exchanges between sexual partners regarding STI testing or status. Soliciting information related to STI risk from partners was described as demonstrating personal responsibility and an unalienable right to self-preservation:

> *You have the right to know.*
>
> *I feel like if you're having sex with me you have the right to know my STD history. If I'm having sex with you, I need to know everything too. I owe that to you, you owe that to me.*

Conversations vary in both timing and depth. Several multi-level factors, such as self-efficacy, partner-type, and intoxication, can impact when and how discussions occur (Table 1). When talks occur, they are either distal, proximal, or after the sexual encounter. Distal discussions happen in a period where individuals are "getting to know each other." While proximal discussions occur when participants are "in the moment." Discussions can range in depth from simply asking, "are you good down there?" to requiring current screening information and information regarding condom use practices with previous partners.

Valuation for risk discussions varied between participants. For most, STI talks are very important to always occur, especially interviewees disclosing a history of STI infection.

> *It's very important to have that conversation.*

Some participants saw no purpose in talking about STI testing when using condoms. Valuation also varied based on dyadic characteristics such as, partner type.

> *If I know that I am going to be in something committed then I want to know your history. But if you are just a casual partner then I don't really care, because I am going to protect myself. I wouldn't have the conversation with someone I'm just casually having sex with.*

Participants described sexual partner dynamics ranging from solely pleasure-seeking sex and noncommittal partnerships to socio or emotional interdependent and committed relationships. To simplify and operationalize, partner types were classified as: (1) main partners, defined as partnerships intended to be exclusive relationships; (2) casual partners, defined as recurring partnerships not intended to be exclusive relationships; and (3) hook-up partners, defined as one-time partnerships. Keeping in mind that dyad characteristics vary within partner-type classifications (for example, casual partners may be long-time friends or recent acquaintances, and others).

Finally, valuation appears to also be determined by the extent to which individuals are aware of the importance of discussing STI testing with partners.

> *I have never discussed STDs with any of my sexual partners. I'm young, so it never really came up. I usually just say, what's the number of people you have had sex with and if I feel comfortable with the number then, okay.*

Barriers to Talking About Sexually Transmitted Infection Testing With Partners: Attitudes and Personal Agency

Self-efficacy contributes to whether STI testing talks are initiated. While some participants described being very comfortable with initiating conversations, many generally describe it as an "[i]t's an awkward conversation." The impact of these beliefs as an inhibitor is based on the level of disruption an individual believes the conversation will cause to a potential sexual encounter or relationship. Low self-efficacy to facilitate risk discussions was mostly described in the context of proximal discussions, where consequences of these events may "ruin the mood." Lack of self-efficacy to initiate STI testing talks without ruining the mood presents as a primary barrier to some.

Table 1. Focus-group and individual in-depth interview quotations and online survey measures derived from qualitative codes. PHR: personal health record; STI: sexually transmitted infection.

Themes and online survey measure	Quotations
Attitudes and practices surrounding dyadic STI health communication	
Timing of dyadic STI health communication	• *It usually occurs before anything else. After I get to know the person, it comes up in the conversation because this person is a potential partner. I always ask to be on the safe side.* • *Before I have sex, we don't have the conversation. It slips my mind until after we have sex.*
Valuation for dyadic STI health communication	• *It is very important to have that conversation, especially if you are going to be dealing with that person sexually, "Have you been tested?" "Are you going to get tested?" "When was the last time you were tested?*
Valuation for dyadic STI communication when using condoms; communications barrier: condom use	• *If I know that I am going to be in something committed, then I want to know your history. But if you are just a casual partner then I don't really care, because I am going to protect myself.*
Self-efficacy to initiate dyadic STI health communication	• *It doesn't make me uncomfortable, I am straightforward. If I feel that we are about to get serious or have any sexual encounters, I simply ask "when was the last time you got tested?" If it's too long, I tell them where to go for testing.*
Communication barrier: precontemplation	• *When I was fresh out of high school, out of my parent's house, I was [sleeping with] 6 or 7 guys at the same time. I was young, so I did not think to ask, have you gotten tested, how many people have you been with?* • *I have never discussed STDs with any of my sexual partners.*
Communication barrier: awkward	• *It kills the mood.* • *(It can be awkward) when you have known the person.*
Communication barrier: people lie	• *People lie. One of the big lies is "I've been tested" or "I don't have anything." Especially when you're in the moment, it happens all the time.*
Expected impacts of electronic PHRs on Dyadic STI Health Communication	
More confidence in STI testing information shared by a partner	• *It's another way of verifying the truth and showing that they did get tested or if we need to get tested—we can go [to a test site] together.*
Easier for potential partners to talk about STI testing; easier check-in talks with partners on STI testing	• *Ultimately the app would make it much easier to have these conversations with someone you are going to have sex with—whether it's casual or long term.* • *I can just show my partners casually when I got tested and my results. It will ease the tension and make it more comfortable, especially if I am willing to share that information with you.*
Impact on frequency of STI talks; earlier STI talks (proximity to potential encounter)	• *If the norm was for people to have the app at hand, then more people would ask to see results. Now, it's not that realistic, because people can easily say, I don't have it with me, it's on paper.* • *If the app is popular, then I'm asking everybody.*
Intentional beliefs to only use electronic PHRs when distrusting of partners	• *I wouldn't have a need for it, but then again if I do want to, you shouldn't be offended, because I'm just trying to be safe. So, if I do bring it up, don't be upset because it's good health.*
Soliciting a partner's electronic record will be awkward	• *If I tell you something and you don't believe it, we shouldn't be having sex in the first place. If I tell you something, that's what you should believe. If I am lying, then strap up [use a condom].* • *It's tricky, it's one thing to ask someone something, but then to tell them to verify it, it messes up the trust. Unless if they are very comfortable.*
Self-efficacy for sharing a positive STI electronic PHR; preferred method to share STI positive status	• *People who are negative would gladly show their results. People who are positive, it would be harder for them.* • *I don't see anyone showing a partner the app unless if they are clean.*
Suspicious of partners unwilling to share electronic PHR	• *Red flag.*

Some participants described talking with partners about STI testing as an exercise in futility because of limitations in the ability to verify shared information.

> *People lie. One of the big lies is "I've been tested" or "I don't have anything". Especially when you're in the moment, it happens all the time.*

Allaying a partner's STI transmission concerns can take precedence over communicating accurate information about STI screening and risk. Several approaches are employed to mitigate risk associated with receiving inaccurate information. For example, some participants reported choosing to avoid risk discussions all together and use condoms. Conversely, some participants said that they engaged in couples testing or require potential partners show verification of STI test results prior to sex.

> *Any boy I ever ask that question to, I make sure I see papers. Paper says clearly negative or positive.*

Though some participants commented that it is unlikely for "papers" to be readily available to validate STI screening information.

Other barriers exist to starting dyadic talks on STI testing. Substance use prior to sex was considered to inhibit ability for facilitating risk discussions with partners.

> *If someone is drunk, then it's not going to be discussed.*

Self-efficacy to initiate risk discussions may also be diminished when dyads have a previously established intimate relationship or a friendship. Difficulty discussing STI testing "when you have known the person" was described by participants as implying distrust.

Impact of Electronic Personal Health Records on Sexually Transmitted Infection Testing Talks: Beliefs and Expectations

Information verification was considered the foremost benefit of incorporating electronic PHRs into risk discussions between sexual partners.

> *It's another way of verifying the truth and showing that they did get tested or if we need to get tested—we can go (to a test site) together.*

Participants used terms such as, "truth-detector," "proof," and "confirmation," in referring to electronic PHR use with partners. Participants also described limitations of electronic PHRs in determining a potential partner's real-time infection status.

> *There is no way to say you are clean today, but you can say you were clean that day.*

Together, electronic PHRs are believed to be a compatible innovation for adding assurance to STI talks.

> *I think this will be something good for the gay community. The gay community is big on electronic dating and meeting people online, Grindr and Jack'd and all that. I feel that it would be really good for that.*

Gaining electronic PHR access was believed to ease the ability to facilitate conversations on STI testing.

> *I can just show my partners casually when I got tested and my results. It will ease the tension and make it more comfortable, especially if I am willing to share that information with you.*

Another participant explained:

> *Ultimately the app would make it much easier to have these conversations with someone you are going to have sex with—whether it's casual or long term.*

Participants added that electronic PHRs could make it easier to have "check-in" conversations with partners who have prior established intimate relationships or friendships. Some participants maintained that practices will be determined by partner-type.

> *If I have a one-night stand, I will use protection. I would not want to ask that question.*

However, for most, the idea of an easier STI talk eliminates partner-type related factors as a barrier.

> *If the app is popular then I'm asking everybody.*

Improvements to personal agency was not anticipated across some constraining conditions, such as intoxication or being infected with an STI.

> *If you're drunk, I don't think people would use it, because you really wouldn't be thinking about that, your mind is somewhere else.*

Similarly, it was expressed that individuals with electronic records positive for STI infection may employ strategies to avoid talking with partners about STI screening records.

> *People who are negative would gladly show their results. People who are positive, it would be harder for them.*

Nevertheless, some participants believed that incorporating educational resources within electronic PHR products might prove useful in explaining positive test results and prevention.

While electronic PHRs were compatible with most participants as a potential tool for facilitating STI talks, some participants suggest electronic PHR solicitation as intrusive or implying distrust.

> *It's tricky, it's one thing to ask someone something, but then to tell them to verify it, it messes up the trust. Unless if they are very comfortable.*

Additionally, partners unwilling to share electronic screening records are anticipated to raise a "red flag" regarding future sexual decisions and relationship progression. Overall, electronic PHR access was anticipated to have the population-level impact of increasing discussions on STI testing.

> *If the norm was for people to have the app at hand, then more people would ask to see results. Now, it's not that realistic, because people can easily say, I don't have it with me; it's on paper.*

Quantitative Phase Results

Table 2 shows demographic information and sexual risk behaviors among online survey participants (n=354). The sample consisted of 167 male and 187 female participants. Forty out of 354 participants (11.3%) reported no history of sexual intercourse and 44.3% reported 2-5 partners. Approximately 43.2% (153/354) reported STI testing seven months prior to the study; 80 out of 354 participants with sexual exposure reported no history of screening (22.1%). Almost half (172/354) of participants reported sex under the influence of alcohol or drugs and 134 out of 354 participants reported recent sex without discussing STI testing (Table 2). Sixty-four percent of participants (38/59) with a history of STI diagnosis reported chlamydia infection. Additionally, five participants reporting gonorrhea, two participants reporting HSV-2, and two participants reporting human papilloma virus also reported chlamydia infections, there was no overlap between any other STIs (not shown).

Sexually Transmitted Infection Testing Talks: Quantitative Attitudes and Practices

Table 3 presents behavioral perceptions on risk discussion practices among online survey participants. Conversations consistently occur before sex for 143 out of 354 participants (40.4%) and inconsistently occur before or after a sexual encounter for 41.0% (145/354). Some participants (51/354) reported never discussing STI testing with partners. Most participants (312/354) value discussing STI testing with partners, however, valuation was slightly greater among women (χ^2=3.79; *P*=.05). In fact, 71.7% (254/354) believed it is extremely important or very important irrespective of condom-use, however over two-fifths (158/354) reported recent sexual encounters where risk discussions were skipped due to condom-use. Furthermore, less than half (169/354) believe that it is easy to talk with partners about STI testing and 28.2% (100/354) reported skipping a recent discussion due to awkwardness. One-third of participants (118/354) reported recently skipping risk discussions due to the possibility of receiving inaccurate information. Many participants (112/354) also reported discussion omission because it never came to mind.

Impact of Electronic Personal Health Records on Discussion Timing

Out of 354 online survey participants, 184 (60.0%) believed that electronic PHR access will lead sexual partners to start conversations on STI testing earlier in the relationship (Table 4). The Wilcoxon signed-rank test results shown in Figure 1 indicate significant differences between perceived discussion timing with and without electronic PHRs (*P*<.001). Discussions occurring before sex increased 20.6% with electronic PHR access; while omitting talks and inconsistent timing both decreased by 10% (Figure 1).

Impact of Electronic Personal Health Records on Personal Agency, Information Assurance, and Assessing Partner Risk

Table 4 presents bivariate relationships between perceptions on incorporating electronic PHRs into risk discussion events and gender. Almost two-thirds (225/354) of participants felt that electronic PHRs would help to improve communication between partners about STI prevention. Similarly, most participants (235/354) believed electronic PHRs would increase their confidence in STI testing information shared by a partner. Electronic PHRs are believed to make it easier to facilitate risk discussions between new potential partners (197/354) and ongoing sexual partners (195/354). Nearly a quarter of participants (85/354) believed soliciting a partner's electronic record would be awkward. Furthermore, two-fifths (154/354) believed it would be difficult to share a positive result with a partner. In fact, more participants (158/354) indicated a conversation without electronic PHRs as the preferred method for STI disclosure compared to using electronic PHRs (81/354). The most commonly held belief was that participants will be suspicious of potential partners unwilling to share electronic PHRs (268/354).

Electronic Personal Health Record–Facilitated Sexually Transmitted Infection Talks: Beliefs by Gender

Male participants were more likely to believe that electronic PHR access would make it easier for sexual partners to discuss STI testing compared to female participants (59.9% vs. 51.9%; χ^2=3.93; *P*=.05). However, the effect size by gender was small (*d*=0.27). Gender differences between beliefs that electronic PHR facilitated conservations would be awkward and self-efficacy beliefs for sharing electronic STI records with positive results had larger effect sizes. A smaller proportion of males (18.0% vs 29.4%) consider electronic PHR–facilitated discussions to be potentially awkward and were additionally more confident in their ability to share a STI-positive electronic result compared to female participants [(χ^2=10.85; *P*=.001; *d*=1.04) and (χ^2=6.48, *P*=.01; *d*= 0.80)].

Table 2. Demographic information and sexual risk behaviors among eSHINE Study online survey participants (n=354). IQR: interquartile range; STI: sexually transmitted infection.

Variables	Total, n (%)	Men, n (%)	Women, n (%)	Chi-square	*P* value
Age				—	—
Median age (IQR)	20 (19-22)	20 (19-22)	20 (19-22)		
Academic classification				23.64	<.001
Freshman	89 (25.1)	57 (34.1)	32 (17.1)		
Sophomore	82 (23.1)	42 (25.1)	40 (21.4)		
Junior	87 (25.6)	37 (22.2)	50 (26.7)		
Senior	88 (24.9)	31 (18.6)	57 (30.5)		
Graduate student	8 (2.3)	0 (0.0)	8 (4.3)		
Sexual preference by gender				267.15	<.001
Men only	172 48.6)	10 (6.0)	162 (86.6)		
Women only	156 (44.1)	149 (89.2)	7 (3.8)		
Men and women	26 (7.3)	8 (4.8)	18 (9.6)		
Reported sex partners (in 12 months prior)				18.88	<.001
No partners in 12 months prior to study or no history of sexual intercourse	56 (15.8)	34 (20.4)	22 (11.8)		
1	116 (32.8)	45 (26.9)	71 (38.0)		
2	79 (22.3)	27 (16.2)	52 (27.8)		
3-5	78 (22.0)	47 (28.1)	31 (16.6)		
6+	25 (7.1)	14 (8.4)	11 (5.9)		
Reported partner-types[a]				—	—
Main partner(s)	213 (60.2)	84 (50.3)	129 (69.0)		
Casual partner(s)	153 (43.2)	77 (46.1)	76 (40.6)		
Hook-up partner(s)	72 (20.3)	47 (28.1)	25 (13.4)		
STI screening history				21.14	<.001
< 7 months	153 (43.2)	53 (31.7)	100 (53.5)		
≥ 7 months	81 (22.9)	39 (23.3)	42 (22.5)		
Never tested	80 (22.6)	51 (30.5)	29 (15.5)		
No history of sexual intercourse	40 (11.3)	24 (14.4)	16 (8.6)		
STI diagnosis history and risky behaviors in 12 months prior to study					
History of STI diagnosis	59 (16.7)	14 (8.4)	45 (24.1)	15.62	<.001
Concurrent sexual partners	68 (19.2)	38 (22.8)	30 (16.0)	2.56	.11
Sex under the influence of drugs or alcohol	172 (48.6)	65 (38.9)	107 (57.2)	11.82	.001
Condom-less sex with a casual partner	106 (30.8)	44 (26.3)	65 (34.8)	2.92	.09
Condom-less sex with a hook-up/one-time partner	26 (7.3)	12 (7.2)	14 (7.5)	0.01	.91
Met sex partners using social websites or applications	56 (15.8)	39 (23.4)	17 (9.1)	13.47	<.001
Sex without discussing STI testing	134 (37.8)	62 (46.3)	72 (38.5)	0.07	.79

[a]Partner type categories reported by participants are not mutually exclusive.

Table 3. Behavioral attitudes and practices related to dyadic conversations on sexually transmitted infection (STI) testing among eSHINE Study online survey participants, bivariate analyses by gender (n=354).

Variables	Total, n (%)	Men, n (%)	Women, n (%)	Chi-square	*P* value
Valuation belief for talking about STIs with partners (n=315)				3.79	.05
Very important/important	312 (88.1)	137 (82.0)	175 (93.6)		
Very unimportant/unimportant	3 (0.8)	3 (1.8)	0 (0.0)		
Valuation belief for talking about STIs with partners when using condoms (n=263)				2.29	.13
Very important/important	254 (71.7)	105 (62.9)	149 (79.7)		
Very unimportant/unimportant	9 (2.5)	6 (3.6)	3 (1.6)		
Self-efficacy belief to initiate risk discussions (n=213)				0.00	.95
Very easy/easy	169 (47.7)	76 (45.5)	93 (49.7)		
Very difficult/difficult	44 (12.4)	20 (12.0)	24 (12.8)		
Intentional belief on likelihood to solicit STI screening from a partner (n=254)				1.57	.21
Very likely/likely	226 (63.8)	93 (55.7)	133 (71.1)		
Very unlikely/unlikely	28 (7.9)	15 (9.0)	13 (6.9)		
Timing of STI testing talks with partners discussion (n=354)				2.77	.43
Before sex	143 (40.4)	68 (40.7)	75 (40.1)		
Sometimes before sex and sometimes after sex	145 (41.0)	64 (38.3)	81 (43.3)		
After sex	15 (4.2)	6 (3.6)	9 (4.8)		
Never	51 (14.4)	29 (17.4)	22 (11.8)		
Reasons for omitting dyadic STI health communication for sexual encounters in 12 months prior to study (n=354)					
Condoms were being used	158 (44.6)	86 (51.5)	72 (38.5)	0.00	.97
The topic would make things awkward	100 (28.2)	47 (28.1)	53 (28.3)	0.14	.71
People can lie about it regardless	118 (33.3)	54 (32.3)	64 (34.2)	6.03	.01
The topic never came to mind	112 (31.6)	58 (34.7)	54 (28.9)	1.40	.24

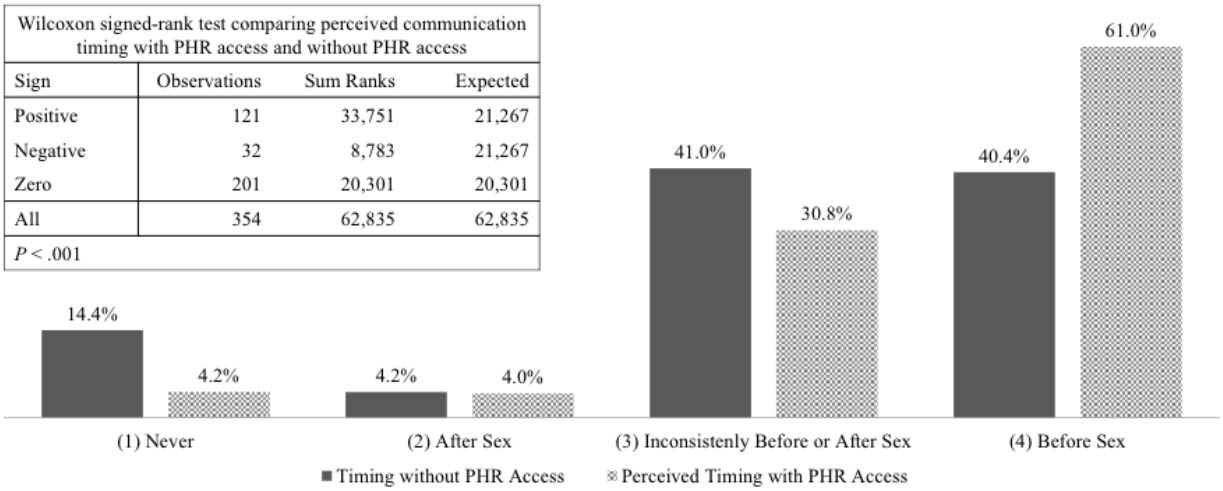
Table 4. Perceptions on incorporating personal health records (PHRs) into risk discussion events among eSHINE Study online survey participants (n=354). STI: sexually transmitted infection.

Variables	Total, n (%)	Men, n (%)	Women, n (%)	Chi-square	*P* value
Semantic belief on the effect of electronic STI record access on communication on STIs between partners (n=227)[a]				1.74	.19
Very helpful/helpful	225 (63.6)	105 (62.9)	120 (64.2)		
Very harmful/harmful	2 (0.6)	0 (0.0)	2 (1.2)		
Semantic belief on the effect of electronic STI record access on confidence in STI testing information shared by a partner (n=238)[a]				0.19	.66
Very helpful/helpful	235 (66.4)	108 (64.7)	127 (67.9)		
Very harmful/harmful	3 (0.9)	1 (0.6)	2 (1.1)		
Belief that electronic PHRs make it easier for potential partners to talk about STI testing (n=213)[a]				3.93	.05
Strongly agree/agree	197 (55 .6)	100 (59.9)	97 (51.9)		
Strongly disagree/disagree	16 (4.5)	4 (2.4)	12 (6.4)		
Belief that electronic PHRs make it easier to check-in with partners on STI testing and prevention (n=206)[a]				0.53	.46
Strongly agree/agree	195 (55.1)	93 (55.7)	102 (54.5)		
Strongly disagree/disagree	11 (3.1)	4 (2.4)	7 (3.7)		
Belief that soliciting a partner's electronic record will be awkward (n=171)[a]				10.85	.001
Strongly agree/agree	85 (24.0)	30 (18.0)	55 (29.4)		
Strongly disagree/disagree	86 (24.3)	52 (31.1)	34 (18.2)		
Self-efficacy belief for sharing a positive electronic STI record with a partner (n=213)[a]				6.48	.01
Very easy/easy	59 (16.7)	36 (21.6)	23 (12.3)		
Very difficult/difficult	154 (43.5)	64 (38.3)	90 (48.1)		
Belief that partners using electronic PHRs will start talking about STI prevention earlier in a relationship (n=200)[a]				0.70	.40
Strongly agree/agree	184 (52.0)	89 (53.3)	95 (50.8)		
Strongly disagree/disagree	16 (4.5)	6 (3.6)	10 (5.3)		
Intentional beliefs to only use electronic PHRs when distrusting of partners (n=232)				24.14	<.001
Strongly agree/agree	93 (26.3)	62 (37.1)	31 (16.6)		
Strongly disagree/disagree	139 (39.3)	47 (28.1)	92 (49.2)		
Attitudinal belief of being suspicious of partners unwilling to share electronic PHR (n=270)[a]				1.49	.22
Strongly agree/agree	268 (75.7)	117 (68.9)	153 (81.8)		
Strongly disagree/disagree	2 (0.6)	0 (0.0)	2 (1.1)		
Preferred method for sharing a positive infection status (n=354)				2.39	.49
Using an electronic PHR	81 (22.9)	42 (25.2)	39 (20.9)		
A conversation without electronic PHRs	158 (44.6)	68 (40.7)	90 (48.1)		
Avoid sharing infection status	16 (4.5)	9 (5.4)	7 (3.7)		
No preference	99 (28.0)	48 (28.7)	51 (27.3)		

[a]Scores between –1 and 1 for belief variables are not reported.

Figure 1. Perceived sexually transmitted infection communication timing with sexual partners with and without electronic personal health record (PHR) access among eSHINE Study online survey participants (n=354). The Wilcoxon signed-rank test indicates significant increases in perceived discussion timing before sex with electronic PHR access (P< .001).

Wilcoxon signed-rank test comparing perceived communication timing with PHR access and without PHR access			
Sign	Observations	Sum Ranks	Expected
Positive	121	33,751	21,267
Negative	32	8,783	21,267
Zero	201	20,301	20,301
All	354	62,835	62,835
P < .001			



Discussion

Principal Results

Together, qualitative and quantitative findings offer several considerations for the potential role of electronic PHRs in facilitating STI health communication between partners. STI health communication is generally an important practice for our study population; however, whether and how discussions occur are functions of multiple individual and dyadic level factors. Inability to validate disclosed STI testing information, low personal agency for initiating discussions, nonawareness of STI testing talks as a health practice, and low discussion valuation related to partner-type or condom use may inhibit STI health communication from occurring. Electronic PHR access for STI screenings pose a viable solution to barriers preventing STI talks. Participants anticipate that access will be accompanied by testing discussions earlier in relationships and more frequently occurring prior to sexual encounters. Electronic PHRs are expected to add novel validation to screening information shared by partners and make it easier to initiate conversations. Male participants were more likely to believe electronic PHRs improve self-efficacy for discussions and in their ability to share positive results. Thus, electronic PHRs additionally offer new avenues for increasing male participation in STI prevention.

Self-reported behaviors potentiating STI transmission such as: sex without discussing STI testing, partner concurrency, sex while intoxicated, and condom-less sex practices is evidence of the need to continue targeting young black populations for STI interventions. Our study supports an increasing amount of burgeoning research on the feasibility and acceptability of delivering effective sexual health interventions through web- and mobile-based platforms [17,19,30-32]. Furthermore, it provides new insight into the role of patient electronic access in improving dyadic communication on STI risk. Participants almost ubiquitously anticipate that refusing to share STI screening results will warrant partner suspicion. These beliefs perhaps indicate that electronic PHR access will influence decisions related to sexual behavior.

Limitations

This study has many strengths and limitations. Our findings offer rich data on electronic PHR access beliefs within our sample population in context of when, how, and why STI talks occur. The mixed-methods design allowed us to formatively identify important variables to study quantitatively for a novel practice. Similarly, the context of perceptions emerging from our study is largely in absence of prior participant exposure to electronic PHR access. Resources were not available for research assistants nor secondary coders; thus, qualitative findings lack inter-coder reliability and are therefore subject to researcher biases. Additionally, significant differences were observed in academic classification by gender in our non-random convenience sample of online survey participants.

Although we determined that many participants reported electronic PHR access would lead to earlier dyadic talks on STI prevention, future studies are needed to better understand whether electronic PHR access would truly extend proximity in time between STI talks and sexual encounters. Furthermore, to determine whether an increase in time between the two events minimizes the length of time to next STI screening between dyad members.

Low self-efficacy beliefs for sharing positive electronic results are likely an indicator of stigma associated with being diagnosed with an STI. Given the sample, our study does not provide substantial insight into perceptions about electronic PHR–facilitated STI talks among people with chronic infections like HIV and genital herpes. Nevertheless, reducing stigma and enabling individuals infected with STIs to safely and comfortably disclose infection status to partners remains an important challenge to prevention and care. Reducing stigma associated with discussing infection with partners may reduce behaviors that accompany non-disclosure of diagnosis, such as condom-less sex; in addition to stigma-related impacts on the HIV treatment cascade [33-36]. Future studies are needed to explore feasibility of addressing stigma-related outcomes with electronic PHRs.

Conclusions

mHealth interventions incorporating electronic PHRs will offer new insight into strengthening infrastructure and the capacity to target disparities in STIs. Findings suggest that access to electronic PHRs for STI screening among subpopulations of black youth may improve both motivation and personal agency for initiating dyadic talks about testing. Results from this study will likely inform novel interventions that use access to electronic PHRs to stimulate important health-related discussions between sexual partners. The preventative capacity of electronic PHRs envisioned by our sample cannot be achieved without policies that support equipping them with patient portal access to STI screening records. Messages presented by healthcare providers on adopting electronic PHR–delivered STI results and electronic PHR–facilitated risk discussions will undoubtedly be key in adoption decisions. Moving forward requires studying strategies for implementing interventions that leverage electronic PHRs to create new sexual health communication channels with providers, peers, and family among black youth. With anticipated proliferation of electronic PHR adoption in generations to come, close attention is needed to ensure that black youth have equitable healthcare access to quality electronic PHR services [36].

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Conflicts of Interest

None declared.

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Abbreviations

CDC: Centers for Disease Control & Prevention
CMS: Centers for Medicare & Medicaid Services
DOI: Diffusion of Innovation Theory
eSHINE: Electronic Sexual Health Information Notification and Education
HITECH: Health Information Technology for Economic and Clinical Health Act
HSV-2: herpes simplex virus-2
IMBP: Integrative Model of Behavioral Prediction
MSM: men who have sex with men
PHR: personal health record
PI: principal investigator
STI: sexually transmitted infection

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Original Paper

Defining Empowerment and Supporting Engagement Using Patient Views From the Citizen Health Information Portal: Qualitative Study

Tracie Risling[1*], RN, PhD; Juan Martinez[1*], RN, BSN, BSc; Jeremy Young[1*], RN, BSN, BSc; Nancy Thorp-Froslie[1*], BS, MPH

College of Nursing, University of Saskatchewan, Saskatoon, SK, Canada

[*]all authors contributed equally

Corresponding Author:
Tracie Risling, RN, PhD
College of Nursing
University of Saskatchewan
4218 Health Sciences Building, E-Wing
104 Clinic Place
Saskatoon, SK, S7N 2Z4
Canada
Phone: 1 306 966 6232
Email: tracie.risling@usask.ca

Abstract

Background: The increasing presence of technology in health care has created new opportunities for patient engagement and with this, an intensified exploration of patient empowerment within the digital health context. While the use of technology, such as patient portals, has been positively received, a clear linkage between digital health solutions, patient empowerment, and health outcomes remains elusive.

Objective: The primary objective of this research was to explore the views of participants enrolled in an electronic health record portal access trial regarding the resultant influence of this technology on their feelings of patient empowerment.

Methods: The exploration of patient empowerment within a digital health context was done with participants in a tethered patient portal trial using interpretive description. Interpretive description is a qualitative methodology developed to pragmatically address clinical health questions. Patient demographics, self-reported health status, and self-identified technology adaptation contributed to the assessment of empowerment in this qualitative approach.

Results: This research produced a view of patient empowerment within the digital health context summarized in two overarching categories: (1) Being Heard and (2) Moving Forward. In each of these, two subcategories further delineate the aspects of empowerment, as viewed by these participants: Knowing More and Seeing What They See under Being Heard, and Owning Future Steps and Promoting Future Care under Moving Forward. This work also highlighted an ongoing interconnectedness between the concepts of patient empowerment, engagement, and activation and the need to further articulate the unique aspects of each of these.

Conclusions: The results of this study contribute needed patient voice to the ongoing evolution of the concept of patient empowerment. In order to move toward more concrete and accurate measure of patient empowerment and engagement in digital health, there must be further consideration of what patients themselves identify as essential aspects of these complex concepts. This research has revealed relational and informational elements as two key areas of focus in the ongoing evolution of patient empowerment operationalization and measure.

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KEYWORDS

digital health; electronic health record; patient engagement; patient empowerment; patient portal

Introduction

Patient-centered care has long been promoted, debated, and pursued, yet substantial reform to established institutional approaches has proved challenging. The increasing presence of technology in health care delivery, coupled with consumer demand, is contributing to a remarkable shift in traditional practices and a renewed interest in patient empowerment as a means to advance this long-sought reform [1,2]. However, decades of debate and varied conceptual application have resulted in a lack of clarity in how to best operationalize or even consistently define patient empowerment [3-6]. Despite these challenges, recent reviews on patient empowerment reveal a global interest in this concept [2,3,5]. The World Health Organization (WHO) European Regional Office included empowerment and patient-centered practice as key elements in its Health 2020 report [7], a follow-up on previous WHO study on the effectiveness of empowerment to improve health [8]. In this earlier work, WHO identified empowerment as an essential public health strategy and also noted a scarcity of refined evaluative measures [8]. Many years later, this need for a comprehensive operational definition of patient empowerment and robust measures to evaluate the concept remains [2,3,5].

Publication on patient empowerment is increasingly present in digital health literature [9-12], with an emerging consideration that "the future of patient empowerment may lie in technological advancements and better access of patients to these technologies" [13]. As technology is promoted as a means to advance patient empowerment [9,10,14,15], the need to address contextual considerations in applying this concept to digital health has also been raised [12,16]. Patient empowerment has been examined in conjunction with technological apps such as electronic personal health records [17,18], patient Web portals [19], and electronic medical records [20]. Patient portals or "tethered" electronic personal health records are Web-based portals linked to electronic health records (EHRs) [14]. Studies on patient portals seem to have emerged as a focal point in this study, with connections made between portal use, patient empowerment, engagement, and activation and ultimately improved personal health outcomes [21-24].

Despite this promising beginning in the exploration of patient empowerment in digital health, a clear linkage among the use of digital health services, patient empowerment, and health outcomes remains elusive. Previous work has characterized the challenges of advancing a clear and comprehensive definition of patient empowerment in digital health app [3-5]. Such challenges emerge from the mixed or combined use of patient empowerment with terms such as patient engagement, enablement, activation, and even patient-centeredness, although calls for the distinct use and application of each of these conceptual entities have repeatedly been made [5,25,26]. A previously published scoping review, by these authors on patient empowerment measures, further highlighted the current discord in operationalizing patient empowerment [27]. The gaps and inconsistencies in the measures of empowerment are further exacerbated by negligible contributions of patient voice [3,27]. As such, incorporating patient perceptions into the development of patient empowerment measures has emerged as a critical need to disentangle the interconnectedness between patient empowerment, engagement, and activation, specifically with regards to the use of patient portals in digital health [3,27]. The primary objective of this qualitative study was to explore the influence of the patient portal use on patient views and perceptions of empowerment. Incorporating an underrepresented qualitative narrative with the current empowerment study maximizes opportunities for patient voice to direct patient-centered care while contributing to the needed delineation of empowerment aspects associated with patient portal use.

Methods

Study Aim

This study aimed to characterize participant experiences and views of empowerment related to the use of patient portals. This study was supported by a previous scoping review, by these authors, which explored current practices in the operationalization of patient empowerment in relation to the use of tethered patient portals [27].

Recruitment, Appraisal of Health, and Technology Adaptation

Following the approval from the Research Ethics Board of the lead author's institution, participant recruitment was conducted in collaboration with eHealth Saskatchewan, which, with the support of Canada Health Infoway, had recently deployed a limited launch of the Citizen Health Information Portal (CHIP). This tethered patient portal was provided to approximately 1000 provincial residents facilitating access to data contained in their EHR. The portal allowed patients to add medical history information and provided views of laboratory results, immunizations, prescriptions, and hospital discharge summaries, as well as an opportunity to set reminders for medications and appointments [28]. All CHIP participants received an email invitation to participate in the study. No geographical limits were imposed during recruitment, but participants did need to be English speakers. The recruitment process resulted in a purposive sample of 26 participants for the study.

Regarding the demographic data collection, participants were asked to self-identify their current health status. The primary means of accessing Web-based information was also assessed by self-report in this group. Finally, the research team used a modified adaptation of Rogers' diffusion of innovations theory [29] to explore participant comfort in adopting and using new technologies. Rogers used the following 5 stages to identify how innovations are transmitted and taken up by members of a social system: (1) Innovators, these individuals are typically risk-takers and lead the way when it comes to new technologies; (2) Early Adopters, includes individuals who will be among the first to try new technologies; (3) Early Majority, represents individuals who take time to consider trying out something new before acquiring and using it; (4) Late Majority, includes the group of individuals that is somewhat cautious about trying new technologies and will tend to adopt the use of technology more slowly than the average; and (5) Questioners, representing the last group that will uptake a new technology with users that

typically require proof that new technology is worth investing in [29].

Data Collection and Analysis

Data collection was primarily achieved through semistructured interviews (Multimedia Appendix 1), and members of the research team also observed and collected data during a CHIP pilot participant focus group run by eHealth Saskatchewan. Once complete, the digital data files were transcribed, deidentified, and reviewed for accuracy, in preparation for analysis.

In this study, interpretive description (ID) was used, a qualitative methodology first detailed by Thorne et al [30]. ID was developed as a way of generating clinically relevant knowledge for health disciplines, and Thorne has since published, and recently updated, full text on this approach [31]. Initially, a detailed line-by-line coding of the data was undertaken within the transcript documents to provide an initial sense of the scope of the data. These early coding efforts revealed a wide diversity in the topic, enhanced by the line-by-line approach. The research team returned to the transcriptions to create a more focused dataset by collating all passages related to empowerment and engagement. In addition, the study team included any mention of either, or both, of these terms in the dataset based on the established interconnection of the concepts in the previously conducted scoping review [27].

The dataset was prepared in a split-page word document format, and the research team returned to the coding process. Moving away from the granular line-by-line approach, the data were instead examined, as Thorne recommended, through an "exploration of commonalities and differences among and between individual experiences" [32], reflective memoing was used during the analysis along with regular interchanges between research team members to share emerging interpretations and code categories. The ongoing dialogue supported the exploration of outlier data and allowed the team to come to consensus on how to integrate these findings. As the code categories began to coalesce and the interpretation emerged, the research team used the proposed descriptive categories and returned to the full transcript data set for a final review; this was done to ensure no other experiences or elements needed to be integrated into the analysis and final interpretation.

Results

Participant Demographics

All participants (N=26) resided in one Western Canadian province. The majority of participants were females (n=18), with fewer (n=8) male participants. Although the age of participants ranged 20-85 years, the predominant age category was 60-69 years (n=14), as shown in Figure 1.

As summarized in Figure 2, there was a diversity of self-reported health status, with the majority of participants rating their health within the well options. The way through which participants gained access to their health information on the portal varied, with most using a combination of personal computers, tablets, and mobile devices (n=15; data not shown). Figure 3 shows the range of self-identified technology adoption among the study participants, spanning the full scope of Rogers' continuum.

Interpretive Description Findings

Categories

From the experiences shared by CHIP participants (N=26) in this qualitative exploration of empowerment and engagement, the following two overarching categories emerged: *Being Heard* and *Moving Forward*. For each of these, 2 subcategories were defined to delineate the aspects of empowerment and engagement further, as viewed by these participants: *Knowing More* and *Seeing What They See* (under *Being Heard*) and *Owning Future Steps* and *Promoting Future Care* (under *Moving Forward*). Figure 4 presents these categories, and each will be reviewed further.

Figure 1. Participants' age ranges.

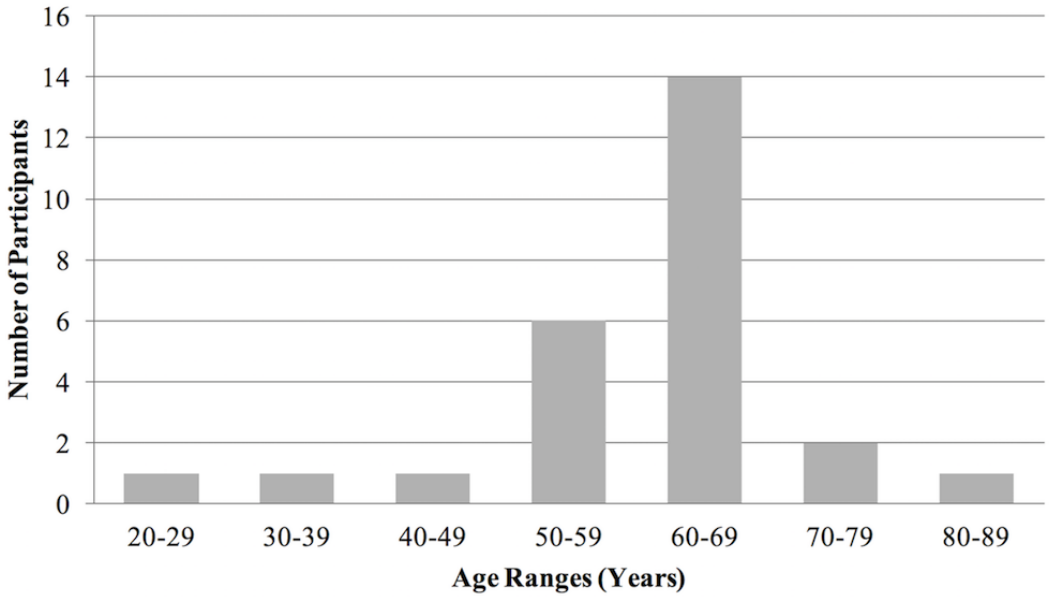


Figure 2. Self-identified health status of participants ranging from well to acutely ill with chronic illness(es).

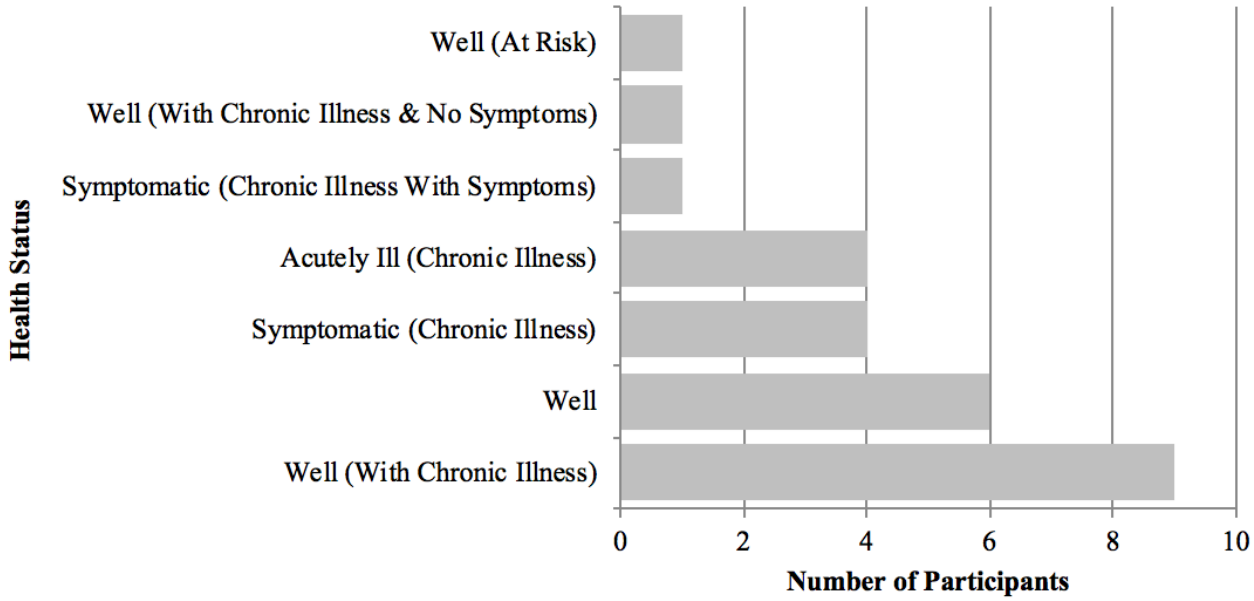
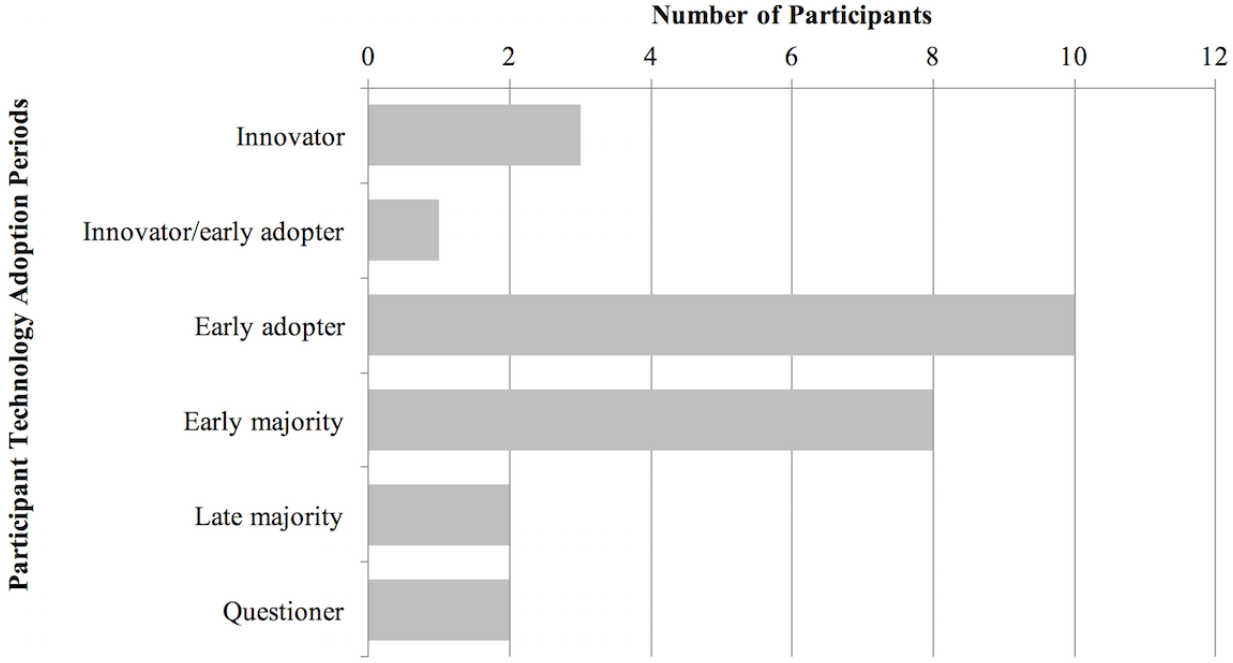


Figure 3. Technology adoption by participants.



ID is especially useful in considering the voice of the outlier or contrasting case [31]. In this way, ID is an opportunity to operationalize a patient-centered approach in the research app. In the case of this interpretive work on empowerment and engagement in relation to the patient portal experience, the research team encountered a participant whose view of empowerment was contrary to what had been commonly expressed. These data supported the emergence of the first overarching category in this interpretation, *Being Heard*.

Being Heard

Very early in the exploration of the participant transcripts, strong support emerged for empowerment, and many positive views about the concept were expressed. However, 1 participant did not seem to share this certainty when asked about the concept of patient empowerment, he responded:

> *I don't know if I like that word. It is just encouraging to see that healthcare is going in a positive direction these days, and it just tells me and it makes me feel like I do have a say in my healthcare and how it's administered to me and I want people to hear me the first time I present them with an issue, and that's something I really appreciate.*

Although the participant was unsure about the use of patient empowerment, there existed an essential element that arose from his statement about *being heard the first time* that resonated with the research team. A code category *Being Heard* was

proposed, and the team returned to the data using the lens of this outlier view to determine whether other participants expressed similar sentiments. From this exploration, the overarching category of *Being Heard* was established. During the interpretative analysis, this category evolved to include 2 further subcategories or themes: *Knowing More* and *Seeing What They See*. Table 1 summarizes participant quotes supporting the development of this category and the included themes.

Knowing More

Pilot participants in the CHIP project could access their EHR, and a familiar sentiment about the availability of this new source of personal data was expressed by 1 study participant: "I guess I could go back to the old adage where you hear people say information is power." In general, there was a significant response to the value of having direct access to personal health care data, especially as laboratory and medication information was updated in near real-time. This knowledge was often connected to the sense of empowerment, as demonstrated in the quoted excerpts in Table 1. Furthermore, the access to information was a foundational element of empowerment for these participants and a primary driver for their ongoing interactions with the portal. Moreover, *Knowing More* was a crucial foundation to support the pursuit of *Being Heard*.

Seeing What They See

The second element of *Being Heard* was a focus on what could be seen. Moving beyond the experience of simply *Knowing More*, *Seeing What They See* reflected not only the information but also an empowered sense of shared access to timely health care data with providers themselves. This access supported a variety of patient initiatives, as detailed in a few patient excerpts highlighting this theme in Table 1. Although some mixed feelings were reported regarding having access to test results, as well as differing opinion on whether this would increase or decrease physician workload, the overall sense of equality in being provided the same type of information that their own providers received was remarkable for study participants. There were recommendations that additional information, or suggestions, from providers to support self-care or behavioral changes, based on the data available in the portal, be incorporated in future offerings.

Together, *Knowing More* and *Seeing What They See* represent the empowered view of *Being Heard*. Overwhelmingly, study participants shared views that demonstrated that they were looking for opportunities to not only be further engaged in their own health care but also feel as though they were valued and knowledgeable team members in the decision making and delivery of this care. This sense of empowerment in future direction was represented in the second category of *Moving Forward*.

Moving Forward

This second overarching categorization comprised 2 subcategories or themes, *Owning Future Steps* and *Promoting Future Care*; these summarize the views of participants first in relation to their own self-care and second regarding their hopes and expectations for future technological advancements to support their ongoing involvement and engagement in their health care. Table 1 details participant quotes supporting this category and resultant themes.

Owning Future Steps

Although many participants in this study reported a history of substantial involvement in directing their own health, there was a profound sense of the significance of this portal technology in cementing the role of patients in the care relationship, especially in relation to decision making and engaging in self-care behaviors, as depicted in several quotes in Table 1. Where *Being Heard* was about taking in information and feeling empowered in the patient-provider relationship, *Moving Forward*, and in particular, *Owning Future Steps*, represented the resulting action when patients worked from an empowered position. Finally, the significance of the portal access in the lives of these participants, and its influence on their views of an evolving digital health care landscape, was summed in *Promoting Future Care.*

Promoting Future Care

Participants in this study provided a powerful contrasting view of a commonly held perception about the willingness of older patients to engage in technological health care solutions. *Promoting Future Care* not only highlights the desire of these participants to have continued access to the citizen portal but also for other technologies that could provide a more connected and supported health care future; details of this can be seen in the participant quotes for this theme in Table 1.

Figure 4. Interpretive categories identified in the qualitative study.

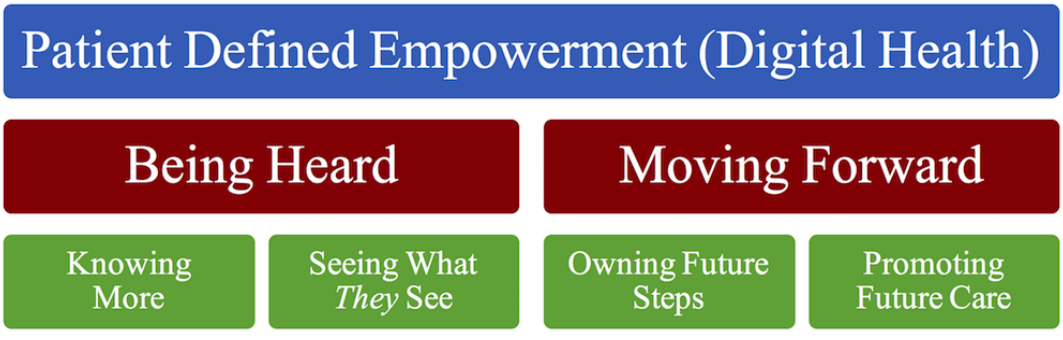


Table 1. Participant quotations supporting the themes in the category *Being Heard*.

Category and theme	Quotations
Being Heard	
Knowing More	• "I mean when I say empower, it empowers me, I would say it just gives me the confidence to know whether I'm asking the right questions or I have asked the right questions." • "It (the CHIP information) makes me a little bit more empowered to help make those decisions." • "Empowerment, so you can understand and know what's going on." • "To be empowered means to be aware of what is happening with your health." • "I can look up and see that information, make decisions, have less repetitive questions with my doctor and focus on the things that I really need to know." • "It's helping me assume responsibility and to be knowledgeable and I think to just be better prepared when I go see the doctor so I can ask meaningful questions." • "You're not anxious about it and, you know, if you're worried about something, you have a resource now that kind of tells you where to go with it or helps you determine where to go with it." • "I think it provides me with some peace of mind, because like I said, instead of hoping and being pretty sure it's all fine, you can look, and you can know."
Seeing What They See	• "If I can see what they are seeing maybe in a little bit in advance, then I can be better prepared when I go to my doctor's office; like have my list of questions ready." • "I go back and look at my numbers, try to make some changes right there. So it gives me more up-to-date information and not having to wait to get in to see the doctor if there was something that's off. If it's something that I'd try to control myself like the blood sugar levels or A_{1C} then that's something that I can take into my own consideration." • "CHIP has literally been a lifesaver for me, because I've been able to get my results before I even see the doctors, I'm able to formulate the questions that I need to ask the doctor and get far more engaged in my health care." • "To be empowered means to be aware of what is happening with your health, and test results can help that. Information from doctors and health care people can help that, and that way you can make the changes and adjustments that you may need to be well."
Moving Forward	
Owning Future Steps	• "When I become engaged in my healthcare and utilizing the resources I can access, I try to garner enough knowledge and understanding to feel empowered to take the next step." • "It has become very apparent the importance of informed self-care, not taking the doctors and the health professionals out of the equation, but to be able to take some of that information and look at what I can do as an individual to help myself." • "I need to be able to manage that, because I'm the one that's doing it every day." • "I can see that it's vital, the way they we're moving, that we have that self-empowerment that comes from using this information, having access and using this information ourselves." • "Well, I think something like that will give you more empowerment because it'll give you a track to follow, it should give you something to follow, and I think that there's even something else that could be done with that, in terms of empowering your healthcare."
Promoting Future Care	• "I think if you want people engaged in the health system, you need to make the health system accessible, and I think this is certainly one way to do it." • "I think this type of technology will also empower physicians to be able to give patients better care, or more timely care." • "So I think that when you talk about technology and what it means, I think it's just endless. There's so much and I think it really has a future that will allow for a whole different kind of coordination and communication." • "CHIP is wonderful. I want very much for it to continue and I would encourage over time for more information to be shared on it, I mean things like perhaps radiologist reports and those kinds of things." • "I think it's a great idea, I really do. We live in a technology age, we're in an online age. People want information at their fingertips, they do a lot of this kind of stuff from home or from their smartphone or whatever. I think this is an idea whose time is here." • "I personally think it's amazing, obviously, it has its limitations, but the only challenge will be presenting it in a way that people with different demographics and all types of background will accept it and be on board." • "I have mixed feelings about the increasing presence [of technology]. I love the access, I like the idea that if I needed care in a hurry people would have access to my information. I think that the more that happens the better, but the trade-off of that is the risk of somebody going in and looking at your information to use it to do you harm." • "Well, I'm probably as ambivalent as a lot of people are. Worrying a bit about security of information, enjoying having the access to it but still kind of okay, is it secure? How secure is it?" • "Technology is, I mean I see it as a double-edged sword. It's lifesaving and also costly as heck. I'm sure this whole CHIP thing doesn't come for free but as a service I think it's very—however much it costs— I'm hoping it's not too much that they don't find that it's not worthwhile, because I think that it is (worthwhile) if it's affordable."

Textbox 1. Participant quotations identifying challenges or limitations with patient portal use.

- "The amount of information that's there, you know it's going to be overwhelming for some people."
- "I don't really think it changed anything, because I knew enough to ask."
- "I sometimes don't think it's always necessary for a doctor to give you that information unless there's an interpretation required."
- "I don't know that I want to be more engaged. I don't know enough about it so I just sort of trust that my doctor's doing what's best."
- "The patient engagement is for people who want it, not everybody is going to want it."

Though enthusiastic about the integration of technology into their health care futures, the study participants also expressed practical views regarding the potential impact of this shift in access and delivery. Concerns about privacy, cost, and the importance of continuing to focus on people in care were expressed. As has been noted, ID promoted the inclusion of outlier views in the interpretative process. Textbox 1 summarizes some key contrasting participants' views about the portal technology and engagement in this type of access.

The use of ID serves as a very effective reminder for researchers, practitioners, and digital solution providers that no single initiative is going to meet every need regarding patient engagement and empowerment. The ongoing exploration of views, like those represented in Textbox 1, is key to recognizing not only potential research limitations but also those in the larger digital health milieu. Overall, a strong positivity associated with the expanding role of technology in health care, especially for services like patient portals, which allowed for improved patient access to their health care data.

Discussion

Principal Findings

Although there has been a considerable amount of academic exploration and publication on patient empowerment, a recent analysis revealed that a clear definition of the concept is still lacking [3,5,6]. In addition, there has been little consideration about the influence digital health may have on key attributes of patient empowerment. Overall, these findings support an existing challenge with the operationalization of this concept for use in digital health research. Following a previously published scoping review on patient empowerment measure in digital health [27], this qualitative study was conducted to contribute the needed patient voice to the ongoing discourse on empowerment in digital health and provide insight for the development of future measures.

Elements of the aspects of empowerment identified in this study through *Being Heard* and *Moving Forward*, and their respective subcategories, can be noted in previously articulated views of empowerment summarized by Bravo et al [3] in their recent analysis of patient empowerment: first, in this widely used definition by Funnell et al [33] from the early 1990s, "We have defined patient empowerment as the discovery and development of one's inherent capacity to be responsible for one's own life. People are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of their decisions" and second in the work of Lau [34] "Patient empowerment begins with information and education and includes seeking out information about one's own illness or condition, and actively participating in treatment decisions."

The alignment of this qualitative interpretation with previous work on conceptualizing patient empowerment is a positive finding; however, it is important to note further complexities that have been proposed through the views of these participants, particularly those that relate to the digital health context. Findings highlighted in *Promoting Future Care* speak to a desire by patients for the continued ability to be able to access their data electronically, as well as their hopes for the interchange of data in the future to support new means of communicating with providers and ultimately more efficient care. However, there are also unresolved concerns represented in these participant views, regarding the privacy and security of information, technology costs, and for some, uncertainty about whether or not the data are actually wanted.

A direct connection among digital health, patient empowerment, and particular health outcomes have been difficult to clearly demonstrate, with conflicting reports on the success of interventions summarized in several previous systematic reviews [35-41]. This challenge is reflected in this study as well in contrasting participant views on particular aspects of this digital health solution. However, despite concerns regarding costs or potential security risks associated with digital data, participants in this study still overwhelmingly identified portal access as an empowering force in the management of their health; this is clearly reflected in *Knowing More*. The impact of having digital access to critical health data appeared to be transformative for participants and supported enhanced preparation for practitioner visits, as a well as an improved sense of well-being or "peace of mind."

CHIP participants identified a positive association between the offered digital health solution and their sense of patient empowerment, which may prompt further reflection on how a lack of patient participation in empowerment conceptualization and measure, as identified by Bravo et al [3], may have contributed to the inconclusiveness of some digital health empowerment study [35-41]. An enhanced understanding of empowerment incorporating patient views is clearly needed to produce a more robust conceptualization. Only when this foundational work is complete should attempts to advance the evaluation and measurement of this concept move ahead. With these considerations, future measures should more accurately demonstrate the effectiveness of digital health tools in supporting patient empowerment. This study has provided a piece of this foundation by using patient voice to provide a set

of conceptual elements from which the work of creating a fulsome operationalization of patient empowerment within digital health can begin.

The results of this study can be used to reflect on the aspects of patient portals that may have the most "empowering effects." In particular, the combined participant views presented in *Knowing More*, *Seeing What They See*, and *Owning Future Steps* lend support to features such as the timely release of diagnostic results and the ability of patients to contribute data into their EHR. Evidence suggests that interventions, such as patient portals, can improve self-efficacy by giving patients tools for enhanced self-management, which, in turn, may contribute to a heightened sense of patient empowerment [9,18]. This study further highlights the empowering sense of equality that results when patients feel they have access to the same data as their health care providers, when they are *Seeing What They See*. Several patients noted a change in the dynamics of their provider relationships and identified the timely delivery of information as a critical element for their ongoing engagement in their health management. Furthermore, the ability to securely exchange information through a portal was acknowledged as a priority for more active patient collaboration and provides support to ongoing advocacy efforts for increasingly open data adoption in digital health solutions.

Limitations

This study is situated in the context in which it was conducted and represents the views of pilot CHIP participants. As such, it is not generalizable or representative of the experiences of all CHIP users or of other patients who are engaged in tethered patient portal use. This interpretation of patient empowerment within a digital health context, focused on the portal use, may however resonate with other patients, practitioners, and service providers. Certainly, it has added much needed patient voice to the ongoing academic pursuit of the comprehensive conceptualization of patient empowerment.

Conclusions

Providing patients electronic access to timely personal health information is a crucial step in supporting a new era of collaborative care. In this study, the use of a tethered patient portal (CHIP) introduced participants to the benefits of technology in supporting positive health outcomes and their own empowerment. CHIP participants shared their views of patient empowerment situated within the context of this digital health experience. This qualitative study produced a more in-depth patient-centric view of patient empowerment, including additional considerations relevant to the operationalization of this concept within a digital health context. This study supports the development of a patient empowerment measure to more effectively capture the influence of digital health initiatives on this vital outcome. The development of this instrumentation is the primary objective of ongoing research by members of this study team.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Semistructured interview guide.

[PDF File (Adobe PDF File), 55KB - medinform_v6i3e43_app1.pdf]

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Abbreviations

CHIP: Citizen Health Information Portal
EHR: Electronic health record
ID: interpretive description
WHO: World Health Organization

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Original Paper

Emergency Physician Use of the Alberta Netcare Portal, a Province-Wide Interoperable Electronic Health Record: Multi-Method Observational Study

Timothy AD Graham[1,2], MD; Mark Ballermann[1,3], PhD; Eddy Lang[4], MD; Michael J Bullard[2], MD; Denise Parsons[5], MSc; Gabriella Mercuur[5], MD; Pat San Agustin[2], MD; Samina Ali[5], MD

[1]Alberta Health Services, Edmonton, AB, Canada

[2]Department of Emergency Medicine, University of Alberta, Edmonton, AB, Canada

[3]Department of Critical Care Medicine, University of Alberta, Edmonton, AB, Canada

[4]Department of Emergency Medicine, University of Calgary, Calgary, AB, Canada

[5]Department of Paediatrics, University of Alberta, Edmonton, AB, Canada

Corresponding Author:
Timothy AD Graham, MD
Alberta Health Services
5th Floor, 44 Capital Boulevard
10044-108 Street
Edmonton, AB, T5J 3S7
Canada
Phone: 1 780 431 2549
Fax: 1 7806139804
Email: tim.graham@ahs.ca

Abstract

Background: The adoption and use of an electronic health record (EHR) can facilitate real-time access to key health information and support improved outcomes. Many Canadian provinces use interoperable EHRs (iEHRs) to facilitate health information exchange, but the clinical use and utility of iEHRs has not been well described.

Objective: The aim of this study was to describe the use of a provincial iEHR known as the Alberta Netcare Portal (ANP) in 4 urban Alberta emergency departments. The secondary objectives were to characterize the time spent using the respective electronic tools and identify the aspects that were perceived as most useful by emergency department physicians.

Methods: In this study, we have included 4 emergency departments, 2 using paper-based ordering (University of Alberta Hospital [UAH] and Grey Nuns Community Hospital [GNCH]) and 2 using a commercial vendor clinical information system (Peter Lougheed Centre [PLC] and Foothills Medical Centre [FMC]). Structured clinical observations of ANP use and system audit logs analysis were compared at the 4 sites from October 2014 to March 2016.

Results: Observers followed 142 physicians for a total of 566 hours over 376 occasions. The median percentage of observed time spent using ANP was 8.5% at UAH (interquartile range, IQR, 3.7%-13.3%), 4.4% at GNCH (IQR 2.4%-4.4%), 4.6% at FMC (IQR 2.4%-7.6%), and 5.1% at PLC (IQR 3.0%-7.7%). By combining administrative and access audit data, the median number of ANP screens (ie, results and reports displayed on a screen) accessed per patient visit were 20 at UAH (IQR 6-67), 9 at GNCH (IQR 4-29), 7 at FMC (IQR 2-18), and 5 at PLC (IQR 2-14). When compared with the structured clinical observations, the statistical analysis of screen access data showed that ANP was used more at UAH than the other sites.

Conclusions: This study shows that the iEHR is well utilized at the 4 sites studied, and the usage patterns implied clinical value. Use of the ANP was highest in a paper-based academic center and lower in the centers using a commercial emergency department clinical information system. More study about the clinical impacts of using iEHRs in the Canadian context including longer term impacts on quality of practice and safety are required.

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KEYWORDS

ambulatory care facilities; cross-sectional studies; electronic health records; utilization; hospital emergency service; statistics and numerical data; health information exchange; humans; information dissemination; medical record linkage; program evaluation

Introduction

Background

The adoption and use of an electronic health record (EHR) can facilitate real-time access to key health information and support improved outcomes [1-9]. Canadian hospitals are still primarily paper based, with only 5.2% of hospitals progressing to stage five or higher on the 7-point Electronic Medical Record Adoption Scale [10]. Although most hospital-based care is still documented on paper, there has been systematic investment and adoption of digital ancillary systems such as laboratory, pharmacy, and diagnostic imaging, sponsored by Canada Health Infoway (*Infoway*). Infoway is an independent, not-for-profit organization funded by the federal government, which works with the provinces and territories to cofund digital health projects throughout Canada.

One of the Canadian strategies for digitizing health care has been the promotion of the interoperable EHR (iEHR), which is equivalent to the health information exchange concept used in other jurisdictions [11,12]. iEHRs are being developed by each province as a part of the wider Canadian initiative to connect health care nationally. iEHRs are intended to be a longitudinal summary of key health events and act as a complement to point-of-service systems such as the electronic *medical* record (EMR) [13]. iEHRs have been shown to reduce duplicative laboratory and radiology testing, emergency department costs, and hospital admissions, with most clinicians also attributing positive changes in care coordination, communication, and knowledge about patients [14]. In contrast to the iEHR, in Canada, EMRs tend to be facility centric and refer to an ambulatory care record primarily linked to one single-care environment (such as a particular physician's office) or a hospital-based clinical information system.

In Canada, 12 of the 13 provincial and territorial governments have implemented iEHRs, but their maturity is quite variable. To date, only 5 of the 12 have made the 4 planned clinical components available, including diagnostic images, laboratory test results, dispensed drugs, clinical reports, and immunizations [15].

Alberta (population 4.2 million) was the first Canadian province to develop a provincial read-only iEHR known as the Alberta Netcare Portal (ANP). The ANP iEHR provides read-only access to province-wide laboratory results, diagnostic imaging (reports and images), electrocardiograms, textual reports (dictated discharge summaries, operative reports, some consultations, etc), scanned reports (including the paper emergency department charts from the Edmonton Zone), dispensed drug information via the provincial Pharmaceutical Information Network, and contains data from more clinical domains than any other province [16,17]. ANP has become an important tool for continuity of care, and although inpatient care is provided on paper charts, the information in the ANP has almost entirely supplanted the need to refer to paper charts in the emergency department. This trend was seen early in the deployment of the ANP [18].

The ANP was introduced in 2004 in 13 hospitals, 22 public health centers, 9 mental health clinics, and a small number of private physician offices within the Edmonton Zone of Alberta Health Services (formerly known as Capital Health Authority) and was rapidly adopted by providers in diverse care environments [17,18].

In 2008, there was a substantial reorganization of health care in Alberta, and multiple health regions were amalgamated into the first Canadian provincial Health Authority called Alberta Health Services (AHS). Currently, AHS comprises 5 functional and regional zones, each with varying degrees of health care digitization. In acute care facilities, including emergency departments, the vast majority of the Edmonton Zone uses paper for documentation and order entry, with digital radiology as well as electronic patient tracking and laboratory results delivery. In contrast, the Calgary Zone uses an emergency department and inpatient clinical information system from a commercial vendor (Allscripts), with virtually 100% computerized provider order entry. The ANP is available as a tab and launched from within the Allscripts interface.

Currently, ANP is used in a read-only fashion in 111 hospitals and more than 650 facilities affiliated within AHS, as well as family practice clinics, pharmacies, and other health care entities in the province. In 2018, over 51,000 physicians, nurses, pharmacists, and other Alberta health care providers had role-based ANP access, with more than 1.9 million patient records accessed monthly [19]. The ANP's evolution from a regional to a province-wide system and the usage patterns and contrasting information systems between zones in AHS presented a natural experiment and an excellent opportunity to study the ANP's utility and usage in 4 busy urban emergency departments.

Objective

The primary objective of this study was to compare the use of an iEHR (health information exchange-type) called ANP and other ancillary electronic systems between emergency department physicians practicing primarily in paper-based emergency departments versus clinical information system-based emergency departments. The secondary objectives were to characterize the time spent using the respective electronic tools and identify the aspects that were perceived as most useful by emergency department physicians.

Methods

Setting and Participants

We included 4 emergency departments in the study, 2 in the Edmonton Zone (University of Alberta Hospital [UAH] and Grey Nuns Community Hospital [GNCH]) and 2 in the Calgary Zone (Peter Lougheed Centre [PLC] and Foothills Medical

Centre [FMC]). Data were collected between October 2014 and March 2016. The UAH and FMC are comparably large academic tertiary care facilities and the GNCH and PLC are comparable community hospitals. The mean number of emergency department visits annually was 66,003 (UAH), 67,300 (GNCH), 80,466 (FMC), and 79,172 (PLC) during the period of the study.

All physicians providing care in at least one of the 4 study sites were eligible for inclusion in the direct observation and interview portions of the study. All uses of the ANP related to the patients presenting to the emergency department of any study hospital during the defined study period (October 2014 to March 31, 2016) were considered eligible for inclusion in the administrative database record review.

Emergency Department Information Systems and Tools

The Edmonton Zone and Calgary Zone emergency departments use different mixes of paper and electronic information systems to provide care and manage health information (Table 1). Patient tracking and emergency department lab results in Edmonton Zone are available on a commercial emergency department information system, but all order entry and charting is done on paper. Diagnostic images are available on stand-alone picture archiving and communication system stations that are not integrated with the emergency department information system. Historical health information in Edmonton is usually obtained via the ANP, which is accessed through a Web browser.

During the study period, care documentation in the Calgary Zone emergency departments was provided using a paper chart. Orders were managed using computerized provider order entry entered into Allscripts, which also provided the relevant laboratory, diagnostic imaging, and pharmaceutical information primarily related to Calgary Zone. ANP is available as a parameter-based launch from within the Allscripts interface. As Allscripts in Calgary contains most relevant patient data, it was hypothesized that the use of ANP would be much less in the Calgary zone and primarily related to patient care that occurred outside the Calgary Zone.

Ethics and Approvals

Research ethics approval was obtained from both the University of Alberta (Approval Pro00033249) and the University of Calgary (Approval REB13-0204) for the observation and interview portions of the study. The database review including the ANP access audit data was obtained following guidelines from provincial legislation that permits the use of data for system quality improvement purposes, which was the primary goal for this data extraction and analysis. The A pRoject Ethics Community Consensus Initiative screening tool was used as a guide in this process, and the resulting risk was assessed as being *low*.

Structured Clinical Observations

Participants

To prepare for the study, emergency department administrators, physicians, nurses, and allied health staff were informed about the study using email notices, visits to departmental meetings, and posted notices in the emergency departments. Physicians were approached by observers during their regularly scheduled shift. Of the 151 physicians approached regarding participation, 146 provided informed consent and 5 declined to participate. At the initial encounter, physicians provided demographic data, including their age, sex, payment model, comfort with computers (Likert scale 0-10), comfort interacting with EMR (Likert scale 0-10), number of years in practice, and medical credentials.

Procedure

Observations were conducted following previously published methods and using the Work Observation Method by Activity Timing (WOMBAT) software (WOMBAT 2.0, University of New South Wales) [20,21]. Research assistants were trained in the study protocol, use of the tablet-based WOMBAT data collection tool, and the emergency department patient-tracking system. The 5 research assistants were trained for at least 12 hours before starting observations. Training also consisted of familiarization with the data collection tool and data definitions (Multimedia Appendix 1), then completion of an observation alongside a more experienced observer.

Table 1. Overview of functions available using different applications at the different sites.

Information system function	Application			
	Emergency Department Information System[a]	Alberta Netcare Portal[b]	Sunrise Clinical Manager Clinical Information System[c]	Picture Archiving and Communication System[b]
Track patients	Yes	Not in real time	Yes	No
View lab results	Yes	Yes	Yes	No
View diagnostic imaging results	No	Yes (images and reports)	Yes (images and reports)	Yes (images and reports)
Order medications	No	No	Yes	No
Clinical documentation	No	Text reports (eg, consult letters)	No	No
Handover typed note	Yes	No	Yes	No

[a]Edmonton.

[b]Calgary and Edmonton.

[c]Calgary.

One of the authors (MB) was responsible for training research assistants and ensured that research assistants achieved inter-rater agreement scores of at least 90% with respect to the time spent on tasks and numbers of different tasks recorded before completing solo observations. Each research assistant conducted observations across multiple sites.

The research assistants approached emergency department physicians during the earlier hours of their shift, as this was posited to be when physicians would be more actively involved in direct clinical care, rather than the end of the shift when sign-overs and charting were being completed. After obtaining consent, the research assistants observed the physician for 90 min of their clinical shift and recorded demographic and clinical information regarding each patient seen and the time and clinician reason for each clinical access of ANP or other information systems. Time-stamped records including the tasks being completed, the people who were present, and which information tools were in use were recorded for later analysis.

Observations were balanced for the time of day (morning 8 am to 12 pm, afternoon 12 pm to 4 pm, and evening 4 pm to 8 pm) and time of week (midweek, weekend, Monday, and Friday). Qualitative field notes supported the capture of additional contextual information, including the number of learners (medical students and residents) on shift with the physician, the busyness of physician shift, type of patients seen (ie, chronic, complex vs ambulatory, pediatric vs geriatric), and type of presentation, when possible. Inter-rater reliability was calculated during training sessions where learning observers were trained to score the activities alongside more experienced observers, including the second author. Observers conducted independent data collection after consistently scoring 90% or higher agreement on participant time spent on patient care tasks.

Administrative Data Matching and Review

Administrative data for visits to the 4 sites, including the length of stay, final disposition (inpatient admission or discharge), and discharge diagnosis were obtained for October 2014 to March 2016. These data are routinely recorded as a part of standard AHS operations and for auditing provider accesses to patient records. emergency department encounters were identified from a national system known as the National Ambulatory Care Reporting System (NACRS) [22], and data matching was conducted using the available patient identifiers in both the NACRS and the ANP access audit databases. The number of screens viewed on the day of an emergency department encounter and the subsequent day was retrieved from the access audit data. The 2 datasets were matched using a common Unique Lifetime Identifier, a provincially assigned specific number used for patient identification purposes. Screen views were included in the analysis if they happened on either the day of the emergency department visit or the subsequent day. A screen view was defined by a change in the context of the information that an emergency department physician accessed on the ANP (Multimedia Appendix 2). For example, after searching for and identifying a patient, the first screen is a demographics screen with a Clinical Document Viewer with links to various types of clinical information. Clicking on a link might provide a single lab value, a lab flow sheet with multiple values, a textual report, a diagnostic image, or an electrocardiogram, each on a different screen view within the ANP, and each counting as a separate access.

Analysis

Quantitative analysis was completed using R (3.4.3, The R-Foundation) and Tableau (10.3). Simple linear regression was completed to evaluate potential effects of demographic, practice, and site-related explanatory variables on the percentage of time spent using ANP and other emergency department information systems tools such as emergency department information system and picture archiving and communication system. Additionally, structured physician observation records included contextual notes to ascertain what information needs were being met when accessing information tools during observations. Differences between sites were evaluated using a Kruskal-Wallis analysis of variance. The initial study questions were used to develop the semistructured questionnaire to evaluate what value clinicians found in the tools they used, including the iEHR, which were evaluated against the quantitative results to support triangulation of the findings.

Results

Structured Clinical Observations

To evaluate the context of emergency department physician use of ANP during clinical work, research assistants recorded structured clinical observations at the 4 research emergency departments. Between October 2014 and July 2015, 376 structured, 90-min clinical observations were completed with 142 physician participants (Sites UAH=97, GNCH=94, FMC=99, and PLC=83). As emergency department physicians in Calgary provide care across the different sites in each city, 26 participants were observed at more than one site. For over 566 hours of observation, study personnel used the tablet-based WOMBAT app to record which information resources were being used, including the content types they accessed and the proportion of time emergency department physicians spent accessing the ANP during each 90-min observation. To evaluate whether the method was correctly applied, the percentages of time spent on high-level task categories were calculated and compared for the 4 emergency departments (Figure 1). The proportions of time spent on the different categories were compared and found to be statistically similar across the sites. The mean proportions of time spent (with 95% CIs) on task categories in this study were compared with previously published literature (Figure 1). These percentages of time spent on different tasks while physician participants provided emergency department care in Australian hospital wards were similar to the values reported in this study than the percentages of time spent on the high-level task categories by physicians providing care in Australian hospital wards [20,23].

The median percentage of physician participant time spent using ANP was 8.5% at UAH (Figure 2; interquartile range, IQR, 3.7%-13.3%), 4.4% at GNCH (IQR 2.4%-4.4%), 4.6% at FMC (IQR 2.4%-7.6%), and 5.1% at PLC (IQR 3.0%-7.7%). The value at UAH was significantly higher than the other sites (P<.001). The tasks physicians were observed completing most often while using ANP are identified in Figure 2.

Figure 1. Comparison of proportions of time spent on different tasks in the 4 emergency departments (A) and 2 other studies using the Work Observation Method by Activity Timing (WOMBAT) method (B). (A) The median and interquartile range of the data for individual observations of physician work at 4 EDs are shown by the symbol and the gray bars. The different task categories are labeled on the x-axis at the top of the figure. University of Alberta Hospital: filled squares; Grey Nuns Community Hospital: filled circles; Foothill Medical Centre: empty squares; Peter Lougheed Centre: empty circles. (B) The mean time spent and 95% CIs are reported for this study (+ sign), an Australian study of emergency department physician work (at a registrar training level comparable with the participants in the current work; x sign), and an Australian study of hospital ward physician work (* sign).

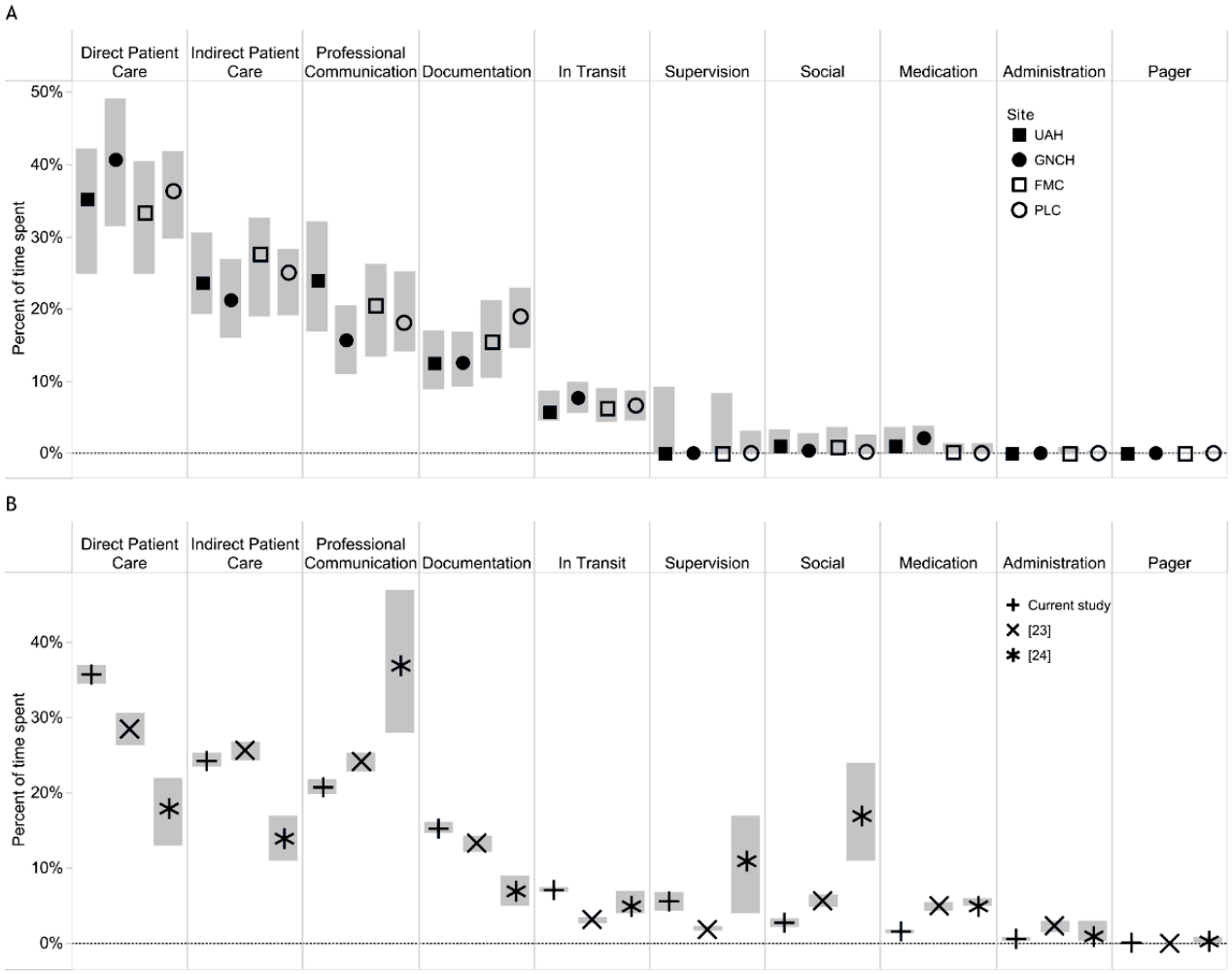
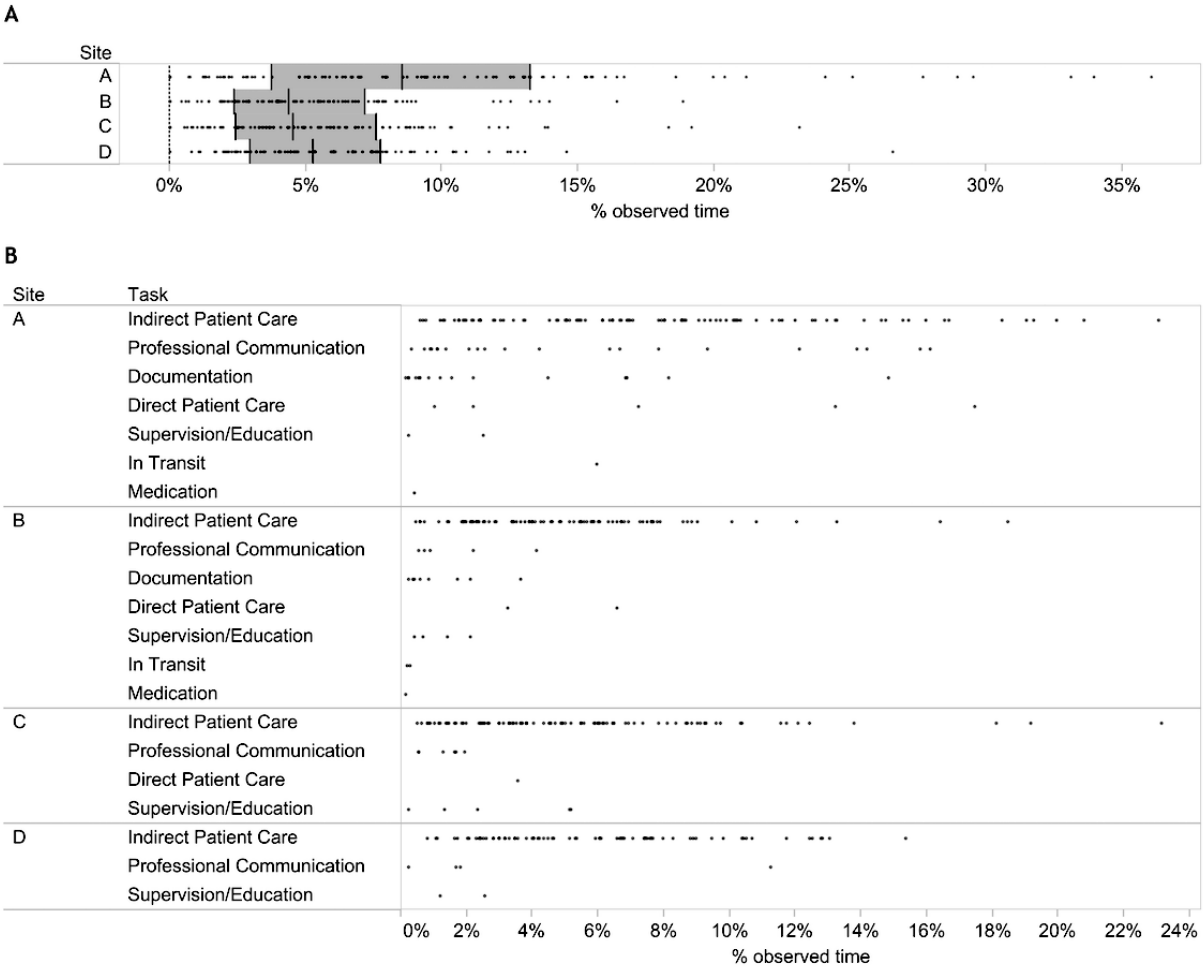


Figure 2. Percentage of observed participant time spent using Alberta Netcare Portal (ANP). (A) Each circle represents the percentage of time spent using ANP for a single 90-min observation session (n=376). The middle black bars represent the median percentage of time spent using ANP and the gray rectangles represent the interquartile range. University of Alberta Hospital site is A, Grey Nuns Community Hospital is B, Foothill Medical Centre is C, and Peter Lougheed Centre is D. (B) Circles represent the proportion of time spent during individual observation sessions using ANP while completing the tasks named at the left-hand side.



ANP was used during 20.9% of time spent on indirect patient care, including reviewing patient information. ANP was used alongside discussions. Of the total recorded time, 1.5% of the recorded time was spent on Professional Communication. Other tasks that were completed while physicians used ANP included Documentation (0.59%), Direct Patient Care (0.55%), Supervision/Education (0.26%), In Transit (0.06%), and Medication-related tasks (0.01%).

To evaluate other factors that may affect the observed use of ANP, physician demographic and practice characteristics were recorded and simple linear regression was used to identify potential effects on ANP use (Table 2). No statistically significant effects were found.

Administrative Data Matching and Review

Audit logs from the same time period as the structured clinical observations (October 2014 to March 31, 2016) were compared with the triangulated findings between the 2 methods of evaluating clinician use. Alongside the structured clinical observations, administrative access audit data from ANP were linked with a routinely generated dataset on emergency department visits. Patient visits to the 4 study emergency departments between October 2014 and April 2016 were identified using administrative data and matched with access audit data to derive the number of ANP screens accessed during 3 periods of time (October 2014 through January 2015, July 2015 to September 2015, and February 2016 to April 2016). An ANP access relating to an emergency department visit was defined as the use of the ANP after presentation to the emergency department on the same and next calendar day. During the study period, emergency department physicians at all sites accessed 1,994,334 lab results, 763,334 diagnostic imaging results, and 666,222 textual reports. Over 376 observations and 142 emergency department physicians, the mean and median number of ANP screens viewed per 90-min observation in the Edmonton sites were 53 (UAH) and 27 (GNCH). In the Calgary sites, the mean number of ANP screens viewed was 15 (FMC) and 13 (PLC; Figure 3). Screen accesses were calculated at each site, and a median of 20 screens was accessed per patient visit at UAH (IQR 6-67), 9 at GNCH (IQR 4-29), 7 at FMC (IQR 2-18), and 5 at PLC (IQR 2-14). When compared with the structured clinical observations, the statistical analysis of screen access data also showed that ANP was used more at UAH than the other sites.

Among the different content types available in ANP, laboratory and imaging data were accessed more often than transcribed reports, dispensed drug information, or information not categorized elsewhere (eg, electrocardiograms; Figure 4). Physicians were observed spending relatively more time reviewing textual reports (mean 4.6%, 95% CI 4.1-5.1) than lab results (mean 2.6%, 95% CI 2.1-3.1) or diagnostic imaging (mean 1.9%, 95% CI 1.6-2.1; Figure 4).

Table 2. Effect of demographic and practice characteristics on Alberta Netcare Portal (ANP) use as measured by the proportion of time spent.

Demographic and practice characteristics	Sites A and B (n)	Sites C and D (n)	Relationship with observed ANP usage (*P* value)
Age (in years)			.68
<30	2	3	—[a]
30-39	24	38	—
40-49	23	25	—
50-59	7	10	—
>60	6	4	—
Sex			.06
Female	13	17	—
Male	49	63	—
Credentials			.06
Medical Doctorate	41	78	—
Fellow of the Royal College of Physicians of Canada–Emergency Medicine	27	44	—
American Board of Emergency Medicine	4	5	—
Special Competence in Emergency Medicine	28	29	—
Other (PhD)	3	0	—
Payment scheme			.47
Fee for service	54	73	—
Salary	7	9	—
Mixed-compensation model	4	0	—
Years in practice, mean (SD)	13.3 (10)	12.9 (9)	.29
Comfort with computers[b], mean (SD)	8.1 (1.6)	8.3 (1.6)	.35
Comfort with electronic medical records[b], mean (SD)	7.9 (1.6)	8.1 (1.7)	.93

[a]Not applicable.

[b]Likert scale 0-10; 10=completely comfortable.

Figure 3. Relative usage of Alberta Netcare Portal across 4 emergency departments from 2014 to 2016 based on access audit data. Each symbol represents the median weekly count of screens accessed per patient visit to the 4 emergency departments. University of Alberta Hospital: filled squares; Grey Nuns Community Hospital: filled circles; Foothill Medical Centre: empty squares; Peter Lougheed Centre: empty circles.

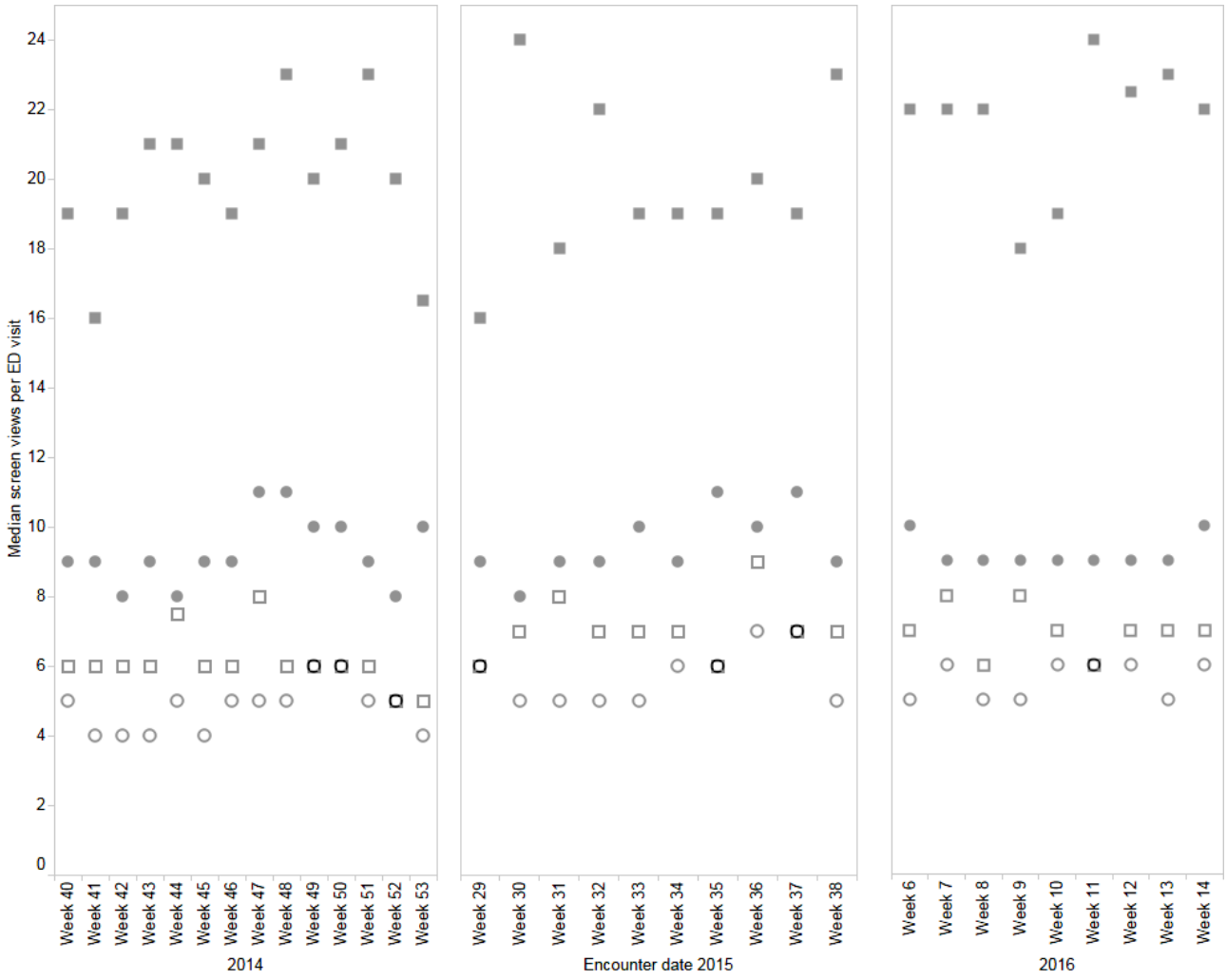
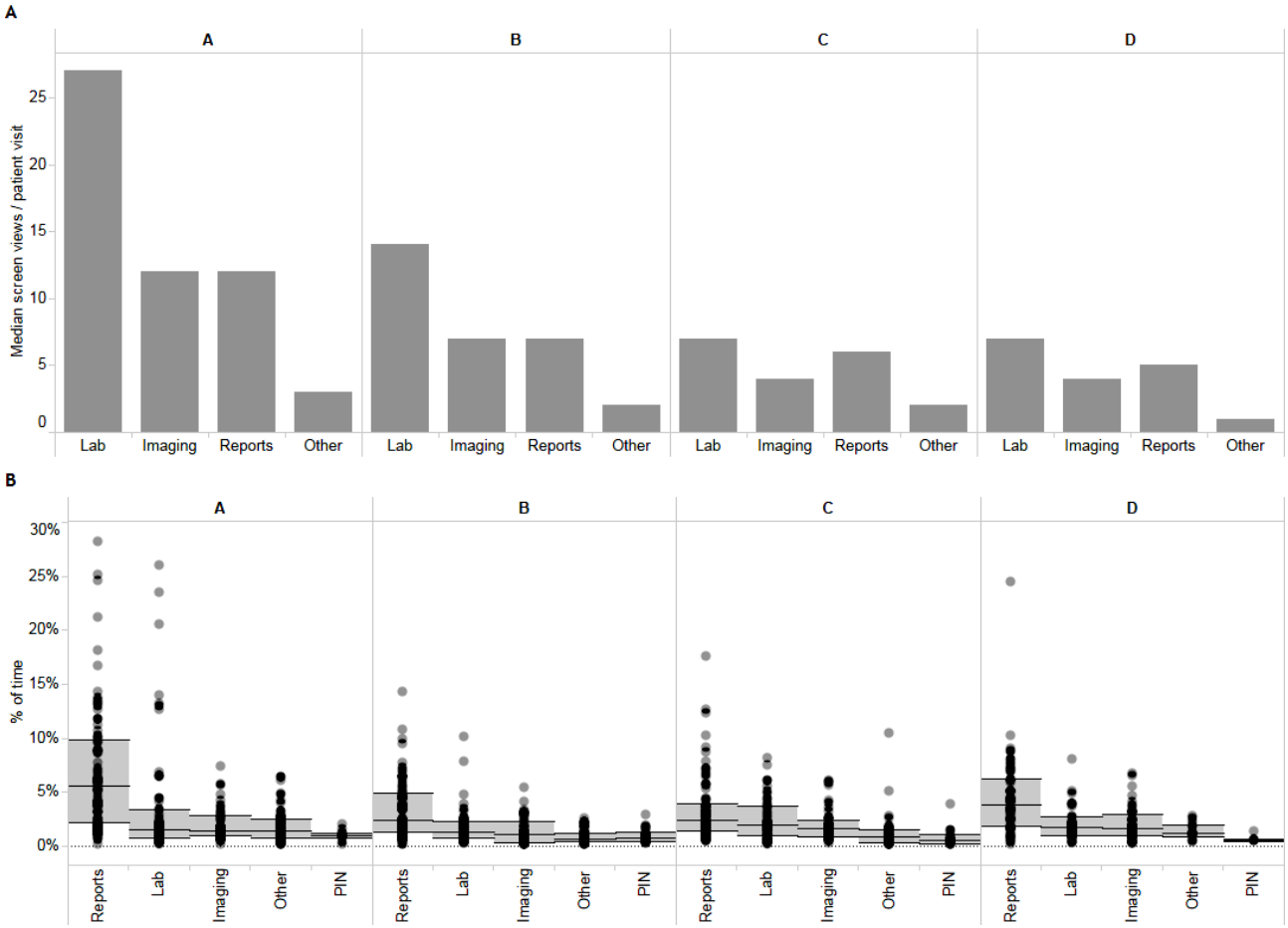


Figure 4. Usage of the different clinical functions in Alberta Netcare Portal based on (A) median counts of screen views from access audit data and (B) observed app usage as measured by the percentage of time spent. The data are shown for each of the 4 sites (A: University of Alberta Hospital; B: Grey Nuns Community Hospital; C: Foothill Medical Centre; D: Peter Lougheed Centre) for laboratory results (Lab), diagnostic imaging (Imaging), textual reports (Reports), Pharmaceutical Information Network (PIN; ie, dispensed medication information), and other information (Other). Circles in (B) represent values for individual 90-min observations. Horizontal black bars and gray areas in (B) represent the median and 95% CIs, respectively.



Discussion

Principal Findings

This work triangulates data to evaluate the use of an iEHR (health information exchange-type) in 4 Canadian emergency departments. To our knowledge, there have been no prior Canadian studies describing the use and utility of an iEHR in the emergency department or any other clinical setting. Across Canada, iEHRs are at various stages of implementation and maturity and have evolved according to provincial and territorial strategies and priorities [16]. The Alberta Netcare Portal iEHR is widely used throughout Alberta. A previous study of ANP use showed 76% of users indicated that it helped provide quality patient care, whereas 82% felt that it integrated easily into their clinical workflow [18]. Canadian survey data from 2006 to 2014 demonstrate that in 6 provinces, the Canadian iEHR is perceived to have positive outcomes in terms of user satisfaction, impact on quality of care, and impact on productivity [1,15].

In the emergency department setting in other jurisdictions, these types of read-only iEHRs have been shown to be valued by physicians [2,24,25] and to increase the ability to identify frequent emergency department users [26]. Usage of iEHRs has been reported to vary across different practice settings even when the technical configuration is identical [27], potentially resulting in inconsistent and poorly understood clinical impacts [28].

The triangulation of results in our study, along with the comparison of the time and motion data with results that have been previously reported using the same method in other countries and care environments, supports the findings. Clinicians spent a significant amount of time accessing the various areas of the ANP and reviewing information relevant to patient care, consistent with their content. The access audit data complement these findings. The counts of screen accesses show information searching behaviors that are temporally linked to individual patient emergency department visits and implying they are of important clinical value. Physician perceptions of the ANP were explored in more detail via semistructured interviews and are reported elsewhere.

In Alberta, it is clear that the ANP has become an integral part of emergency department care and is used extensively, with the highest observed usage in the complex environment of a paper-based tertiary care academic center. ANP was more heavily used at the UAH and GNCH (where they document care primarily on paper and order laboratory testing, diagnostic imaging, and other interventions either using paper forms or by verbally or telephonically communicating with different services), compared with sites using a clinical information

system that provided similar information but greater integration into point-of-care workflows. In contrast to the UAH, the tertiary care academic site in the Calgary Zone (FMC) had an emergency department clinical information system, and their relative use of ANP was considerably less—most of the information related to their local patients was usually embedded within the context of the emergency department clinical information system.

EHR disuse may result when users and owners do not accrue the benefits of their use [29]. Here, we found that ANP use was independent of the characteristics we evaluated and consistent with emergency department physicians perceiving that content available via ANP supported medical decision making. In particular, information related to the medical management of patients and clinical decision support was not available in ANP and was noted as a potential area of improvement by participants in the structured clinical observations.

Given that the ANP was utilized less frequently in Calgary emergency departments where they were able to access much of the ANP information in their regional clinical information system, as clinical information system implementations increase across the country, the role of separate provincial iEHRs needs further evaluation. Physicians also seek to have clinical documentation, electronic referral, computerized provider order entry, and clinical decision support all accessible in a single point-of-care system to support their clinical practice, rather than logging in and out of multiple systems. Currently, the iEHR is a read-only app (with some small exceptions) and does not support the clinical documentation and ordering needs. Potential important benefits of clinical information system and electronic records relate to patient safety, particularly around medication management and clinical decision support [2,5-7,18], which are not available in the ANP.

Limitations

Although hybrid paper and computerized practice environments are common in Canada, our results may or may not generalize to other settings that do not have the particular mix of these systems present in the study emergency departments. The Alberta context, where an iEHR is available alongside a more transactional clinical information system in some sites, afforded a unique opportunity to study its use and clinical utility systematically.

In defining the access of ANP related to an emergency department visit, the audit logs were not detailed enough to identify from what part of the hospital the ANP was accessed. Our ANP accesses may be slight overestimates when a patient was admitted to the hospital and the ANP was accessed by the inpatient care team. We believe this possibility to be small because the majority of patients presenting were not admitted to an inpatient service, and it can take many hours for an admitted patient to move from an emergency department to the inpatient bed.

More generally, partially adopted clinical documentation applications may lead to hybrid environments where some forms of information are charted on paper and others are charted in a clinical information system [30-32]. This work illuminates the need to use multiple methods while evaluating the impacts of different methods of information storage and retrieval in the context of fast-paced emergency department care while showing the clinical utility of a single iEHR accessible across a province.

Conclusions

The current evaluation shows that ANP iEHR is well utilized at the 4 sites studied, and physicians participating in the study perceived ANP has a positive impact on knowledge of their patients, patient safety, and quality and continuity of care. Physicians at the paper-based tertiary care hospital utilized ANP markedly more than those at the clinical information system-based tertiary care hospital or the 2 community hospital sites. Physicians working at all 4 sites accessed lab results and diagnostic imaging more often than textual reports, such as discharge summaries and operative reports, but spent relatively more time reviewing textual reports. Physician demographic and practice characteristics did not predict this common usage pattern. In its current form, ANP features that could be enhanced include electronic referral, clinical documentation, and medication ordering and management. Given the trend of moving toward comprehensive clinical information systems to run hospital systems, the future design, development, and importance of the iEHR need further evaluation.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

WOMBAT Workflow Definitions.

[PDF File (Adobe PDF File), 89KB - medinform_v6i3e10184_app1.pdf]

Multimedia Appendix 2

Access audit data definitions.

[XLSX File (Microsoft Excel File), 9KB - medinform_v6i3e10184_app2.xlsx]

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Abbreviations

AHS: Alberta Health Services
ANP: Alberta Netcare Portal
EHR: electronic health record
FMC: Foothill Medical Centre
GNCH: Grey Nuns Community Hospital
iEHR: interoperable electronic health record
IQR: interquartile range
NACRS: National Ambulatory Care Reporting System
PLC: Peter Lougheed Centre
UAH: University of Alberta Hospital
WOMBAT: Work Observation Method by Activity Timing

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Original Paper

Task-Data Taxonomy for Health Data Visualizations: Web-Based Survey With Experts and Older Adults

Sabine Theis[1], MSc; Peter Wilhelm Victor Rasche[1], MSc; Christina Bröhl[1], MSc; Matthias Wille[1], Dr Phil; Alexander Mertens[1], Dipl-Inform, Dr Ing, Dr rer medic

Human Factors Engineering and Ergonomics in Healthcare, Chair and Institute of Industrial Engineering and Ergonomics, RWTH Aachen University, Aachen, Germany

Corresponding Author:
Sabine Theis, MSc
Human Factors Engineering and Ergonomics in Healthcare
Chair and Institute of Industrial Engineering and Ergonomics
RWTH Aachen University
Bergdriesch 27
Aachen, 52062
Germany
Phone: 49 492412418099469
Email: s.theis@iaw.rwth-aachen.de

Abstract

Background: Increasingly, eHealth involves health data visualizations to enable users to better understand their health situation. Selecting efficient and ergonomic visualizations requires knowledge about the task that the user wants to carry out and the type of data to be displayed. Taxonomies of abstract tasks and data types bundle this knowledge in a general manner. Task-data taxonomies exist for visualization tasks and data. They also exist for eHealth tasks. However, there is currently no joint task taxonomy available for health data visualizations incorporating the perspective of the prospective users. One of the most prominent prospective user groups of eHealth are older adults, but their perspective is rarely considered when constructing tasks lists.

Objective: The aim of this study was to construct a task-data taxonomy for health data visualizations based on the opinion of older adults as prospective users of eHealth systems. eHealth experts served as a control group against the bias of lacking background knowledge. The resulting taxonomy would then be used as an orientation in system requirement analysis and empirical evaluation and to facilitate a common understanding and language in eHealth data visualization.

Methods: Answers from 98 participants (51 older adults and 47 eHealth experts) given in an online survey were quantitatively analyzed, compared between groups, and synthesized into a task-data taxonomy for health data visualizations.

Results: Consultation, diagnosis, mentoring, and monitoring were confirmed as relevant abstract tasks in eHealth. Experts and older adults disagreed on the importance of mentoring (χ^2_4=14.1, P=.002) and monitoring (χ^2_4=22.1, P<.001). The answers to the open questions validated the findings from the closed questions and added therapy, communication, cooperation, and quality management to the aforementioned tasks. Here, group differences in normalized code counts were identified for “monitoring” between the expert group (mean 0.18, SD 0.23) and the group of older adults (mean 0.08, SD 0.15; t_{96}=2431, P=.02). Time-dependent data was most relevant across all eHealth tasks. Finally, visualization tasks and data types were assigned to eHealth tasks by both experimental groups.

Conclusions: We empirically developed a task-data taxonomy for health data visualizations with prospective users. This provides a general framework for theoretical concession and for the prioritization of user-centered system design and evaluation. At the same time, the functionality dimension of the taxonomy for telemedicine—chosen as the basis for the construction of present taxonomy—was confirmed.

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KEYWORDS

classification; data display; computer graphics; task performance and analysis; medicine; telemedicine; user/machine systems; human factors

Introduction

Overview

Health care services are currently undergoing a digital transformation that is increasing the amount of clinical and personal health data. Data visualizations enable people to analyze and understand these data to make more informed decisions and to promote health-improving behavior [1-3]. Information and communication technology (ICT) development is the driving force behind the digitization of health services. In the 1990s, digital tools were differentiated from their analog counterparts with the prefix "e-." Mail became email and commerce became e-commerce. Likewise, health became eHealth. The term describes all health services supported by ICT [4]. A definition covering all aspects of the term has not been achieved to date because it depends on ongoing technological development and diversity [5]. The major part of eHealth systems processes data to make it accessible to the user.

Data Visualization

But what does the term data actually mean? Data—as the plural of the Latium *datum*—labels "factual information such as measurements or statistics used as a basis for reasoning, discussion, or calculation" [6]. Data results from a measurement [7]. In computer science, "data" is understood as machine-readable, digital representation of information encoded into character(s) (strings) following a syntax [8]. In order to abstract the information from data, it must be interpreted in a context of meaning; therefore, the user must be able to perceive and understand it [9]. Data visualizations are a way to make use of the effective visual perception channel to exchange information inherited in data [7]. By assigning graphical attributes to data, users can grasp data characteristics or identify new patterns [10-12]. As a graphical representation of data and statistical concepts, data visualizations particularly support decision making [13]. Data analysts, scientists, and statistical experts have been among the primary users of data visualization to date [14], but digitization of health services together with demographic change [15] and the recently observable shift toward patient empowerment are leading to an increase in the number of older adults without special background knowledge using data visualizations [16-21]. Accordingly, research on the visualization of health data is increasingly taking into account the perspective of older adults for design and evaluation [22-24].

Task Models and Taxonomies

Before developers visualize data, they identify tasks relevant to users and data relevant to these tasks [25]. This ensures that visualization dashboards optimally support users in reaching their goals. In user-centered development, this is called task analysis as one method of the requirement analysis [26-28]. Thus, knowledge of visualization tasks is important for the selection or construction of suitable visual representations, at the same time it supports the empirical visualization evaluation during the selection of experimental tasks.

Tasks differ in their granularity and degree of abstraction [29,30]. For example, "curing a disease" is a domain task with low granularity (high-level task), whereas "compare a patient's heart rate variability data to detect anomalies" describes a granular domain task (low-level task). Visualization tasks are determined by the user perspective [31] and numerous models exist to capture those inferring layers of data visualization tasks or processes [32-35]. Our work refers to Munzner's model of nested layers [36]. Munzner's nested model describes the procedure of data visualization design, starting with the investigation of domain tasks and data, because users have their own vocabulary to describe it. Subsequently, the domain problems have to be translated into abstract visualization tasks and data types as a vocabulary for data visualization. Data types in this context are defined by the kind of data to be visualized. In the third layer of Munzner's nested model, visual encodings and interaction methods for data and task abstractions are developed so that corresponding algorithms can be developed at the innermost level. In this model, the output of one layer is the input for the subsequent one.

Abstract visualization tasks have often been listed alone or together with data types in the form of taxonomies [37]. Taxonomies are hierarchical structures originally used to classify organisms. Later, computer science used them to structure knowledge within knowledge-based systems or for software-testing research [38]. They provide conceptual clarity of a domain and categorize information for increased theoretical understanding. Another advantage is that taxonomies foster generalizability in empirical research if evaluation considers its tasks and data types [27,37,39-43]. Taxonomies also allow precise comparisons across different visualization tools and application domains. Work procedures can be analyzed using a domain-independent language, so that comparative analyses of tasks involving different visualization tools in different disciplines can be carried out [38,39]. A taxonomy is empirically built as the hierarchy of the concepts are classified by reason or measured similarity found in observed variables. A typology, in contrast, classifies various types that have equal characteristics and splits concepts into different types along at least two dimensions. It does not necessarily rely on empirical methods, and elements are less strictly reliant on the hierarchy as with a taxonomy.

An abstract task typology emerged from Munzner's [36] nested model and was developed by Brehmer and Munzner [44]. Their typology includes a set of visualization tasks and data types with different levels of granularity (high level to low level), covering objectives on the "why dimension," actions on the "how dimension," and data types on the "what dimension." We adopt their definition of data types: kind of data that can be visualized. The authors state that their typology is relevant for nearly all application domains. Thus, it might be assumed that it is also relevant for the eHealth domain. Empirical evidence has yet to be provided and it is one of the objectives of the investigation presented in this paper. The typology by Brehmer and Munzner partly overlaps with the data types from Shneiderman's task-by-data-type taxonomy [37]. In a subsequently published article, Brehmer et al [45] characterized task sequences related to the visualization of dimensionally reduced data. Brehmer et al [46] also encourage detailed investigations of domain problems and tasks before the actual design and evaluation.

In the health and eHealth domain, taxonomies of general tasks have so far been applied to make concepts and their relation understandable. Furthermore, they are applied to differentiate ambiguous medical vocabulary [47-51]. For example, Bashshur et al [47] focused on the differentiation of different terms describing ICT-mediated health. The authors constructed a taxonomy of telemedicine by differentiating the subdomains telemedicine, telehealth, eHealth, and mHealth. They differentiated, as a part of the functionality dimension, the abstract tasks consultation, diagnosis, mentoring, and monitoring. The described taxonomy was built based on the expertise of the authors. A user study or literature review was not undertaken.

Problem Statement

Previous literature illustrated the importance of task analysis with users for the description, evaluation, and creation of data visualizations. The problem is that if someone wants to develop a data visualization system, he or she must first find out which tasks the users consider relevant by means of user studies. Abstract visualization tasks as well as data and application-specific tasks play a role here. However, if all users had already been asked for their opinion on relevant tasks and data, developers could spare this time-consuming step of task analysis or at least parts of it.

In addition, it is almost impossible for scientists to adhere to the tasks that are relevant for users during an empirical evaluation of health data visualizations because this would require a separate study as a preanalysis of relevant user tasks. We believe not only developers may profit from using general tasks relevant to users as input for a more specific requirement analysis, but also researchers may consider them to select experimental tasks so that results from their evaluation become comparable and more generalizable across applications [52].

Although an extensive list of task taxonomies for data visualization exists, they are not suitable to lead developers and scientists to select tasks relevant to users because they are based on authors' experience or on literature studies. They lack users' perspectives. Another problem is that existing health taxonomies do not consider visualization-specific tasks and data, and taxonomies or typologies of abstract visualization tasks and data lack a definition of the domain problem and corresponding user tasks. Additionally, it remains unclear to what extent existing visualization task and data type classifications [44,47] are relevant to prospective eHealth users, who we—given the context of demographic change—consider to be older adults. Older adults are the ones who will use the future systems that developers can build based on the output of current research efforts. Furthermore, incidence, prevalence, and mortality are strongly age dependent. For this reason, the risk of developing age-dependent chronic diseases or psychological decline is rising. Thus, older adults are more likely to use eHealth systems than younger people are.

Purpose of the Study

With this study, we want to make a first step toward generalizable results of user-centered task analysis, so that results are valuable to as many developers and researchers in the domain of eHealth as possible. Therefore, the purpose of this study is to construct a taxonomy of abstract domain and abstract visualization tasks and data types. To the best of our knowledge, we are the first to investigate the relation between abstract visualization tasks and data types in the eHealth context and thus the first to create a taxonomy that has domain relevance but remains general across different eHealth applications. In contrast to existing work, we construct the task taxonomy with the help of prospective eHealth users (older adults), so that it can foster the understanding of the user, the users' tasks, and the users' domain understanding in order to become a language among researchers from different domains. In this regard, the study will answer the following questions:

1. Which abstract eHealth tasks do older adults consider relevant for eHealth systems?
2. Which abstract visualization tasks and data types do older adults consider relevant for medical consultation, diagnosis, mentoring, and monitoring?
3. Does the rating from older adults differ from that of eHealth experts?

Methods

Study Design

We devised a structured cross-sectional study with a nonrandom sample to collect data from prospective eHealth users (older adults) and eHealth experts.

Participants

Prospective eHealth users were targeted by focusing on participants older than 50 years because they are the ones who will use the future systems that developers can build based on the output of current research efforts. Furthermore, incidence, prevalence, and mortality are strongly age dependent with risks rising, for example, for chronic diseases or cognitive and physical decline [53]. Finally, yet importantly, the handling and perception of technology or relevant tasks is strongly influenced by the experiences individuals have made with technological artifacts during their lives. The so-called technology generations represent a major influence here [54]. We wanted to focus on the third group, called the "generation of technology spread" aged between 53 and 67 years. Thus, a perspective uninfluenced from existing digital technology could be taken, so that developers and researchers are able to orient toward the users' native needs.

We additionally approached eHealth experts to provide evidence for the validity of the answers from the group of older adults. Basically, the expert's answers served as baseline information to show if and where background knowledge has an impact or not.

Recruitment

The sampling procedure was nonprobabilistic and purposive and respondents were selected based on their voluntary willingness to participate [55,56]. To approach described experimental groups with differing eHealth background knowledge, different recruitment channels were applied. For control purposes, the background knowledge was queried with

only one question instead of with a battery of standard eHealth literacy questions. This way we could keep the questionnaire as short as possible.

We sent the link to an online survey to eHealth experts from our existing network in Germany. The survey was presented in the German language. Then we automatically extracted additional expert email addresses from the e-health-com webpage, where readers recommend experts. Editors of the website review the propositions and, if they consider a person an expert, the website lists them all alphabetically and provides one profile page per expert containing the name and position together with a short description, contact information, and affiliation description. We extracted all email addresses of experts automatically from the website by means of a Python script. We subsequently sent the link to the online questionnaire to 70 of these experts by email. Of these 70, 24 came from eHealth industry companies either as chief executive officer of a company selling eHealth products or as consultant active in the domain, and 40 came from research institutes working with information technology in the health sector. The remainder were medical experts from various domains or politics.

Older adults were selected by a clickworker platform [57] according to the demographic characteristic of being older than 50 years. Only participants who stated they were 50 years or older were able to access the survey. The link to the survey was displayed as a task on the website of the platform. At the end of the survey, participants were provided with an individually generated password. The participants had to provide the password to be credited with money to their accounts. We opted for a fee of €3 for completing the survey, which is relatively high because it was an abstract, and probably a more difficult subject, for participants not familiar with it.

Survey Instrument

Data were collected via an online survey. The rationale for the use of an online questionnaire was that abstract tasks could be investigated by means of a sample larger than would have been possible with observations or qualitative in-depth interviews. The survey instrument was programmed and made available on a website using SurveyMonkey software [56].

The survey was introduced as a study “improving digital health care systems according to user needs” and consisted of five questions (for introduction text and survey questions see Multimedia Appendix 1). All participants were informed about the duration of the survey, data storage, and the leading investigator. After an introductory page, individual pages with one question per screen were displayed. The participant was able to skip to the next question, but was not able to return to the previous one. On all survey pages, it was ensured that the user could see all answer options without the need for scrolling. The answer options for all questions contained a checkbox with the label “no answer” (n/a) to keep track if the participant just forgot, or could not, or did not want to provide an answer. Therefore, answering a question was not mandatory in order to not frustrate participants and to collect as much information as the participants wanted to provide.

Subsequent to the introductory page, experts and older adults were asked to list medical tasks that they considered relevant for health systems (see question #1 in the questionnaire in Multimedia Appendix 1). This was presented as an open question to not restrict the participants’ views and to collect as much input as possible, while excluding priming effects that may occur if a list of possible answers was given. The second question was a closed question asking users to rate the relevance of consultation, diagnosis, mentoring, and monitoring for eHealth on a five-point Likert scale (question #2). Subsequently, participants had to rate the importance of abstract visualization tasks (“why” dimension) [44] for each task in Bashshur et al’s functionality dimension (consultation, diagnosis, mentoring, and monitoring; question #3). Finally, the relevance of data types [37,44] for consultation, diagnosis, mentoring, and monitoring [47] was assessed by means of a checkbox matrix (see question #4) and the background knowledge was assessed by a five-point Likert scale (see question #5). The survey was tested by two independent examiners with regard to wording and technical functionality.

Data Collection

Data were collected between February 29 and March 14, 2016, from a sample of eHealth experts, and on November 16, 2016, from a sample of people older than 50 years without experience in eHealth. The time interval between the elicitation with experts and the one with older adults was because of prolonged approval for using the clickworker portal.

In total, 163 unique individuals visited the website of our Web-based survey. Identifying individuals was ensured by using the IP address and cookie function. Of these 163 visitors, 65 never started the survey. In total, 98 visitors participated in the survey; the participation rate was 74.4%. The average time spent completing the survey was 16 minutes 52.96 seconds.

Analysis

The open-ended answer (see Multimedia Appendix 1, question #1) was first analyzed in terms of the overall word frequencies with the help of MaxQDA software [58]. Word frequencies were computed and all occurring words were listed. After the elimination of stop words (eg, in, on, where, why), the resulting word list was manually scanned for activities and tasks. The most frequent tasks became an item within a hierarchical dictionary. The dictionary items were named and structured referring to Bashshur et al’s [47] functionality dimensions. Each dimension (consultation, diagnosis, mentoring, or monitoring) became an item in the dictionary as a child of the root node eHealth tasks as soon as it occurred in the word list. Tasks from the word frequency list that did not have a “part of” relation with existing categories were considered the child of the root node eHealth tasks—and thus a sibling of consultation, diagnosis, mentoring, or monitoring. Two experienced qualitative analysts conducted the manual scanning of tasks and the structuring of the dictionary independently. The two analysts then discussed differing opinions when they assigned an item from the frequency list to the dictionary or when they sorted the dictionary and then implemented a common solution. Then, each item (task) in the dictionary contained a list of synonyms from the word frequency list. For example, the dictionary item

"prevention" contained the words from the frequency list: prevention, explanatory work, hospital stay, tertiary prevention, avoidance, and care.

Subsequently, the MaxQDA software automatically coded all words in the answer texts with the item name from the dictionary they were assigned to. As a result, the dictionary contained code frequencies per dictionary item, which added up from lower to higher structural levels. Consequently, lower levels meant lower code frequencies. Code frequencies of items on higher levels were a sum of the item's own code frequency together with the code frequencies of all subordinate levels (child items).

For the statistical computation of code count differences among the two experimental groups, the root level was included up to a maximum of the third level down the hierarchical structure. For statistical computation, the code frequencies were normalized with the total number of words the participants gave in their answer. Therefore, for the analysis of the answers on the closed questions, we used SPSS software, version 22 (IBM Corp, Armonk, NY, USA). To compare answers of eHealth experts and older adults, *t* tests for independent samples and chi-square tests were calculated, both at a significance level of .05.

Taxonomy Construction

Our taxonomy for eHealth visualization tasks and data included the perspective of both experimental groups: the tasks and data types that they agreed on and group differences. Individual items have been ranked from top to bottom, according to task relevance. The more important an element was, the higher it was positioned.

Taxonomy construction started with abstract eHealth tasks resulting from closed question # 2 (see Multimedia Appendix 1) that participants rated as relevant. Tasks resulting from the open question #1 that were not already referred to by results from question #2 were then added as siblings. Subsequently, we added data types from question #3 and the top-ranked abstract visualization tasks resulting from question #4 to each of the four abstract eHealth tasks from question #2 (consultation, diagnosis, mentoring, and monitoring).

Group differences were reflected by the outline of a taxonomy item. Thick outlines of items illustrated that there were no significant differences between older adults and eHealth experts, whereas dotted outlines were significantly more important for experts and thin-outlined items were significantly more important for older adults.

Abstract visualization tasks that users most frequently considered relevant were included in the taxonomy. To determine the most relevant, we initially ranked all visualization tasks based on the amount they were considered relevant ("relevance count"). Then we computed the difference between the relevance counts of consecutive tasks ("relevance count difference"). The relevance count difference measure served to intensify the differentiation between relevant and nonrelevant abstract visualization tasks. This reinforcement of the distance between abstract visualization tasks became necessary in order to not include too many of them.

All abstract visualization tasks mentioned more frequently than the one with the second-biggest relevance count difference to its successor were included in the taxonomy. For example, the relevance of visualization tasks for consultation exhibited the two biggest differences between perceive information and search information (relevance count difference=8) and query information and lookup information (relevance count difference=6). In this case, query information and all tasks with higher total frequency exhibiting no group differences became part of the taxonomy.

Approval and Informed Consent

The Ethics Committee at RWTH (Rheinisch-Westfälische Technische Hochschule) Aachen Faculty of Medicine, Germany, authorized this study and its ethical and legal implications in its statement EK236/16.

Results

Participants

A total of 98 people participated: 47 eHealth experts and 51 older (≥50 years) adults. The mean age of the eHealth experts was 42.3 (SD 7.3) years, and the mean age for the older adults was 55.8 (SD 5.9) years. The eHealth knowledge of the eHealth experts was comprehensive (8/47, 17%) or very good (39/47, 83%), whereas for the older adults it was neutral (15/51, 29%), low (27/51, 53%), or very low (9/51, 18%).

Relevance of Medical Tasks

The most frequently mentioned eHealth tasks in open-answer texts were cooperation, consultation, mentoring, monitoring, documentation, communication, therapy, and quality management (see Table 1). In contrast to Bashshur et al [47], diagnosis constituted a subtask of therapy. Of all therapy subtasks, it had the highest frequency, followed by treatment. Extensions of the original taxonomy could be made concerning the scope of eHealth tasks, their structure, their validity, and their user relevance.

Group differences in the code count were computed on the first and second level except for the functionality dimension subconcept therapy, which together with all its child nodes reached a triple-digit code count. All normalized frequencies showed a normal distribution. An independent sample *t* test was conducted—as the normalized code frequencies were continuous variables not originating from predefined categories—to compare the code count of tasks and all child nodes of "therapy" between older adults and the eHealth experts. There was a significant difference in the scores for the code frequency of monitoring for eHealth experts (mean 0.18, SD 0.23) and older adults (mean 0.08, SD 0.15; t_{96}=2.43, *P*=.02). Monitoring was more important for experts than for older adults.

The closed question on eHealth task relevance revealed that across groups the relevance of eHealth systems for consultation and monitoring was most frequently considered very high. We received 70 valid answers, of which 51 came from older adults and 19 from the eHealth expert group (Figure 1, Table 2).

Table 1. Task relevance based on code frequencies in open answers in older adults and eHealth experts.

eHealth tasks and subtasks	Word frequencies in older adults, n	Word frequencies in experts, n	Total, N
Cooperation	10	14	24
Consultation (total)	39	66	105
Consultation	25	37	62
Physician-physician	3	18	21
Physician-patient	10	11	21
Physician-pharmacist	1	0	1
Monitoring (total)	42	82	124
Monitoring	23	48	71
Patient condition	0	1	1
Observation	3	0	3
Interpreting data	2	1	3
Data transmission	3	4	7
Data collection	6	8	14
Patient behavior	0	1	1
Medication	0	1	1
Therapy progression	0	4	4
Vital signs	0	13	13
Health condition	1	0	1
Wound surveillance	1	0	1
Identifying saliences	3	1	4
Patient condition	0	1	1
Mentoring (total)	22	21	43
Mentoring	11	11	22
Assistance	5	2	7
Health suggestions	0	2	2
Instructions	6	2	8
Education	0	4	4
Documentation (total)	12	11	23
Documentation	6	7	13
Symptoms	1	0	1
Surgery	1	0	1
Wound documentation	0	2	2
Experience reports	2	0	2
Patient information	2	2	4
Communication (total)	44	52	96
Communication	25	29	54
Data handling/review	7	16	23
Information search	10	3	13
Date arrangement	2	3	5
Billing	0	1	1
Therapy (total)	98	165	263
Therapy	54	95	149

eHealth tasks and subtasks	Word frequencies in older adults, n	Word frequencies in experts, n	Total, N
Home care	2	5	7
Diagnosis	30	37	67
After treatment	2	4	6
Treatment	6	12	18
Rehabilitation	2	3	5
Prevention	2	9	11
Quality	1	3	4

Figure 1. Mean relevance of individual eHealth tasks according to older adults and eHealth experts. Task relevance rated from 0=very low to 5=very high. Error bars represent 95% CI.

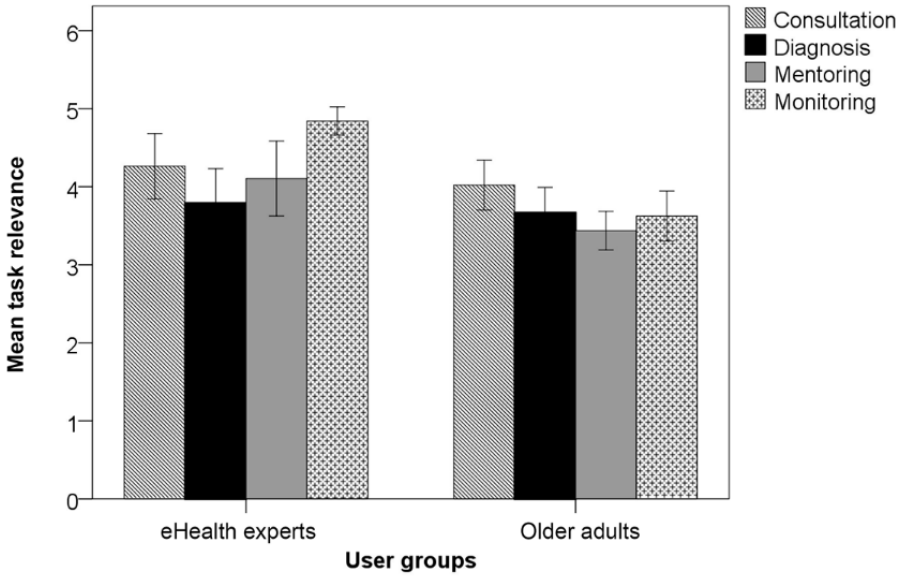


Table 2. Relevance of eHealth tasks in older adults (older) and eHealth experts(expert).

eHealth task	Very low, n (%)		Low, n (%)		Neutral, n (%)		High, n (%)		Very high, n (%)		Total, N	
	Experts	Older	Experts	Older	Experts	Older	Experts	Older	Experts	Older	Experts	Older
Consultation	0 (0)	3 (6)	1 (5)	1 (5)	2 (11)	8 (16)	7 (37)	19 (37)	9 (47)	20 (38)	19	51
Diagnosis	0 (0)	2 (4)	2 (11)	7 (14)	4 (21)	7 (14)	9 (47)	21 (41)	4 (21)	14 (28)	19	51
Mentoring	0 (0)	2 (4)	2 (11)	2 (4)	2 (11)	20 (39)	7 (37)	21 (41)	8 (42)	3 (6)	19	48
Monitoring	0 (0)	3 (6)	0 (0)	5 (10)	0 (0)	11 (22)	3 (16)	20 (38)	16 (84)	12 (24)	19	51

A chi-square test of independence was performed to examine the relation between relevance counts and user group (older adults, eHealth experts). The relation between these variables was highly significant for mentoring (χ^2_4=14.1, P=.002) and monitoring (χ^2_4=22.1, P<.001). Descriptive values of significant relevant differences are illustrated in Figures 2 and 3.

Relevance of Abstract Visualization Tasks

The tasks perceive, search, record, present, annotate, and query information were most important for consultation across the whole sample. For diagnosis, the priorities were perceive, discover, search, locate, and identify information. For mentoring, the most relevant abstract visualization tasks were present, compare, generate, browse, and select information, whereas monitoring included generate, encode, consume, select, browse, and compare information (Table 3).

Relevance of Data Types

A chi-square test of goodness-of-fit revealed that data types relevant to consultation, diagnosis, mentoring, and monitoring differed significantly between groups for most data types. The five most relevant data types were included into the taxonomy.

Additionally, the data type relevance for eHealth tasks (Tables 4-7) exhibited few cases in which the relevance frequency exceeded half the number of valid answers. The most relevant data types for consultation were quantitative data, nominal data, time-dependent data, points in time, and single values.

For diagnosis, time-dependent data, quantitative data, anomalies, single values, and points in time were most important across groups. Mentoring exhibited time-dependent data, rates of change, single values, quantitative data, and points in time as the most relevant data types.

According to the participants, monitoring required time-dependent data as the most important data type, followed by temporal patterns, rates of change, and quantitative data, and single values. In total, time-dependent and quantitative data could be numbered among the types with the highest frequencies.

Figure 2. Relevance of eHealth for mentoring.

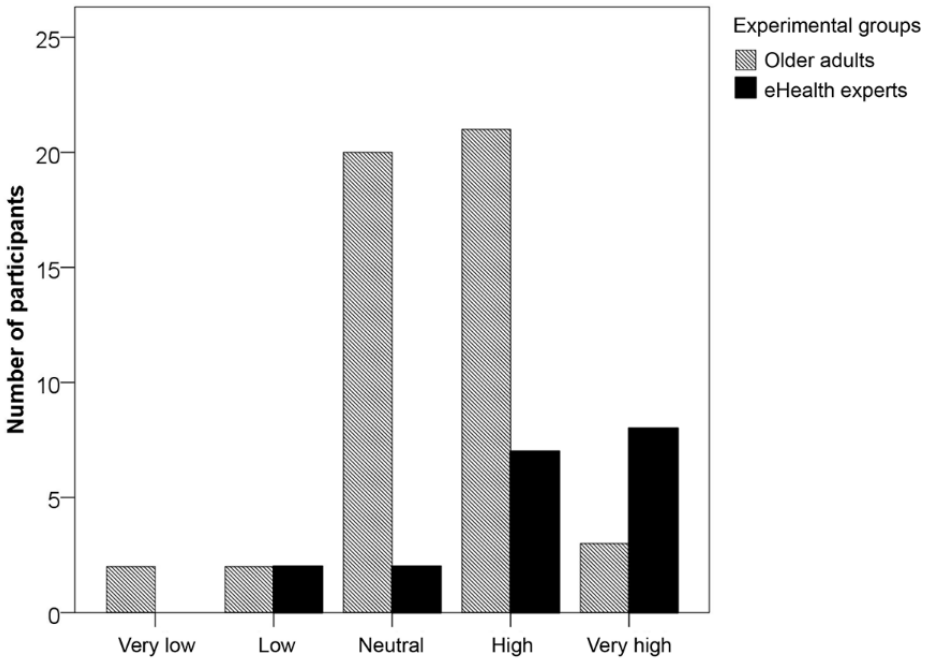


Figure 3. Relevance of eHealth for monitoring.

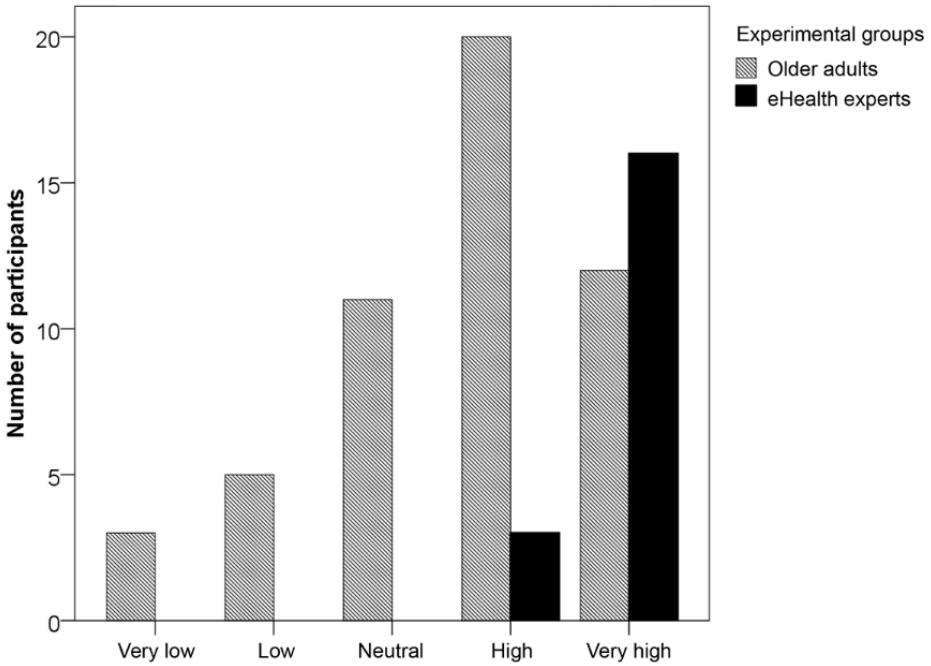


Table 3. Abstract visualization tasks relevant for consultation, diagnosis, mentoring, and monitoring in older adults and eHealth experts (N=68).

Visualization task	N	Older adults, n (% from group)	eHealth experts, n (% from group)	χ^2_1	*P* value
Consultation					
Perceive information	53	39 (74)	14 (26)	0.3	.75
Search information	41	27 (66)	14 (34)	4.6	.05
Record information	41	31 (76)	10 (24)	0.1	.88
Present information	40	27 (68)	13 (33)	2.9	.15
Annotate information	40	29 (73)	11 (28)	0.3	.78
Query information	39	29 (74)	10 (26)	0.1	.88
Diagnosis					
Perceive information	47	34 (72)	13 (28)	0.6	.55
Discover information	47	34 (72)	13 (28)	0.6	.45
Search information	46	33 (2)	13 (28)	0.8	.37
Locate information	43	33 (77)	10 (23)	0.2	.66
Identify information	42	34 (81)	8 (19)	2.0	.15
Mentoring					
Present information	36	24 (67)	12 (33)	2.8	.09
Compare information	36	27 (75)	9 (25)	0.0	.99
Generate information	33	23 (70)	10 (30)	1.0	.33
Browse information	33	22 (67)	11 (33)	2.4	.12
Select information	33	22 (67)	11 (33)	2.4	.16
Monitoring					
Generate information	38	25 (66)	13 (34)	3.9	.05
Encode information	37	33 (89)	4 (10)	8.7	.01
Consume information	35	21 (60)	14 (40)	8.7	.01
Select information	35	26 (74)	9 (26)	0.2	.89
Browse information	34	24 (71)	10 (29)	0.7	.40
Compare information	34	24 (71)	10 (29)	0.7	.40

Table 4. Data types relevant for consultation.

Data types	N	Older adults, n (% from group)	eHealth experts, n (% from group)	Total relevant, n (% from N)	χ^2_1	*P* value
Quantitative data	92	32 (71)	15 (32)	47(43)	14.1	.001
Time dependent	95	27 (56)	13 (32)	40 (42)	8.0	.001
Single values	91	25 (57)	13 (28)	38 (42)	7.9	.01
Points in time	92	28 (62)	9 (18)	37 (40)	17.7	.001
Nominal data	79	19 (59)	13 (28)	32 (40)	7.9	.01
Ordinal data	77	16 (53)	13 (28)	29 (38)	5.1	.03
Time spans	92	22 (49)	7 (15)	29 (32)	12.3	.001
Temporal patterns	90	19 (43)	9 (17)	28 (31)	6.6	.01
Time intervals	91	20 (46)	7 (15)	27 (30)	10.2	.001
Anomalies	88	19 (46)	8 (17)	27 (31)	8.9	.01
Outlier	82	14 (30)	7 (39)	22 (27)	1.7	.21
1-D data	74	9 (33)	12 (26)	21 (28)	0.5	.59
Distributions	79	14 (44)	7 (15)	21 (27)	8.1	.01
Rates of change	91	21 (30)	10 (28)	31 (34)	7.1	.01
Groups	69	8 (15)	8 (17)	16 (23)	3.2	.12
Time sequences	88	14 (34)	5 (11)	15 (17)	7.2	.01
Synchronizations	82	9 (26)	6 (13)	15 (18)	2.3	.16
Multidimensional data	75	5 (18)	10 (21)	15 (20)	0.1	.78
Clusters	68	6 (29)	5 (11)	11 (16)	3.4	.08
2-D data	76	3 (10)	7 (15)	10 (21)	0.3	.73
3-D data	74	2 (7)	8 (17)	10 (21)	1.4	.31
Tree data	73	7 (27)	7 (15)	14 (19)	1.6	.23
Network data	70	3 (13)	7 (15)	10 (14)	0.1	>.99
Graphs	78	7 (14)	9 (19)	16 (21)	0.1	.78

Table 5. Data types relevant for diagnosis.

Data types	N	Older adults, n (% from group)	eHealth experts, n (% from group)	Total relevant, n (% from N)	χ^2_1	*P* value
Time dependent	95	37 (77)	16 (34)	53 (56)	17.8	.001
Quantitative data	92	32 (71)	16 (34)	48 (52)	12.7	.001
Anomalies	88	36 (88)	12 (25)	48 (55)	34.3	.001
Single values	91	32 (73)	13 (28)	45 (50)	18.5	.001
Points in time	92	32 (71)	11 (23)	43 (47)	21.0	.001
Outliers	82	24 (69)	14 (30)	38 (46)	12.1	.001
Time intervals	91	27 (61)	10 (21)	37 (41)	15.1	.001
Time spans	92	27 (60)	9 (19)	36 (39)	16.1	.001
Nominal data	79	24 (75)	11 (23)	35 (44)	20.5	.001
Rates of change	91	23 (52)	11 (23)	34 (37)	8.1	.01
Temporal patterns	90	26 (61)	7 (15)	33 (37)	20.1	.001
Time sequences	88	24 (59)	7 (15)	31 (37)	18.3	.001
Ordinal data	77	18 (60)	11 (23)	29 (38)	10.5	.01
2-D data	76	17 (59)	12 (26)	29 (38)	8.3	.01
1-D data	74	17 (63)	11 (23)	28 (38)	11.0	.001
Graphs	78	19 (61)	9 (19)	28 (36)	14.4	.001
3-D data	74	15 (56)	11 (23)	26 (35)	7.8	.01
Distributions	97	17 (53)	9 (19)	26 (33)	10.0	.01
Multidimensional data	75	12 (43)	12 (26)	24 (32)	2.4	.13
Groups	96	15 (68)	8 (17)	23 (33)	17.7	.001
Clusters	86	13 (62)	9 (19)	22 (32)	12.1	.001
Synchronizations	82	13 (37)	5 (11)	18 (22)	8.2	.01
Net data	70	8 (35)	9 (19)	17 (24)	3.0	.23
Tree data	73	10 (39)	6 (13)	16 (22)	6.5	.02

Table 6. Data types relevant for mentoring.

Data types	N	Older adults, n (% from group)	eHealth experts, n (% from group)	Total relevant, n (% from N)	χ^2_1	*P* value
Time dependent	95	18 (38)	13 (28)	31 (33)	1.1	.38
Rates of change	91	19 (43)	12 (26)	31 (34)	3.1	.08
Single values	91	23 (52)	8 (17)	31 (34)	12.6	.001
Quantitative data	92	17 (38)	12 (26)	29 (32)	1.6	.26
Points in time	92	18 (40)	11 (23)	29 (32)	2.9	.12
Time spans	92	19 (42)	9 (19)	28 (32)	5.8	.02
Temporal patterns	90	17 (40)	11 (23)	28 (31)	2.0	.12
Anomalies	88	18 (40)	9 (19)	27 (31)	6.3	.02
Nominal data	79	13 (41)	13 (28)	26 (33)	1.5	.33
Time intervals	91	14 (32)	10 (21)	24 (36)	1.3	.34
Time sequences	88	16 (39)	8 (17)	24 (27)	5.3	.03
Graphs	78	15 (48)	8 (17)	23 (30)	8.8	.01
Ordinal data	77	9 (30)	13 (28)	22 (29)	0.1	.99
1-D data	74	12 (44)	9 (19)	21 (29)	5.4	.03
Clusters	68	10 (48)	9 (19)	19 (28)	5.	.02
2-D data	76	10 (35)	8 (17)	18 (24)	3.0	.10
Distributions	79	10 (31)	8 (17)	18 (23)	2.2	.18
3-D data	74	8 (30)	9 (19)	17 (23)	1.1	.39
Synchronizations	82	12 (34)	5 (11)	17 (21)	6.8	.01
Multidimensional data	79	10 (36)	7 (15)	17 (21)	4.3	.05
Outlier	82	10 (29)	7 (15)	17 (21)	2.3	.02
Tree data	73	10 (39)	6 (13)	16 (22)	6.5	.02
Groups	69	8 (36)	8 (17)	16 (23)	3.2	.12
Net data	70	8 (35)	7 (15)	15 (21)	3.6	.07

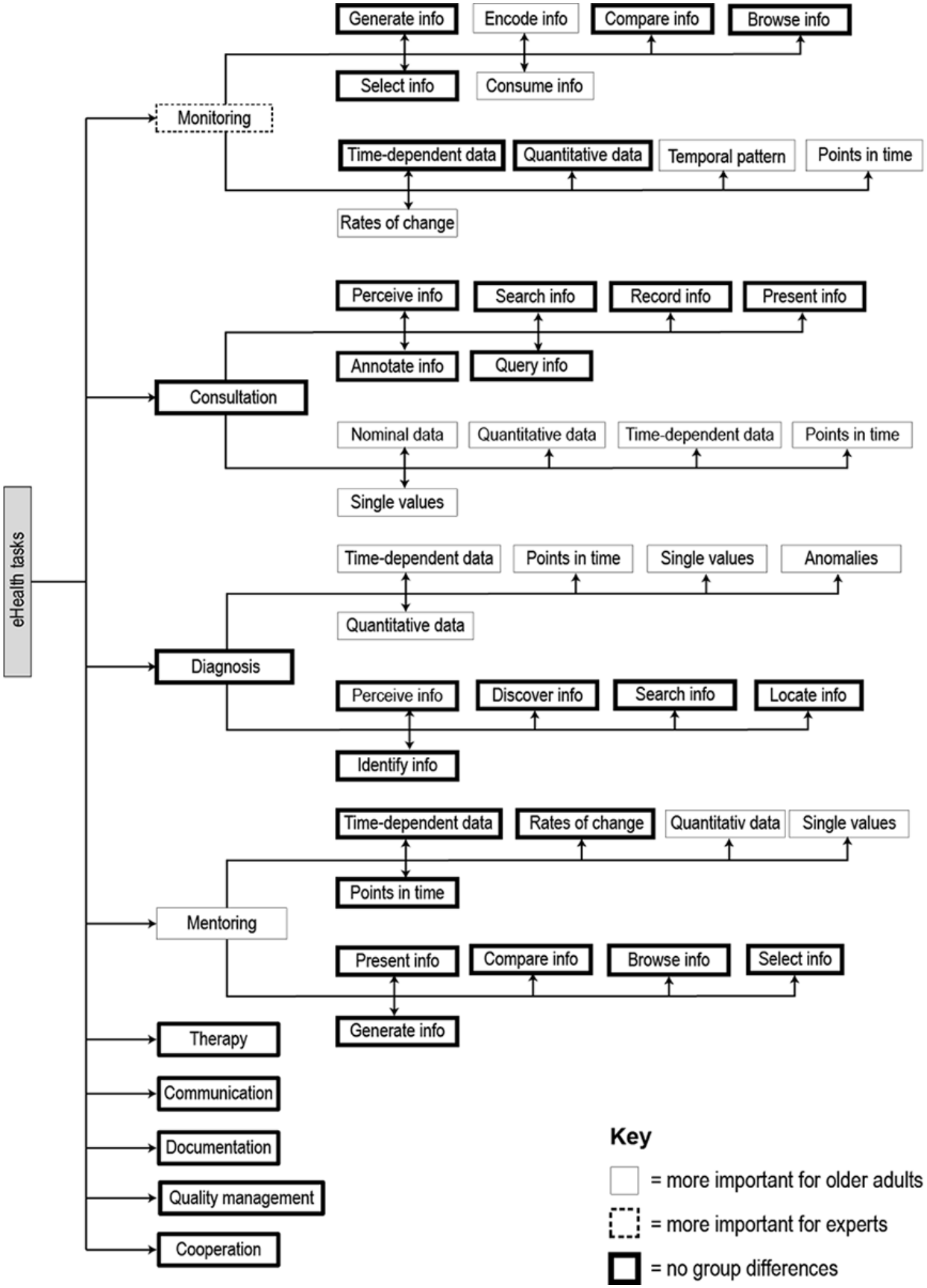
Table 7. Data types relevant for monitoring.

Data types	N	Older adults, n (% from group)	eHealth experts, n (% from group)	Total relevant, n (% from N)	χ^2_1	*P* value
Time dependent	95	22 (46)	15 (32)	37 (40)	1.9	.21
Temporal patterns	90	22 (51)	13 (28)	35 (39)	5.2	.03
Rates of change	91	21 (48)	12 (26)	33 (36)	4.8	.03
Quantitative data	92	14 (31)	17 (26)	31 (34)	0.3	.66
Points in time	92	20 (44)	11 (23)	31 (34)	4.6	.05
Single values	91	18 (41)	13 (28)	31 (34)	1.8	.19
Time spans	92	19 (43)	11 (23)	30 (33)	3.7	.08
Graphs	78	20 (65)	10 (21)	30 (39)	14.6	.001
Synchronizations	82	21 (60)	8 (17)	29 (35)	16.2	.001
Multidimensional data	75	16 (57)	13 (28)	29 (39)	6.4	.02
Time intervals	91	16 (36)	12 (26)	28 (31)	1.3	.36
2-D data	76	18 (46)	9 (19)	27 (36)	14.4	<.001
Time sequences	88	17 (42)	10 (21)	27 (31)	4.5	.06
Outliers	82	14 (40)	12 (26)	26 (32)	1.9	.23
Anomalies	88	17 (42)	9 (19)	26 (30)	5.2	.03
3-D data	74	14 (53)	11 (23)	25 (34)	6.2	.02
Distributions	79	16 (50)	9 (19)	25 (32)	8.4	.01
Nominal data	79	15 (47)	9 (19)	24 (30)	6.9	.01
Ordinal data	77	9 (30)	12 (26)	21 (27)	0.2	.79
Groups	69	11 (50)	10 (21)	21 (30)	5.8	.02
1-D data	74	10 (37)	10 (21)	20 (27)	2.2	.18
Clusters	68	10 (48)	9 (19)	19 (28)	5.8	.02
Tree data	73	11 (42)	7 15	18 (25)	6.8	.01
Net data	70	9 (39)	8 (17)	17 (24)	4.1	.07

Task-Data Taxonomy for eHealth Visualizations

The task-data taxonomy for eHealth visualizations was constructed as described in the Methods section of our paper. It shows which health tasks are important for them and which abstract visualization tasks and data types are relevant for the abstract health tasks monitoring," consultation, diagnosis, and mentoring. Group differences within the taxonomy are marked with different outline characteristics of the taxonomy item, which gives it higher meaning (dotted line=experts, thin line=older adults, thick line=no difference). It is striking that all relevant abstract visualization tasks were considered relevant by both groups, so there were no significant differences in relevance (see Figure 4).

Figure 4. The eHealth visualization task-data taxonomy.



Discussion

Principal Findings

This section offers a discussion and interpretation of the results regarding the task analysis of eHealth and visualization tasks and the corresponding data types across the two experimental groups: eHealth experts and older adults. We additionally elaborate on the limitations of our findings and describe future work.

The eHealth experts' answer texts led to a total of 244 codes, whereas 155 codes could be derived from the older adults' answer texts. Here, therapy was most frequently mentioned across the whole sample with a number of 263 counts including all subtasks (see Table 1), followed by monitoring (n=124), consultation (n=105), communication (n=96), mentoring (n=43), documentation (n=23), and quality management (n=4). Monitoring was seen differently across user groups: it was significantly more important to the experts than to the older adults. Diagnosis was found to be the most frequently mentioned subtask of therapy followed by treatment, prevention, home care, aftertreatment, and rehabilitation. The tasks at the second level were cited less frequently. The therapeutic tasks users considered most important were diagnosis and treatment. The former is important for both groups, whereas medical or eHealth experts cited treatment and prevention twice or more frequently. Collecting data as well as monitoring of vital data were the most commonly mentioned subtasks of monitoring in the participants' opinions. Similar to the task at the first level (monitoring), there is a clear group difference with a focus on the maximum in the expert group.

It appears that code frequencies are relatively low compared to the whole sample size. This can be explained by the short, keyword-like answers most participants gave. For example, the sample group of 98 mentioned monitoring only 61 times. Considering that each code count cannot even be exclusively assigned to one person, results from a starting point for taxonomy construction requires future iterative improvement with a larger sample size as well as a validation of the hierarchical arrangement of individual elements [59,60].

Results of the open answers confirm the relevance of the functionality dimension within the taxonomy of telemedicine and that given task classification could be extended by the tasks therapy, cooperation, documentation, communication, and quality management. Results regarding confirmation of the functionality dimension of the taxonomy of telemedicine are in line with the results of our previous work [61].

The abstract eHealth tasks of the functional dimensions formed the root nodes of our taxonomy by their later assignment to abstract visualization tasks and data types; therefore, the validity of the analysis of the open and uninfluenced responses was validated by directly querying their importance with five-point Likert scales. The analysis of those closed questions on the relevance of the tasks consultation, diagnosis, mentoring, and monitoring supported results from the qualitative content analysis of open questions. Here, both user groups considered monitoring and diagnosis the most important eHealth tasks. The discrepancy between groups regarding the importance of the task monitoring was replicated as well.

Against the background of current work on the development of eHealth applications [9,62-66], we would have expected monitoring to be the most relevant eHealth task. The results of code count frequencies do not match this expectation. Because the results of previous studies on the investigation of health-related information need are consistent with the fact that, for adults older than 50 years, diagnosis is the most important information during the maintenance and administration of their personal health [67], it can be assumed that older adults regard the relevance of individual eHealth tasks less from a technology perspective. Tasks that are important for personal health have increased importance for older adults.

The background knowledge of older adults regarding the technical possibilities of eHealth systems differs from that of eHealth experts. Conventional constant monitoring or medical control has been less important to laypeople because it might be unclear to them that when it comes to continuous monitoring of sensor data, technical systems are often more accurate and stable at monitoring patients than medical personnel. The mental model that seems to influence the answer—even if the term was explained at the beginning of the survey—is more strongly characterized by health-relevant tasks users know from their everyday life, where the extensive introduction of digital monitoring systems is still pending in Germany.

At first sight, one might suspect this is a problem for the utility of the developed task-data taxonomy. However, this is only the case if one assumes that our taxonomy should precisely represent the tasks currently present in systems. However, the aim of the taxonomy is—as described at the outset—an increase in the user-centricity of future systems. For our taxonomy, it is not important which tasks and data actually exist, but which are relevant for prospective users, so that systems developed based on presented taxonomy have the greatest possible value. However, users' perceptions of the relevance of individual tasks and data types are of great importance.

The question on the relevance of abstract visualization tasks was not answered by nearly a third of the participants (30/98). Whether a lack of knowledge or a lack of motivation is responsible cannot be determined on the basis of the data. Because 75% of older adults and only 25% of experts answered the question, despite experts having higher background knowledge, motivation seems to be more likely an influencing factor here.

We also assume that the eHealth systems including such visualizations are not available to some participants. Therefore—as in the case of the abstract eHealth tasks—the results identify potential areas where data visualizations could enable experts or patients to be supported in the corresponding medical task.

Our ranking of general eHealth tasks supports the general understanding of the application context of eHealth and eHealth visualizations from the perspective of prospective users (older adults). Visualizations that support those general domain tasks are expected to have a stronger impact. The intention here is

not to invite visualization researchers to contribute designs to the eHealth domain, but to identify potential for the application of visualizations within eHealth systems, an aspect that has often been overlooked.

Transfer of Knowledge

The presented results add to the increasing number of papers that target hierarchical task structures to establish a common vocabulary and understanding of visualization tasks and data [68,69]. This work goes beyond that by considering the context of eHealth including the perspective of the prospective user and synthesizing their input in the form of eHealth task-data taxonomy. In this way, eHealth system developers and researchers can use it as an orientation during requirement analysis or as a guideline for the definition of experimental tasks in visualization evaluation experiments.

Limitations

We consider the described eHealth task-data taxonomy as provisional and subject to validation in the field. In addition, we only tracked the subjectively perceived knowledge about eHealth systems, so participants might lack familiarity with abstract data types or task-data taxonomies or they may not be familiar with online surveys and interactive Web tools such as those used for our Web survey. Thus, we are not able to quantify participants' familiarity with concepts mentioned in this study and this may have influenced our findings. Familiarity with abstract data types and visualization tasks and styles common to the survey website would have likely reduced some of the barriers participants might have experienced.

Furthermore, as with subjective methods in general, results are limited in a way that they reflect the perspective and mental model of the participants together with their experiences. But observations will have the drawback that achievable sample sizes are much smaller, so that the results are hardly generalizable to the whole eHealth domain.

Additional limitations of our study lie in the selective sample caused by using an online questionnaire. People who are familiar with technology are more likely to answer the questionnaire than people who are not. Additionally, the older adults were paid, whereas the experts were not. This leads to different motivations between the two groups, which could be an influencing variable. This might have been the reason why the numbers of completed answers varied in the expert group over the length of the questionnaire (more were answered at the beginning than at the end).

Conclusion

We successfully constructed a task-data taxonomy for eHealth data visualizations by providing a general description of tasks and data useful for health data visualizations. We have shown that semantic approaches [26] are feasible to generally perform task analysis. Furthermore, the results empirically validated and ranked Brehmer and Munzner's [44] typology of abstract visualization tasks, as well as the functionality dimension of Bashshur et al's [47] taxonomy of telemedicine. Time-dependent data and searching for information within visualizations of monitoring data had the highest relevance across user groups.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Text survey introduction and questionnaire.

[PDF File (Adobe PDF File), 355KB - medinform_v6i3e39_app1.pdf]

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Abbreviations

ICT: information and communication technology

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Original Paper

Implementing a National Electronic Referral Program: Qualitative Study

Marcella McGovern[1], PhD; Maria Quinlan[1], PhD; Gerardine Doyle[1,2], PhD; Gemma Moore[1], PhD; Susi Geiger[1,2], PhD

[1]Applied Research for Connected Health, University College Dublin, Dublin, Ireland

[2]UCD College of Business, University College Dublin, Dublin, Ireland

Corresponding Author:
Marcella McGovern, PhD
Applied Research for Connected Health
University College Dublin
G41, NEXUS UCD
Dublin, D04 V2N9
Ireland
Phone: 353 1 716 5407
Email: marcella.mcgovern@ucd.ie

Abstract

Background: Electronic referrals or e-referrals can be defined as the electronic transmission of patient data and clinical requests between health service providers. National electronic referral systems have proved challenging to implement due to problems of fit between the technical systems proposed and the existing sociotechnical systems. In seeming contradiction to a sociotechnical approach, the Irish Health Service Executive initiated an incremental implementation of a National Electronic Referral Programme (NERP), with step 1 including only the technical capability for general practitioners to submit electronic referral requests to hospital outpatient departments. The technology component of the program was specified, but any changes required to embed that technology in the existing sociotechnical system were not specified.

Objective: This study aimed to theoretically frame the lessons learned from the NERP step 1 on the design and implementation of a national health information technology program.

Methods: A case study design was employed, using qualitative interviews with key stakeholders of the NERP step 1 (N=41). A theory-driven thematic analysis of the interview data was conducted, using Barker et al's *Framework for Going to Full Scale*.

Results: The NERP step 1 was broadly welcomed by key stakeholders as the first step in the implementation of electronic referrals—delivering improvements in the speed, completeness of demographic information, and legibility and traceability of referral requests. National leadership and digitalized health records in general practice were critical enabling factors. Inhibiting factors included policy uncertainty about the future organizational structures within which electronic referrals would be implemented; the need to establish a central referral office consistent with these organizational structures; outstanding interoperability issues between the electronic referral solution and hospital patient administration systems; and an anticipated need to develop specialist referral templates for some specialties. A lack of specification of the sociotechnical elements of the NERP step 1 inhibited the necessary testing and refinement of the change package used to implement the program.

Conclusions: The key strengths of the NERP step 1 are patient safety benefits. The NERP was progressed beyond the pilot stage despite limited resources and outstanding interoperability issues. In addition, a new electronic health unit in Ireland (*eHealth Ireland*) gained credibility in delivering national health information technology programs. Limitations of the program are its poor integration in the wider policy and quality improvement agenda of the Health Service Executive. The lack of specification of the sociotechnical elements of the program created challenges in communicating the program scope to key stakeholders and restricted the ability of program managers and implementers to test and refine the change package. This study concludes that while the sociotechnical elements of a national health information technology program do not need to be specified in tandem with technical elements, they do need to be specified early in the implementation process so that the change package used to implement the program can be tested and refined.

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KEYWORDS

electronic referrals; scale-up; eHealth; implementation; policy

Introduction

Electronic Referrals

Electronic referrals or e-referrals can be defined as the electronic transmission of patient data and clinical requests between health service providers [1]. Shifting from paper-based referrals (ie, postal letter or fax) to electronic referrals offers the opportunity to transform the interface between primary and specialty care [2]. Historically, the default clinical request from a general practitioner (GP) referring to a specialist was to request a face-to-face consultation with a given service user [3]. Electronic referral technology, however, can support a two-way channel of communication between referrer and referee, creating the opportunity for more flexible and consultative forms of data exchange and clinical requests [4]. In addition, electronic referrals provide health systems with the capability to optimize system capacity, whereby GPs can be supported by specialists to care for service users in the community until they genuinely require a specialist appointment [5].

Development of Electronic Referrals in the Irish Health Service Executive

The initiation of an Irish electronic referral pilot program in January 2011 was not solely motivated by the potential for electronic referrals to transform the interface between primary and specialty care. A crisis emerged in March 2010, when the media reported that one of Ireland's largest hospitals had 30,000 unopened or unprocessed GP outpatient referrals. The Irish Health Service Executive (HSE) commissioned an investigation [6] and the Health Information and Quality Authority (HIQA) partnered with the Irish College of General Practitioners (ICGP) to conduct a review of the referral management between GPs and hospital outpatient departments (OPDs; GP-OPD). This HIQA-ICGP partnership created a standardized general referral template, specifying the essential information that needs to be contained in a referral from a GP to a hospital OPD. In addition, the HIQA-ICGP partnership recommended that their standardized template could form the informational basis for an electronic referral solution between GPs and OPDs [7].

Meanwhile, an advisory group had been established in the South of the country, comprising clinical, management, information technology (IT), and patient representatives, to reconfigure hospital services in that region. The group partnered with *Healthlink*—an Irish structured health care messaging platform—to develop and pilot an electronic referral pathway between GPs and OPDs for 7 hospitals in their region. The pilot project revealed several challenges for implementing an end-to-end electronic referral solution, capable of offering a two-way interface between GPs and hospital OPDs. Foremost of these challenges were the outstanding interoperability issues between the *Healthlink* platform and hospital patient administrative systems (PAS); second, the human resourcing of hospital central referral offices (CROs) to process electronic referrals.

Despite these obstacles to the implementation of an end-to-end electronic referral solution, the pilot project successfully established the technical capability, through the *Healthlink* platform, for GPs to electronically submit their referrals to hospital OPDs. This first step in the electronic referral process has been described as the electronic referral request [8]. Furthermore, the pilot project found that the use of electronic referral requests resulted in the following improvements: (1) improved legibility because all information is typed in a standardized template, (2) improved completeness of data because of the mandatory fields in the standardized template, (3) assurance for GPs and patients that their referral had been received because an automated email is returned to the referring GP once it is digitally opened in the hospital, and (4) improved traceability and visibility for hospitals in the referral management because *Healthlink* creates a digital record of when and how many electronic referrals have been received by each hospital, and when they were triaged [9].

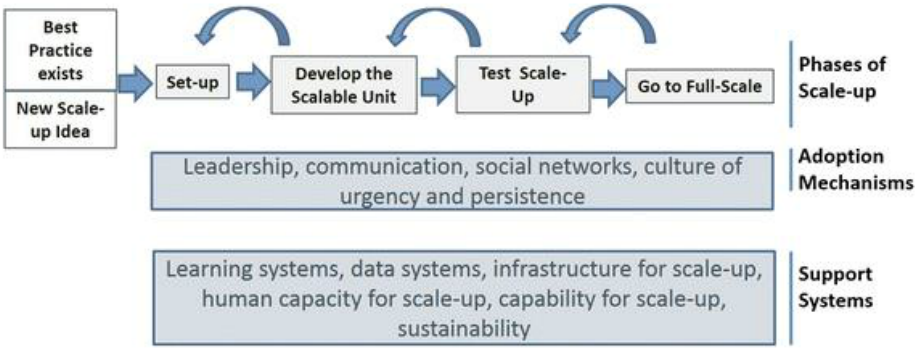
These simple and yet important patient safety benefits informed a decision by a newly established unit in the HSE, called *eHealth Ireland*, to establish a National Electronic Referral Programme (NERP) with step 1 involving the scale-up of the technical capability for GPs to submit electronic referral requests to hospital OPDs.

Impact of Scale on a Sociotechnical Approach

Reviews from some of the earliest deployments of national electronic referral systems, including Norway [10], the Netherlands, and Denmark [11], recommend a sociotechnical approach to implementing electronic referrals. A sociotechnical approach considers how the technical features of a health information system interact with the social features of a health care work environment [12]. *eHealth Ireland* 's decision to initiate the NERP on an incremental basis, that is, step 1 with only the technical capability for electronic referrals, appears to be at odds with this sociotechnical approach. The only target specified was to establish, within 12 months, the technical capability for GPs to submit electronic referral requests to at least one OPD specialty in all hospitals. Regarding the adoption of that technical capability, no targets were set for which OPD specialties would be included in the program, what the target volume of electronic referrals versus paper referrals would be, or what proportion of GPs would be engaged. That is, the technology component of the program was specified, but the extent at which that technology would interact with the sociotechnical system was not specified.

In the UK, Eason applied a sociotechnical lens to the implementation of the National Health Service's National Programme for IT and highlighted that in national health IT programs, the desired technical and social systems are not designed and implemented simultaneously [13], as suggested by many interpretations of a sociotechnical theory approach [14].

Figure 1. Theoretical framework—Barker et al's [16] *Framework for Going to Full Scale* (reprinted with permission from P Barker).



Instead, standard technical systems are predefined at the national level, and flexibility needs to be provided for local implementation sites to adopt technical systems in ways that meet local needs and enable them to engage in sociotechnical systems design at a level where the local user community can play a full part [13]. This suggestion that the sociotechnical approach needs to be modified for national health IT programs is reflected in the design of the NERP step 1 [15], where the technical system was predefined nationally, but it was left to local implementation sites to undertake the sociotechnical systems design work. However, it remains unclear from Eason's critique of sociotechnical systems theory if or when the sociotechnical elements of a national health IT program should be defined at the national level [13].

Study Goal

To contribute to this discussion on the design and implementation of national health IT programs, this paper presents the findings from qualitative, in-depth interviews conducted with key stakeholders in the implementation of the NERP step 1. The following two research questions seek to explore the arguments for and against progressing with the scale-up of only the technical elements of a national health IT program, using Ireland's NERP step 1 as an empirical case study: (1) What were the strengths and limitations of the scale-up of the NERP step 1, as a technical-only intervention? and (2) Do the sociotechnical elements of a national health IT program need to be specified at the national level?

This study aims to theoretically frame the lessons learned from Ireland's NERP step 1 for policy makers and implementers seeking guidance on how to design and implement national health IT programs.

Theoretical Framework

We adopted the Institute for Healthcare Improvement's *Framework for Going to Full Scale* [16] as the theoretical framework to guide our empirical inquiry and analysis. This framework proposes that to take a health care quality improvement to full scale, it is first necessary to account for the factors required to promote the adoption of changes and support scale-up, and second, to design at the outset a phased plan to reach full-scale implementation.

The *phases of scale-up* proposed by this framework for health care quality improvement include: (1) Set-Up; (2) Develop the Scalable Unit; (3) Test Scale-Up; and (4) Go to Full Scale. Each of these phases is either enabled or inhibited by the availability of certain *adoption mechanisms* and *support systems* (Figure 1). *Adoption mechanisms* to account for include better ideas, leadership, communication, policy, and a culture of urgency and persistence. *Support systems* include human capability for scale-up, infrastructure for scale-up, data collection and reporting systems, a learning system, and the need to design for sustainability.

An important reason for selecting this theoretical framework is that it can accommodate the NERP's incremental design, whereby this study only examines step 1 in the implementation of electronic referrals and not the complete implementation of electronic referrals. The *phases of scale-up* in this framework are informed by Plan-Do-Study-Act (PDSA) cycles of quality improvement. It is not assumed that what is being implemented is the complete program. A PDSA cycle requires only that for any given program or program component, a theory of change can be specified and then tested across a range of contexts before being implemented at full scale. The framework contains a feedback loop so that the first three *phases of scale-up* can be revisited and adapted if new learnings at a later phase reveal that an adaptation would optimize the scale-up. Figure 1 presents this feedback loop by the counter-clockwise arrows above the four *phases of scale-up*.

Methods

Methodological Approach

This study explored the implementation of the NERP step 1 using qualitative, in-depth interviews with key program stakeholders. This approach captures individual participants' experiences, narratives, ideas, and discourses [17] and informs an analysis of the scale-up strategy employed.

Recruitment

Ethics

Ethical approval was granted by the Office of Research Ethics in University College Dublin (UCD). No vulnerable populations participated in this study, and no patient data were collected. All participants were interviewed in a professional capacity as stakeholders in the scale-up of electronic referrals in Ireland. Participant anonymity and confidential data management were the dominant ethical considerations for this study and were maintained in line with UCD Research Ethics Guidelines.

Participants

This study investigated the lessons to be learned from the NERP step 1 on scaling-up only the technical elements of a national health IT program. Access to 1 of 7 pilot sites and 5 of 42 sites targeted by the NERP step 1 was facilitated by *eHealth Ireland*. Although not randomly selected, the 5 NERP step 1 sites included public and voluntary hospitals, as well as regional and urban hospitals, providing a broad representation of implementation sites. The key inclusion criterion for recruiting participants was as follows: Has this stakeholder been involved in the design or implementation of the NERP step 1? If not, it was considered unsuitable for stakeholders to serve as key informants on the strengths or limitations of a technical-only scale-up or in offering an empirical assessment of whether the sociotechnical elements of a national health IT program should be specified at the national level. Based on this criterion, we did not include service users and hospital specialists in our study design because they were not directly involved in designing or implementing the program at this early step 1 stage of the NERP. However, studies of later stages of the implementation should include these crucial stakeholders, where, for example, service users might have access to a Web-based appointment portal, or hospital specialists might be engaged to design specialist referral templates and therefore, will be in a position to speak about their experiences of designing and implementing the program.

The following participants were recruited from the pilot site: pilot management (n=3); hospital administration or management (n=3); general practice (n=3); and information communication technology (ICT; n=3). In addition, the pilot general practice and ICT stakeholders were involved in the NERP step 1 and therefore appear in Table 1 as both pilot and NERP national-level stakeholders. Moreover, the NERP national-level stakeholders included NERP management (n=2) and other HSE stakeholders (n=3) who were involved in the design and implementation of the NERP step 1. At the implementation site level, we recruited 4 additional general practice stakeholders, including 3 GPs and 1 general practice secretary, bringing the number of GPs who participated in the study to 6 out of approximately 3000 GPs [18] operating in the Irish health system. Furthermore, participants recruited from within the NERP step 1 hospital sites included the following: hospital administration or management (n=17) and hospital ICT (n=3). As a qualitative study, participants (N=41) were recruited as key stakeholders and informants on the design and implementation of the NERP step 1; they did not constitute a representative sample of their peers in the Irish health system.

Overall, 28 interviews were scheduled. Of 41 participants, 19 participated in face-to-face group interviews and the remaining 22 were interviewed individually. The group interviews involved a range of 2-5 participants and were predominantly undertaken with the hospital administration or management stakeholder group. Of 22 interviews conducted with individual participants, 5 were conducted via telephone and 17 on a face-to-face basis. All participants consented to have their interview recorded at the outset, using a digital voice recorder.

Data Analysis

We conducted a thematic analysis, using Braun and Clarke's [19] 6-phase procedure for thematic analysis and Barker et al's [16] framework to organize the data from a scale-up perspective. Thematic analysis is a method for identifying, analyzing, and reporting patterns (themes) within data [19]. The audio recordings of all 28 interviews were transcribed by the interviewing author (GM). Thematic analysis does not require a full verbatim transcription, including nonverbal cues (eg, silences, body language, and external noises) or emotional aspects (eg, laughs, coughs, and sighs) [20]. Such data would have contributed little toward answering this study's research questions but would have taken a substantial amount of time and resources. All transcripts were cross-checked by the lead author (MMG) who audited transcription by listening through all audio recordings while reading the transcripts.

Table 1. Participant involvement in the National Electronic Referral Programme (NERP; N=41).

Key stakeholder types	Involvement, n (%)		
	Pilot (n=12)	NERP (n=35)	Both (n=6)
Pilot			
Pilot management	3 (25)	—	—
Hospital administration or management	3 (25)	—	—
NERP national level			
NERP management	—	2 (6)	—
Health Service Executive	—	3 (8)	—
Information communication technology	3 (25)	3 (8)	3 (50)
General practice	3 (25)	3 (8)	3 (50)
NERP implementation sites			
Hospital administration or management	—	17 (49)	—
Information communication technology	—	3 (8)	—
General practice	—	4 (11)	—

Furthermore, any points of divergence in the interpretation of how the spoken word should be written in the transcripts were documented and later discussed by MMG and GM to obtain an agreement on transcription.

In the first analytical step, we conducted an inductive thematic analysis [19]. Overall, 149 initial codes were generated and collated into 7 initial themes as follows: (1) Stakeholder Consultation (12 codes); (2) Scope and Pace of Change (15 codes); (3) Technological Design (31 codes); (4) Organizational Change (25 codes); (5) Engagement (18 codes); (6) Quality Improvement (37 codes); and (7) Irish Context (11 codes). The two research questions aimed to explore the arguments for and against progressing with the scale-up of only the technical elements of a national health IT program. Among the diverse stakeholders interviewed, contradictory perspectives were articulated on whether or not it was the correct decision to progress to the large-scale implementation with a technical-only solution.

In the second analytical step, Barker et al's *Framework for Going to Full Scale* was identified as a framework suitable for guiding a more theoretically driven thematic analysis [19] of the data, which could then be overlaid with the inductive coding. Coding and analyzing the data within this framework's *phases of scale-up*—each of which was either enabled or inhibited by specific *adoption mechanisms* and *support systems*—produced a coherent and accurate representation of the diverse perspectives expressed in the data. An initial, comprehensive report was produced by MMG, using the data coded under each theme to present a theory-driven response to the two research questions. Through an iterative process of review and revisions involving first, MQ and GM, and then GD and SG, the authors reached consensus on the final structure of the findings and the selection of representative quotes. This collaborative process facilitated an investigation of any contradictory evidence or possible alternative interpretations of the data to ensure the minimization of individual bias in the results presented.

Results

Data Presentation

This section presents data collected via qualitative in-depth interviews with key stakeholders of the NERP step 1 using the theoretical structure provided by Barker et al's *Framework for Going to Full Scale*. Figure 2 illustrates a stakeholder map of the number and type of stakeholders, who informed these results and where they come in the process flow of the NERP step 1.

Figure 3 illustrates the application of *Framework for Going to Full Scale* to this study's data, by indicating the *phases of scale-up* that each adoption mechanism and support system emerged in the analysis, as an enabler or inhibitor of scale-up.

Finally, to provide some context for these results, Multimedia Appendix 1 charts the number of electronic referrals submitted to the pilot hospital OPD and the 5 NERP hospital OPDs who participated in this study in 2015 and 2016, when NERP step 1 was implemented.

New Scale-Up Idea

The *phases of scale-up* are triggered by the discovery of a *new scale-up idea* or a new best practice, which is perceived by the stakeholders as a "better idea" (*adoption mechanism*). A national-level participant commented that the NERP step 1 was:

> *...an easy sell, [its] patient safety...a solution has been developed so it's a matter of taking the solution and rolling it out to different acute hospitals*. [Participant 28]

Similar to the pilot experience, the NERP step 1 participants cited speed, complete demographic information, legibility, and traceability as the 4 key patient safety improvements delivered in the NERP step 1. Participants commented that *"speed of referral would be the biggest thing...The GP knows it's got here"* (Participant 10) because an automated notification is returned to the GP once the electronic referral has been opened within the hospital.

> *It's instant, it sells itself. You send in the referral, the hospital has it, there's no post, you're not waiting a day for it to be delivered.* [Participant 29]

> *It's good they have a minimum data set...Like we'll never be missing a date of birth or [receive]...only one line of an address...They will always give you a phone number on it.* [Participant 40]

Another hospital administrator pointed out that full contact details, including mobile phone numbers, are very important so that they can *"text remind people...to help reduce the DNA* (Do Not Attend) *rate"* (Participant 5). Finally, several participants commented on the legibility benefits of electronic referrals in that they save time trying to decipher difficult hand-writing or calling GP surgeries to confirm details or to seek missing information.

> *It's legible you know. Many times you have to ring them up [GP surgeries]*. [Participant 40]

However, with electronic referrals, they *"can find a patient much easier on the system now"* (Participant 24).

One important sociotechnical element built into the pilot program had been the requirement for hospitals to return a triage outcome message, via *Healthlink*, to referring GPs. Manpower planning issues identified in hospital CROs during the pilot stage resulted in the GP triage outcome message not being specified as an element of the NERP step 1. One of the pilot GPs commented that:

> *...it remains to be seen...how negative that will be...It reduces the communication back to the GP, and it doesn't tell the GP how the patient has been triaged.* [Participant 16]

A national-level participant commented that:

> *...we thought the GPs would be up in arms and they would go crazy about it but actually when we did go back to the ICGP...they said, "we'd be disappointed but at the same time...we would prefer that they [hospitals] went with it without responses than not go at all.*" [Participant 12]

Figure 2. The stakeholder map. GP: general practitioner, ICT: information communication technology, NERP: National Electronic Referral Programme.

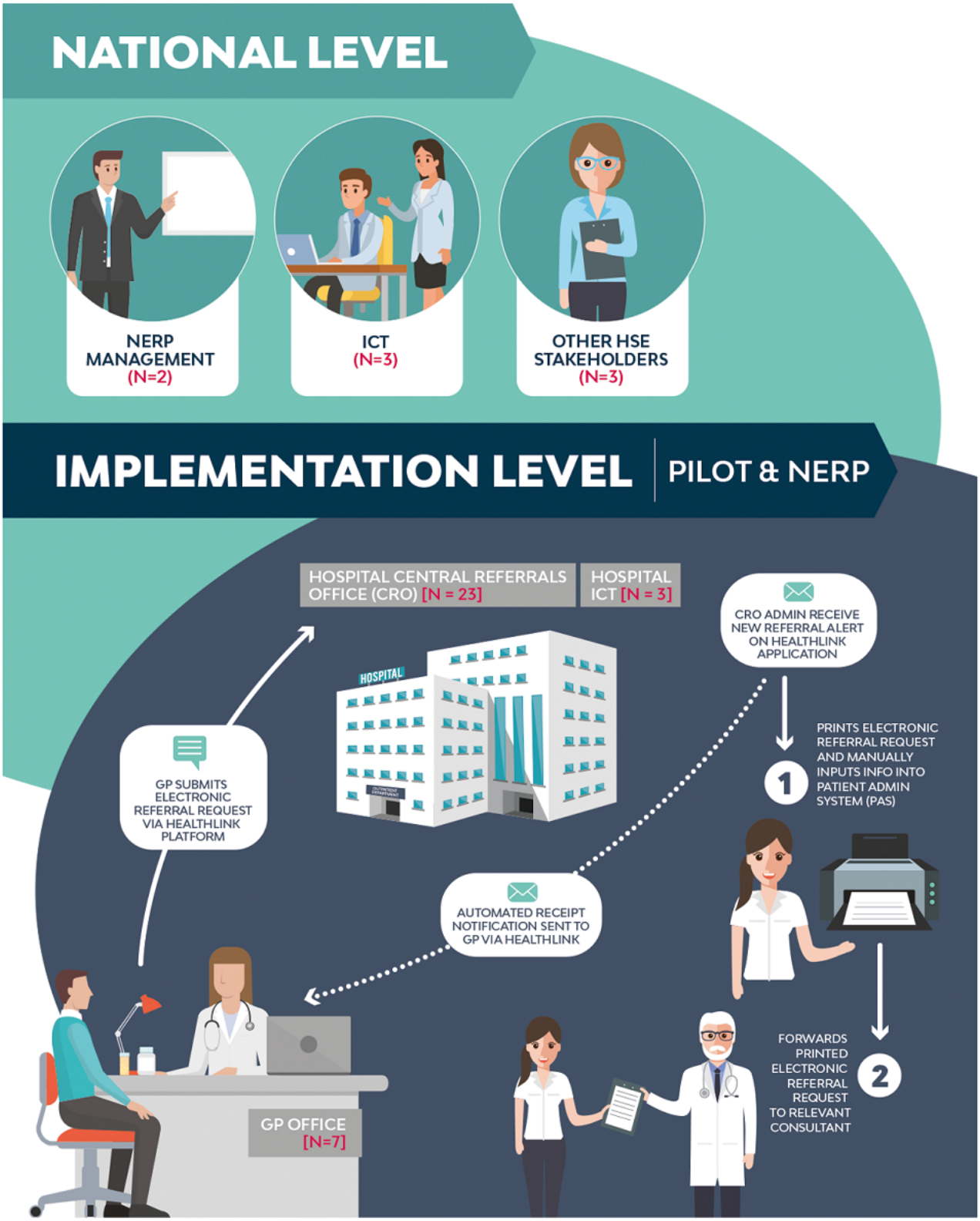
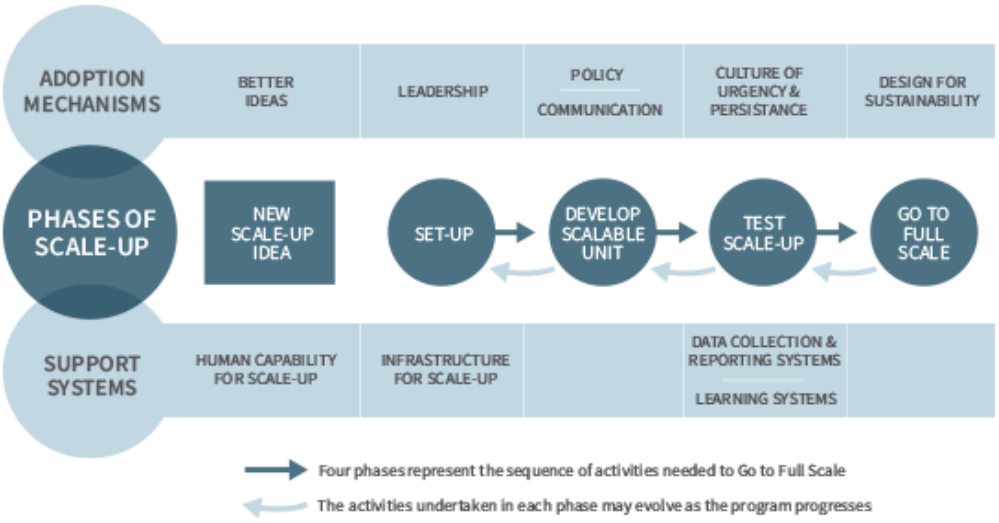


Figure 3. Application of the *Framework for Going to Full Scale* to the NERP step 1.



As such, GPs supported the NERP step 1 in proceeding with the scale-up of the technical capability for all hospitals to receive electronic referral requests, with the knowledge that hospitals did not have the "human capability for scale-up" (*support system*) to support an electronic processing of referrals (ie, eTriage and eAppointments). This acceptance among key stakeholders that the NERP step 1 is only about paving the way for the complete implementation of electronic referrals is also captured in a comment by a national-level participant who described the NERP step 1 as getting: "...the footprint of eReferrals out to all hospitals around the country" (Participant 18).

Set-Up

Set-Up is the first *phase of scale-up*, where the ambition for full scale is defined. Limiting the scope of the NERP step 1 to the technical capability was explained by national-level participants as a pragmatic decision. A national-level stakeholder explained that they did not *"have the bandwidth within* [their] *resources to go to each site"* to support a sociotechnical implementation.

> *When we are asked to rollout eReferrals within 12 months, what we can do is we can put the capability in place for each of the sites.* [Participant 18]

In terms of the "ask" to rollout electronic referrals in 12 months, the "leadership" provided by the HSE's new *eHealth Ireland* unit was widely cited as a critical *adoption mechanism* for the set-up of the NERP. One pilot participant suggested that the *"timing was impeccable"* (Participant 28) for the appointment of a chief information officer (CIO) to lead the *eHealth Ireland* unit.

> *If he hadn't arrived I would say that at this stage, we'd have rolled it out in the South or Southwest Hospital Group [pilot] and possibly no further.* [Participant 28]

A national-level participant commented that:

> *...this is the first...of any of the projects we've done, where there's been a national focus. Where from the top, it's been said, "everyone has to accept electronic referrals by X date."* [Participant 12]

In addition, a GP who was involved in the pilot commented that the new CIO was *"providing a vision for where the service needs to go"* but...

> *...there's a huge amount of work that needs to be done and huge investment that needs to take place, and I suppose that remains to be seen, whether that will be available.* [Participant 16]

This last comment suggested that leadership requires not only vision but also the ability to secure funding. A comment by a national-level stakeholder supported this suggestion in referring to the *"credibility piece,"* whereby:

> *...if we can deliver a project of this type in a timeline that's considered sensible...then it provides more confidence that the Office of the CIO and the Healthlink team can actually deliver significant change in a reasonable amount of time.* [Participant 18]

This comment provided context for the ambitious 12-month time-frame to scale-up the technical capability for electronic referrals, particularly because further resources need to be secured to proceed beyond step 1 of the NERP.

Second, defining the ambition of the NERP step 1 as putting the technical "capability" in place for all hospitals to receive electronic referral requests from GPs indicated confidence that GPs will submit their referrals electronically, should this facility be available to them. The level of digitalization of general practice health records represents an important "infrastructure for scale-up" *support system*. The *Healthlink* solution is fully integrated into general practice software packages, and GP participants emphasized the importance of this integration in their interviews.

> *[GPs] have all the information in the system and being able to extract it and package it up and send it off electronically is kind of a side effect of the investment that they've [GPs] made over the years.* [GP 1]

No formal incentives are offered to GPs to use electronic referral requests and, therefore, their adoption of the solution relies upon their technical capability to submit electronic referrals and the perception that this solution is a "better idea."

Develop the Scalable Unit

The second *phase of scale-up* is developing the scalable unit, which is the smallest unit of the system targeted for the full-scale implementation. This analysis proposes that the scalable unit of the NERP step 1 should specify the proportion of (1) hospitals targeted, (2) OPD specialties targeted, (3) electronic versus paper referral requests targeted, and (4) GPs targeted to use electronic referral requests. In practice, the scalable unit specified by *eHealth Ireland* only included the first of these elements, with a full-scale target of all public hospitals.

Implementing this first element was the focus of the NERP step 1 throughout this study period (October 2015-May 2016) and was achieved in May 2016, after 17 months of implementation, when (1) all public hospitals had (2) at least one specialty accepting (3) outpatient electronic referrals from (4) referring GPs. With all hospitals targeted, a minimal specification of at least one OPD specialty in each hospital can be assumed. However, no specification was provided for the target proportion of electronic versus paper referral requests or the proportion of GPs targeted to use electronic referral requests. The remainder of the description of the NERP step 1's progression through the *phases of scale-up* will, therefore, be dealing with what remains to be scaled rather than what has been scaled.

Interview data collected suggested that the incomplete development of the scalable unit reflects uncertainty in national "Policy" (*adoption mechanism*). The Irish health system is undergoing a process of de-centralization, from a highly centralized HSE to the creation of hospital groups and community healthcare organizations [21,22]. These structures are yet to be finalized [23], creating a challenge for the NERP step 1 because it is envisioned that CROs will ultimately be created at the hospital group level, rather than within individual hospitals [24]. Arguably, it would be a duplication of effort to implement the sociotechnical process changes associated with electronic referrals at the hospital level only for those processes to be changed again once there is certainty about the hospital groups. A national-level stakeholder highlighted that it is not a decision for *eHealth Ireland* whether outpatient electronic referrals will be managed in each hospital or at a hospital group level.

> *[It is] not something that IT can make a call on...we'll certainly drive it once we're clear this is a direction that is best for the patient and for the service.* [Participant 18]

This quote illustrated a governance challenge faced by national health IT programs like NERP, in that the authority to make key decisions about the design of such programs might lie outside of the program team.

In addition, shortcomings emerged at this phase in the "communication" *adoption mechanism*. Barker et al suggested that it is necessary to communicate the value of a scale-up to both leadership and implementers, ideally by providing real-time data from one scale-up phase to garner support for the next phase [16]. Among implementers, hospital administrative staff, in particular, reported a lack of engagement or opportunity to contribute to developing the scalable unit, which negatively affected their *"sense of ownership of it"* (Participant 37). In addition, CRO staff commented that:

> *...there are meetings and different groups but...the administrative end is not heard all the time...they come looking for secretarial support but then no budget or nothing available.* [Participant 23]

Perhaps, stemming from this lack of consultation, there was an unmet expectation from CRO staff that electronic referrals were going to save them time.

> *Everything that's been done electronically, it's supposed to save time and resources but actually it doesn't. It does exactly the opposite mostly.* [Participant 22]

While electronic referrals will reduce the administrative burden for CRO staff once the interoperability issues between *Healthlink* and PAS are resolved, in the short term, it increases the workload because they have to manage an additional mode of referral request, in addition to traditional post and fax.

Furthermore, participants reported that the strategy for communicating the value of electronic referrals to GPs requires clarification to increase the proportion of GPs submitting electronic referral requests. This element of the scalable unit was not specified for the NERP step 1, and therefore, nobody was officially tasked with the responsibility to increase the proportion of GPs using electronic referrals. A hospital-based implementer suggested that:

> *I felt like why was I having to try to promote Healthlink?...Nobody could give me any communication tools to use for the GPs—so we had to try and figure out the best way to do it.* [Participant 29]

National-level participants suggested that ultimately, GPs are *"independent sole traders"* (Participant 27). The key authority capable of shaping the referral behaviors of GPs are the hospitals receiving those referrals.

> *That is really, a HSE hospital led kind of initiative...[The] ultimate step would be for management to say, "this is how we want you to refer"...unless there is an exception.* [Participant 27]

In this study, participant GPs broadly agreed with this perspective, suggesting that local hospitals are in the best position to change GPs' referral behaviors together with local peer promotion through the ICGP's Continuing Medical Education meetings. GPs commented that:

> *I think it would be great to see the hospitals running with the ball on this one alright.* [Participant 13]

They also said, *"...people listen to their peers"* (Participant 39). These comments illustrated the importance of acknowledging GPs' professional independence in the Irish health system, when designing a communication strategy to engage GPs in the scale-up of a national IT program.

Test Scale-Up

Test Scale-Up is where the underlying theory of change and the change package are tested in a broader range of settings to refine program hypotheses and build the belief and will of leaders and frontline staff to support the changes [16]. To progress the implementation beyond the NERP step 1, developing appropriate data collection and reporting systems (*Support System*) would require a more complete development of the scalable unit. Participants reported that electronic referrals present an opportunity to standardize what data are collected (Participant 7), especially through automatically populating demographic information (Participant 40], clinical history (Participant 22), and medication and allergy information [(Participant 29) from the GPs' medical records. In addition, participants reported that electronic referrals are:

> *...giving greater visibility on referral volume, referral tracking, all those sorts of things by specialty within hospitals.* [Participant 27]

> *...whereas before we were relying on staff members putting them in an Excel...So now every referral to be processed must be on PAS.* [Participant 5]

The disadvantage of structured messaging is that it might limit GPs' ability to communicate details about a referral. One GP commented that:

> *You can write a very good clinical note using free text, probably the best quality clinical notes because it captures what the patient and yourself are saying. You can't do that with something that's completely structured. When you're picking from drop-down menus or whatever.* [Participant 30]

Moreover, participants highlighted the importance of buy-in from stakeholders on the type of data collected. One participant commented that:

> *I maintain that no clinician wants to work to a political target...They don't mean anything clinically* [Participant 35]

A pilot participant cautioned that:

> *...when you use data in a punitive way...people are resistant to it.* [Participant 19]

These quotes highlighted the potential for electronic referrals to greatly improve the volume and quality of data collected on referral management as well as the importance of engaging with stakeholders to determine what data would offer the most constructive and meaningful insights for the quality improvement.

Regarding reporting systems, participants reported receiving a monthly *Healthlink* escalation report, showing electronic referral requests that were received by the hospital but for which no triage outcome had been logged on *Healthlink*. Although logging the triage outcome to *Healthlink* was beyond the scope of the NERP step 1, participants reported that this report supports CRO staff in tracking and tracing electronic referrals.

> *It has actually highlighted that we weren't doing it [managing referrals] as well as we thought we were doing it.* [Participant 22]

Participants described two other national programs to which they submit data and receive reports relevant to electronic referrals, namely the HSE's Outpatient Services Performance Improvement Programme (OSPIP) and an independent statutory body called the National Treatment Purchase Fund (NTPF). Crucially, however, neither OSPIP nor NTPF targets are formally aligned with any specific targets for the NERP step 1. A CRO participant commented that "in the Health Service, there's no picture of what's happening" (Participant 22).

This suggests a lack of data feedback to implementers, either on the NERP step 1 on its own, or a more strategic data reporting system that utilizes the data collected across HSE and statutory programs.

This lack of development in data collection and reporting systems exerts knock-on effects on the "learning system" (*support system*) for the NERP step 1. "Large-scale change requires a mechanism for collecting, vetting, and rapidly sharing change ideas or interventions"...to assemble a "change package" for scale-up [16]. Participants interviewed indicated that informal learning from the pilot sites was encouraged by the national implementation team, but no evidence emerged of any formal learning system. A national-level stakeholder commented that as part of the "go-live" training, it is:

> *...normally suggest[ed] that they [implementers] speak to other counterparts in other hospitals that have already gone live.* [Participant 18]

Furthermore, one implementation site participant commented that he had *"two conference calls"* (Participant 21) with a member of the pilot implementation team to learn from their experience, but otherwise, the data did not suggest that a learning system was in place for the NERP step 1.

Besides these support systems, an important *adoption mechanism* at this phase is a "culture of urgency and persistence" (*adoption mechanism*), motivating stakeholders to take action and sustain their efforts to take the program to full scale. A troubling theme emerged around how legacy IT failures have created a culture of caution rather than urgency for national health IT programs. One pilot participant explained that *"there's the legacy belief around HSE ICT projects fail"* (Participant 38), and a national-level participant referred to how:

> *...some of them are not open to new stuff because they've been burnt in the past...Most sites need reassurance as to the impact it's [NERP step 1] likely to have operationally for them.* [Participant 18]

Conversely, CRO participants reported that while they were cautious about electronic referrals, now that they are using *Healthlink*, they find it very straightforward to use, and there is a strong appetite for the implementation of an end-to-end electronic referral solution. In addition, one participant commented that:

> *Now that we know how easy it is to go electronic, it would be amazing to cut out all the filling.* [Participant 4]

Similarly, another CRO participant commented that:

> *...rather than sitting on this for a year and everyone would just get too complacent with it and then it's more change...If you're in the middle of a project and there's more coming on board, you just take it.* [Participant 25]

These comments highlighted the importance of developing a complete, scalable unit, whereby participants are clear on what the vision for full scale is and they can then maintain momentum in going to full scale.

Go to Full Scale

Go to Full Scale is the fourth and final phase of the *Framework for Going to Full Scale*. This is the rapid deployment phase in which a well-tested set of interventions, supported by a reliable data feedback system, is adopted by frontline staff on a larger scale [16]. "Design for sustainability" is a critical *adoption mechanism* for reaching this fourth *phase of scale-up*, whereby throughout the 3 activity phases (Develop the Scalable Unit, Test Scale-Up, and Go to Full Scale), the learnings about sustainability are used to refine the change package.

Policy uncertainty is a key sustainability issue for the NERP step 1, which has already been described above as the uncertainty about whether to proceed with the sociotechnical process changes for electronic referrals at the hospital level [25] or to postpone process changes until the hospital group CROs can be established [24]. An associated sustainability issue is the reconfiguration of administrative staff to work within newly established CROs. Historically, each hospital consultant would have their own secretary who manages referrals sent to that consultant. A national-level participant suggested that the consultant-level referral management creates *"a lot of duplication"* because secretaries *"wouldn't be at full capacity all the time"* (Participant 28). Such a reconfiguration of staff is perceived as a challenge at the implementation level, where participants explained that:

> *...resources are still an issue with the Central Booking and the Central Office. So, to do it from within your current compliment [of staff] initially is difficult.* [Participant 5]

Similarly, another CRO participant commented that:

> *We do [have a CRO] only we have no one to sit in it. That's why it comes to me. I'm the central office.* [Participant 40]

The variation in terminology used by participants to refer to the CRO in the above quotes reflects the variation in set-up and functions of these offices across sites. This variation helps to explain why some hospitals experience greater difficulty than others in implementing electronic referrals, if their administrative staff has not been reconfigured into a CRO.

The third key sustainability issue for the NERP is the persisting interoperability issues between *Healthlink* and the hospital PAS. One national-level participant explained that hospitals that have been upgraded from the old PAS to an Integrated Patient Management System (iPMS) can be integrated with *Healthlink*. The HSE Integrated Patient Management System (IPMS) team is working to *"incorporate that functionality...but again, it's just purely staff dependent"* (Participant 32) as this team does not have the human capacity to keep all hospitals technologically and procedurally up-to-date with the latest version. A CRO participant claimed that:

> *...it is a great system (new iPMS)...if the correct processes were in place, it would be perfect.* [Participant 2]

The process changes involved in implementing iPMS require CRO staff training. CRO staff reported that while the HSE IPMS team did train on-site trainers, these *"trainers only had a short period of time to get trained themselves"* (Participant 22), and as a consequence, the training *"wasn't specific to your job, it was a general training group everyone went to"* (Participant 2). Moreover, upgrading hospital PAS to iPMS and providing the necessary training to CRO staff on how to use this upgrade are objectives beyond the scope of the NERP step 1. It is important to highlight, however, that to progress beyond the step 1 of the NERP (ie, eTriage, eConsult, eAppointments, ePrescribing, and eDischarge), this interoperability issue must be addressed.

Furthermore, consultant engagement was beyond the scope of the NERP step 1 because electronic referrals were printed once they reached the hospital. Implementing a more complete electronic referral solution will require hospital consultants triaging electronic referral requests online. An implementation site participant explained that they have had consultants from certain specialties requesting that *"their own referral form"* be accommodated within *Healthlink* to enable the collection of specialty-specific information to inform triage decisions. The *"way we got around"* that was by saying:

> *...well Healthlink said they would take on certain forms but if we could just run with this...and see how we get on with it.* [Participant 21]

Similarly, a national-level participant commented that:

> *...we get a consistent message from the hospitals that they'd like to do more in the way of specialist referral.* [Participant 18]

The challenge is that consultants throughout the country *"have to agree with those extra parameters* [for the electronic referral template] *that are unique for that speciality"* and then *"avoid a scenario that says well actually ideally we'd like 20 extra parameters from a GP"* (Participant 18). An implementation-level participant commented that:

> *I know that Healthlink did have some issues with [specialist referral forms]. They just want to consolidate as much as possible.* [Participant 21]

The *Healthlink*'s reluctance to integrate multiple specialist forms may, however, be driven by technical and financial obstacles to working with GP software vendors rather than a concern about whether or not GPs would have the time to complete specialist referral templates. Some national-level participants suggested that:

> *Engaging with the vendors is a challenge...because we're very reliant on them doing the initial work to get their products modified.* [Participant 12]

Healthlink worked with the ICGP's national General Practice Information Technology (GPIT) group *"to do a specification for the vendors...and coming up with agreements on cost and implementation time-frames"* (Participant 12). For *Healthlink* to integrate specialist referral templates, it would again need the support and cooperation of the ICGP GPIT group to engage with GP vendors to make the necessary upgrades. If specialist referral templates are perceived by GPs as unnecessarily burdensome, the ICGP GPIT group might not be willing or able to support this integration work in future.

Discussion

Principal Findings

This study aimed to theoretically frame the lessons learned from the NERP step 1 on the design and implementation of a national health IT program. The NERP step 1 presented an interesting case study of implementing a national health IT program because it explicitly committed to a technical-first implementation rather than a sociotechnical approach. A key strength of the program was that it was welcomed by most key stakeholders as the first step in the implementation of electronic referrals, delivering important patient safety benefits. A national implementation of electronic referrals was progressed, despite limited resources and outstanding interoperability issues. In addition, it gained credibility for a new *eHealth Ireland* unit, which demonstrated that it can deliver national health IT programs. Conversely, the limitations of the NERP step 1 were that it was poorly integrated in the wider policy and quality improvement agenda of HSE. Moreover, the lack of specification of the sociotechnical elements of the scalable unit created challenges in communicating the scope of the program to key stakeholders and restricted the ability of program managers and implementers to test and refine the change package. Regarding design, the theory-driven analysis of the NERP step 1 highlighted that it is necessary to specify the sociotechnical elements of a national health IT program at the national level. Of note, these do not need to be specified in tandem with technical elements but do need to be specified quite early in the implementation process, so that the change package can be tested and refined as a set of interventions for implementing the scalable unit (technical and sociotechnical elements). These principal results are detailed and compared with prior work in the next section.

Comparison with Prior Work

Strengths and Limitations of the Scale-Up of the NERP Step 1

The first research question posed by this paper asked what are the strengths and limitations of the scale-up of the NERP step 1 as a technical-only intervention. A key strength of the NERP step 1 is that it scaled-up the technical capability of GPs to submit electronic referral requests to at least one OPD specialty in all public hospitals. The four patient safety improvements reported by the NERP step 1 participants, including speed of transfer, more complete demographic information, legibility, and traceability, have been recognized internationally as key benefits of implementing an electronic referral solution [3,26]. Second, the NERP step 1 has maintained progress in implementing a national electronic referral solution between GPs and hospital OPDs beyond the pilot stage. This commitment to enact learnings from a pilot stage must be commended since eHealth initiatives have been described as "plagued by 'pilotitis', with many small initiatives sprouting without any real coordination or ability to scale" [27]. Specifically, in reference to electronic referral systems, Bouamrane and Mair have reported that deployment is often "slow and characterized by limited and localized uptake, or regional rather than nation-wide implementations" [1]. Driven by executive leadership [5] within *eHealth Ireland*, as well as GPs' appetite and technological capability for electronic referrals, the NERP step 1 has gained a considerable foothold at a national scale. Latest figures from February 2018, for instance, indicate that 16,752 electronic referral requests were submitted by GPs to hospital OPDs (Multimedia Appendix 2), representing 22.5% of the overall number of electronic referral requests submitted to Irish hospital OPDs in that month (Multimedia Appendix 3) [28]. The third key strength of the NERP step 1 is that it was perceived by national-level participants as building "credibility" within the health system for a newly established *eHealth Ireland* unit. This finding is important because it supports Eason's suggestion that when scaling national health IT programs, there are "many agencies involved in shaping the system that reaches the users. Each agency can be considered a locus for part of the decision making" [13]. That is, agencies like *eHealth Ireland* set the strategic priorities in the program design, but crucially, they then need to have the credibility to successfully engage implementation sites (GPs and hospital OPDs) to adopt the technology. Huang et al flagged that the implementation of national health IT programs can just as easily fail at this institutional level as it can if the technology is not accepted by the end users [29]. This credibility is particularly important in the context of participant references to a "legacy belief that HSE ICT projects fail."

Associated with this institutional complexity, a key limitation of the NERP step 1 was that it was poorly integrated within the wider policy and quality improvement agenda of the health service. The program was designed and implemented by *eHealth Ireland* to achieve a technical objective. National-level participants described the program as a separate piece of work to the HSE's OSPIP, which is responsible for service improvement more generally within hospital OPDs. Greenhalgh et al cautioned that postponing the collaborative, cross-institutional work needed to deliver a sociotechnical implementation only increases the chances that a technical system will be met with resistance from other stakeholders [26], particularly if the aims of the program do not align with the professional norms of the end users [30]. In addition, Huang et al suggested that major health sector innovations typically "emerge from negotiations between diverse stakeholders who compete to impose or at least prioritize their preferred version of that innovation" [29]. Instead of a top-down approach to technology deployment, Coiera advocated for a "middle-out" approach to developing national health IT systems, whereby technical goals are set to help achieve clinical or service

standards [31]. These standards are not static, and therefore, a partnership approach is required between health care providers (clinicians and managers) and government and the IT industry to constantly develop national health IT systems in line with health service priorities and the evolving potential of technology. Under this approach, "implementation never stops" [31] and implementing technical capability as an objective separate from a specific clinical or service target would not be pursued.

The second, related limitation of the NERP step 1 was the incomplete specification of the program's scalable unit. Once all hospitals had at least one OPD specialty accepting electronic referral requests from GPs, the single objective for step 1 of the program was achieved. In this study, participants reported an implementer burden owing to this lack of specification. Hospital participants reported having to try and figure out for themselves how to engage local GPs, although they did not consider this their responsibility. Some hospital administrators expressed dissatisfaction with the low level of consultation, which inhibited them from communicating the "double-jobbing" challenges associated with sending the GP triage outcome message. Sending this message was a feature of the pilot project but not the NERP step 1; however, interviews with hospital administrators suggested that the scope of the NERP step 1 was neither clearly specified nor communicated to them. This limited program specification also restricted the potential to develop data collection and reporting systems, through which individual implementation sites could monitor their progress [32]. If the program had been better integrated within the wider quality improvement agenda in the HSE, a broader range of mandatory clinical or service targets could have been set, as was the case in the rollout of electronic referrals in Scotland [1]. Importantly, as described by participants, clinicians do not wish to work to "political targets." Any additional targets set must be patient-centered to ensure that the learnings gained from the data are meaningful for various stakeholders [26,33].

Going to Full Scale With a National Health IT Program

The second research question asked whether the sociotechnical elements of a large-scale national health IT program need to be specified at the national policy level. Analyzing the NERP step 1 using the *Framework for Going to Full Scale* [16] revealed that the scalable unit for the NERP step 1 did not include a minimum specification of the sociotechnical elements, and critically, this incomplete specification of the scalable unit inhibits the scale-up of the NERP step 1. The one element specified for the NERP step 1 was that all publicly funded Irish hospitals would be set-up with the technical capability to accept electronic referral requests. No specification was provided for the proportion of OPD specialties targeted, the proportion of electronic versus paper referral requests targeted, or the proportion of GPs targeted to use electronic referral requests. Consequently, data collection and reporting systems were not put in place to capture what change package was used to implement these elements of the scalable unit at each implementation site. For example, OPD specialties requiring a specialist referral template instead of the standard GP-OPD referral template remain unclear. For NERP to progress to the Test Scale-Up phase, a more complete scalable unit needs to be formally specified. In addition, data collection and reporting systems need to be put in place to monitor progress in implementing this scalable unit, and a learning system established to utilize the data collected. The learning system synthesizes the lessons from early implementation sites to guide future implementation sites on the design of a well-tested change package. The answer to this second question, therefore, is yes, the sociotechnical elements of a large-scale national health IT program do need to be specified at the national policy level if it is to progress to full scale. Importantly, it is the "scalable unit" (ie, goals of the program) and not the "change package" (ie, the set of interventions) that needs to be specified at the national level, and therefore, it is not a one-size-fits-all approach to implementation which is advocated by this study or the *Framework for Going to Full Scale*. Furthermore, each implementation site is given the flexibility to undertake a local sociotechnical design of their "change package," in that they can select a set of interventions that fit the priorities and circumstances of their local context. Ultimately, however, their implementation will be assessed nationally on the extent to which the scalable unit is delivered.

The wider literature is highly critical of designing national health IT programs with rigid top-down change packages that do not leave space for local adaption. Coiera, for instance, argued that centrally defined, top-down implementations of national health IT programs become increasingly out of step with service needs, and clinical providers will have to build workarounds to make the aging system meet emerging needs [31]. If emerging needs are left unaddressed, the workarounds will add unmanageable local variations to what was intended to be a singular national design [31]. Regarding a technical-only scale-up, a dynamic cost-benefit analysis study reported that the potential gains of implementing an electronic message exchange could be reduced by 40%-50%, if old working procedures to fit old technology are maintained after new technology is implemented [34]. This type of economic argument warrants careful consideration for the NERP step 1 in light of the outstanding interoperability issues between *Healthlink* and hospital PAS, which until resolved will require the "double-jobbing" of old and new working procedures. These arguments illustrate that the overall success of the technical elements of a national health IT program depend on their interaction and fit with the sociotechnical system.

As such, the academic literature's advocacy of a sociotechnical approach to implementing national health IT programs is not contradicted by this study. This paper started with an observation that the NERP step 1 was initiated with a technical-only intervention and uncertainty about whether this type of implementation strategy [13] put the NERP step 1 at odds with the best practice, sociotechnical approach. The key learning from this study is that the implementation of a national health IT program requires an interaction and ultimately a fit between the new technical solution and the existing sociotechnical system. A program may be initiated with a technical-only intervention, similar to the NERP step 1; however, the priority for such an intervention is then to fit the technical elements of the program to the sociotechnical system within which it is being implemented. It is recommended that policy makers and implementers use a quality improvement framework such as

Barker et al's *Framework for Going to Full Scale* [16] to help guide them in the design and implementation of national health IT programs.

Critique of the Framework for Going to Full Scale

Barker et al's *Framework for Going to Full Scale* [16] informed a theoretically driven thematic analysis of the semistructured interview data. The concept of the "scalable unit" proved crucial to identifying the *phases of scale-up* achieved by the NERP step 1 and informing an understanding of the limitations of a technical-only scale-up. One challenge encountered in using this framework was that the distinction and interaction between the "scalable unit" and the "change package" are not made explicit in the original paper. Both elements are described as being generated at phase 2, Develop the Scalable Unit, with the scalable unit defined as "the smallest representative facsimile of the system targeted for full-scale implementation"; the change package is described as "a set of context-sensitive strategies and interventions" [16]. Having applied the framework to the NERP step 1, it is suggested that future applications of the framework might find it helpful to think of the "scalable unit" as the goals of a program, whereas the "change package" is the set of actions undertaken to deliver each goal. As such, both constructs are interdependent. As the scalable unit is developed, the change package for implementing that scalable unit needs to be tested and refined, and if the scalable unit changes, so must the change package. A comprehensive critique cannot be provided on phases 3 and 4, Test Scale-Up and Go to Full Scale, because the NERP step 1 did not reach these phases. In particular, it will be important for future applications of the framework to detail the process through which an implementation site selects, tests, and refines their change package (set of interventions), and at the national level, to explore the degree of variation in the change packages employed across implementation sites and the impact this variation has on delivering the scalable unit.

Study Limitations

A key limitation of this study is that hospital specialists were not interviewed. Hospital specialists were not formally engaged in the design or implementation of the NERP step 1 and therefore were not considered key informants in this early stage of the program. Upon the receipt of an electronic referral request, the Hospital CRO prints the electronic referral request. By the time it reaches a specialist, it is a paper-based referral request, just like any other. The only change encountered by specialists is that electronic referral requests from GPs are presented to them for triage on a standardized template. The triage phase of referral management was not included in the NERP step 1, and therefore, specialist dissatisfaction or satisfaction with the standardized GP-OPD referral template was beyond the remit of this study. Issues were raised within the study, however, for which it would have been valuable to have obtained a specialist medical perspective. These include the centralization of the referral management to a CRO at a hospital or hospital group level or the suitability of using the standardized GP-OPD referral template for all OPD specialties. Hence, future research should focus on these issues as they relate to the later stages of the *phases of scale-up*.

The second limitation is that the participants were not recruited from randomly selected implementation sites. Access to 1 pilot site and 5 NERP step 1 implementation sites was arranged through *eHealth Ireland*. Although not randomly selected, the 5 NERP step 1 sites did include public and voluntary hospitals, as well as regional and urban hospitals, and so, a broad representation of implementation sites was achieved.

Conclusions

This qualitative study of the early-stage implementation of the NERP provides empirical insights into the complexity of implementing a national health IT program. The incremental design of this program—with step 1 only seeking to scale-up the technical capability for the e-request phase of an electronic referral solution—made the NERP step 1 an interesting case study from a sociotechnical perspective.

The strengths of this implementation were that it successfully scaled-up the technical capability for GPs to submit electronic referral requests to at least one specialty in all hospitals in the Irish public health system. In addition, it maintained progress in the implementation of an electronic referral solution beyond piloting despite limited resources and outstanding interoperability issues. Finally, it built credibility and confidence in the new *eHealth Ireland* unit's ability to successfully implement a national health IT program. Conversely, the limitations of this program were that it was poorly integrated within the wider quality improvement agenda of the HSE. The incomplete specification of the vision for full scale created uncertainty for stakeholders on their roles and responsibilities within the program, as well as a lack of clarity on the emerging change packages, which need to be tested and refined.

These limitations were a consequence of not specifying a complete scalable unit, including the sociotechnical elements of the program. In conclusion, although the sociotechnical elements of a program do not have to be specified in tandem with technical elements, they do need to be specified quite early in the implementation process so that the potential change packages for implementing the scalable unit can be tested and refined into a scalable set of interventions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Number of electronic referral requests submitted to participating hospital outpatient departments in 2015/2016. Data collection period is Oct 2015-May 2016. Source: *eHealth Ireland*.

[PNG File, 48KB - medinform_v6i3e10488_app1.png]

Multimedia Appendix 2

Monthly number of electronic referral requests (Sep 2015-Feb 2018). Source: *eHealth Ireland*.

[PNG File, 67KB - medinform_v6i3e10488_app2.png]

Multimedia Appendix 3

Upward trend in % of general electronic referrals to outpatient departments (Mar 2016-Feb 2018). Source: *eHealth Ireland*.

[PNG File, 48KB - medinform_v6i3e10488_app3.png]

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Abbreviations

CIO: chief information officer
CRO: central referral office
GP: general practitioner
GPIT: General Practice Information Technology Group (Ireland)
HIQA: Health Information and Quality Authority (Ireland)
HSE: Health Service Executive (Ireland)

ICGP: Irish College of General Practitioners (Ireland)
ICT: information communication technology
iPMS: Integrated Patient Management System
IPMS: Integrated Patient Management System Programme (Ireland)
IT: information technology
NTPF: National Treatment Purchase Fund (Ireland)
NERP: National Electronic Referral Programme (Ireland)
OPD: outpatient department
OSPIP: Outpatient Services Performance Improvement Programme (Ireland)
PAS: patient administrative system
PDSA: Plan-Do-Study-Act cycle of quality improvement
UCD: University College Dublin

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Original Paper

Validating a Framework for Coding Patient-Reported Health Information to the Medical Dictionary for Regulatory Activities Terminology: An Evaluative Study

Sonja Brajovic[1], MD; David A Blaser[2], PharmD; Meaghan Zisk[2], RN, MPH; Christine Caligtan[2], RN, MSN; Sally Okun[2], RN, MMHS; Marni Hall[3], PhD, MPH; Carol A Pamer[1], RPh, MSc

[1]Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food And Drug Administration, Silver Spring, MD, United States

[2]PatientsLikeMe, Cambridge, MA, United States

[3]Center for Advanced Evidence Generation Real World Insights, IQVIA, Rockville, MD, United States

Corresponding Author:
David A Blaser, PharmD
PatientsLikeMe
160 Second Street
Cambridge, MA, 02142
United States
Phone: 1 781 718 6382
Fax: 1 866 850 6240
Email: dblaser@patientslikeme.com

Abstract

Background: The availability of and interest in patient-generated health data (PGHD) have grown steadily. Patients describe medical experiences differently compared with how clinicians or researchers would describe their observations of those same experiences. Patients may find nonserious, known adverse drug events (ADEs) to be an ongoing concern, which impacts the tolerability and adherence. Clinicians must be vigilant for medically serious, potentially fatal ADEs. Having both perspectives provides patients and clinicians with a complete picture of what to expect from drug therapies. Multiple initiatives seek to incorporate patients' perspectives into drug development, including PGHD exploration for pharmacovigilance. The Food and Drug Administration (FDA) Adverse Event Reporting System contains case reports of postmarketing ADEs. To facilitate the analysis of these case reports, case details are coded using the Medical Dictionary for Regulatory Activities (MedDRA). PatientsLikeMe is a Web-based network where patients report, track, share, and discuss their health information. PatientsLikeMe captures PGHD through free-text and structured data fields. PatientsLikeMe structured data are coded to multiple medical terminologies, including MedDRA. The standardization of PatientsLikeMe PGHD enables electronic accessibility and enhances patient engagement.

Objective: The aim of this study is to retrospectively review PGHD for symptoms and ADEs entered by patients on PatientsLikeMe and coded by PatientsLikeMe to MedDRA terminology for concordance with regulatory-focused coding practices.

Methods: An FDA MedDRA coding expert retrospectively reviewed a data file containing verbatim patient-reported symptoms and ADEs and PatientsLikeMe-assigned MedDRA terms to determine the medical accuracy and appropriateness of the selected MedDRA terms, applying the International Council for Harmonisation MedDRA Term Selection: Points to Consider (MTS:PTC) guides.

Results: The FDA MedDRA coding expert reviewed 3234 PatientsLikeMe-assigned MedDRA codes and patient-reported verbatim text. The FDA and PatientsLikeMe were concordant at 97.09% (3140/3234) of the PatientsLikeMe-assigned MedDRA codes. The 2.91% (94/3234) discordant subset was analyzed to identify reasons for differences. Coding differences were attributed to several reasons but mostly driven by PatientsLikeMe's approach of assigning a more general MedDRA term to enable patient-to-patient engagement, while the FDA assigned a more specific medically relevant term.

Conclusions: PatientsLikeMe MedDRA coding of PGHD was generally comparable to how the FDA would code similar data, applying the MTS:PTC principles. Discordant coding resulted from several reasons but mostly reflected a difference in purpose. The MTS:PTC coding principles aim to capture the most specific reported information about an ADE, whereas PatientsLikeMe may code patient-reported symptoms and ADEs to more general MedDRA terms to support patient engagement among a larger

group of patients. This study demonstrates that most verbatim reports of symptoms and ADEs collected by a PGHD source, such as the PatientsLikeMe platform, could be reliably coded to MedDRA terminology by applying the MTS:PTC guide. Regarding all secondary use of novel data, understanding coding and standardization principles applied to these data types are important.

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KEYWORDS

adverse drug events; Food and Drug Administration; MedDRA; patient-generated health data; PatientsLikeMe; vocabulary, controlled; data curation

Introduction

Patients describe their medical experiences differently compared with how clinicians or researchers would describe their observations. The interpretation of data gathered from patients is typically based on a clinician's perspective of how a patient is feeling or functioning or what is of most concern to a clinician. However, a clinician's impression may differ from a patient's experience and therefore may not be an accurate or complete interpretation [1-3]. For example, a patient may find a nonserious, known adverse drug event (ADE) to be an ongoing, daily concern, which impacts tolerability and adherence. Clinicians, however, must be vigilant for medically serious or potentially fatal ADEs. Having both perspectives can provide patients and clinicians with a complete picture of what to expect from drug therapy options for a given medical condition.

With new advances in technology, the availability of and interest in patient-generated health data (PGHD) have grown steadily. PGHD are distinct from data generated in clinical settings, such as within clinical trials or during encounters with health care practitioners. Most importantly, patients directly report and record these data and are responsible for sharing and distributing them [4]. The internet democratized access to and sharing of health information, leading to the creation of Web-based patient networks. The growing popularity and advancement of mobile sensors, wearable devices, and smartphones have created enormous opportunity for innovative approaches to understanding, managing, and improving health through the collection and application of PGHD [5]. Several ongoing initiatives incorporate patients' perspectives into drug development processes. For example, the Patient-Centered Outcomes Research Institute was established to address challenges with traditional research and integrate patients as key stakeholders and partners in the research process [6]. In addition, the US Food and Drug Administration (FDA) Prescription Drug User Fee Act V mandated public engagement through patient-focused drug development workshops and development of patient-reported outcomes to better understand the impact of symptoms and treatments on patients' lives [7]. The 21st Century Cures Act, among other provisions, also requires the FDA to consider real-world evidence and patient-experience data in its review of drugs and devices [8].

The FDA Adverse Event Reporting System (FAERS) contains case reports of postmarketing adverse events submitted to the FDA Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research [9]. The FDA uses these reports to generate and evaluate signals of potential adverse reactions to drugs and biologics [10]. To facilitate searching and analysis of the case reports in FAERS, all suspected ADEs, such as medical diagnoses and stand-alone signs or symptoms, as well as medication errors and product quality issues included in case narratives, are coded using the Medical Dictionary for Regulatory Activities (MedDRA). MedDRA is a terminology endorsed by the International Council on Harmonisation (ICH) to be used by regulators and the pharmaceutical industry to codify ADEs reported with the use of medical products [11]. The ICH MedDRA Term Selection: Points to Consider (MTS:PTC) document provides valuable guidance on best practices for term selection and promotes accuracy and consistency in coding [12]. Pharmaceutical companies precode the reported suspected adverse reactions to drugs or biologics to MedDRA according to the MTS:PTC guide. The FDA then samples and reviews the submitted MedDRA codes for coding quality, medical accuracy, and alignment with MTS:PTC. Moreover, the FDA applies the MTS:PTC guide to internally code FAERS case reports received directly through MedWatch, the FDA's voluntary reporting system for health care professionals, consumers, and patients [13]. Medically accurate and thorough MedDRA coding is an essential prerequisite for subsequent reliable and comprehensive retrieval of pertinent cases through electronic querying by MedDRA codes. While MedDRA terminology is critical for searching databases and conducting data mining activities, these terms do not necessarily fully reflect a patient's experience.

PatientsLikeMe (PLM) is a Web-based network where patients report, track, share, and discuss their health information. PLM captures PGHD through free-text entries and structured data fields; these data have previously been used to conduct research from patients' perspectives [14-16]. The structured fields for entering data, such as patients' conditions, symptoms, or treatments, are coded by PLM to several established medical terminology systems, including MedDRA, to increase its usefulness for research and enable interoperability with external systems.

This study aimed to evaluate the concordance and discordance of MedDRA coding results of verbatim patient reports in a structured PGHD setting compared with how the same submissions would be coded based on the MTS:PTC coding guide, the current standard for regulatory settings.

Methods

We conducted a retrospective evaluation of PLM MedDRA coding of PGHD of signs, symptoms, and ADEs collected in structured data fields on the PLM platform and compared this

with how the same PGHD data would be coded to MedDRA applying the MTS:PTC. Medical terminology systems, such as MedDRA, are typically developed to be used by health care professionals, regulators, pharmaceutical industry, and researchers. Although MedDRA contains "lay-person" terms, it does not contain all the language familiar to most patients. To help bridge the gap between clinical terminology in MedDRA and patient-friendly language, the PLM terminology was created using the words and phrases reported by patients. The PLM terminology, which is maintained and curated by a team of medical professionals, consists of several types of medical entities, each of which is coded to one or more external medical terminology systems (Table 1).

Patients who wish to share and track their personal health history can search the PLM terminology to find an item (eg, condition, symptom, and treatment) to add to their profile. As patients enter text in the search field, a range of possible matches in the PLM terminology are suggested; patients may choose an appropriate match or submit a request to add a new item. A medical professional at PLM reviews the request and determines whether it can be merged to an existing item in the PLM terminology (Figure 1).

When a new item is added to the PLM terminology, a detailed entry is created to describe and distinguish the concept appropriately (Figure 1). For each new item, PLM writes an appropriate patient-facing description, codes the item to appropriate medical terminologies, and sets any relevant customizations to guide data entry for future patients. Once this process is complete, the curated PGHD becomes a new item in the PLM terminology and appears on the patient profile. Finally, PLM sends a message to notify the patient that the new item has been added to the PLM terminology. When a verbatim patient report is curated for any reason, the patient receives a message alerting them to the change and providing them with the option to accept or reject the change and to request the original entry be retained.

A data file was generated containing PGHD for symptoms and ADEs entered through the PLM platform from January 1, 2013 to September 1, 2015; this file contained the patient's verbatim text, the item(s) it was merged to in the PLM terminology, and the MedDRA term associated with the item(s) as assigned by PLM. Only PGHD from patients with an active account from the United States were included in the data file. Notably, the data file did not include any patient-level, personally identifiable information. A MedDRA terminology expert reviewer from the FDA evaluated each record in the file for accuracy and specificity of the MedDRA terminology coding, applying the MTS:PTC guide. MedDRA has a hierarchical structure with 5 levels as follows: System Organ Class (SOC), High-Level Group Term (HGLT), High-Level Term (HLT), Preferred Term (PT), and Lowest-Level Term (LLT). The PT level is considered a distinct descriptor (single medical concept) [10]. The LLTs under a PT are synonyms and lexical variants of the PT; each LLT is linked to only one PT. LLTs reflect how information might be reported and represent the coding level. Symptoms and ADEs in the PLM database are coded to an LLT, as per the established coding practice.

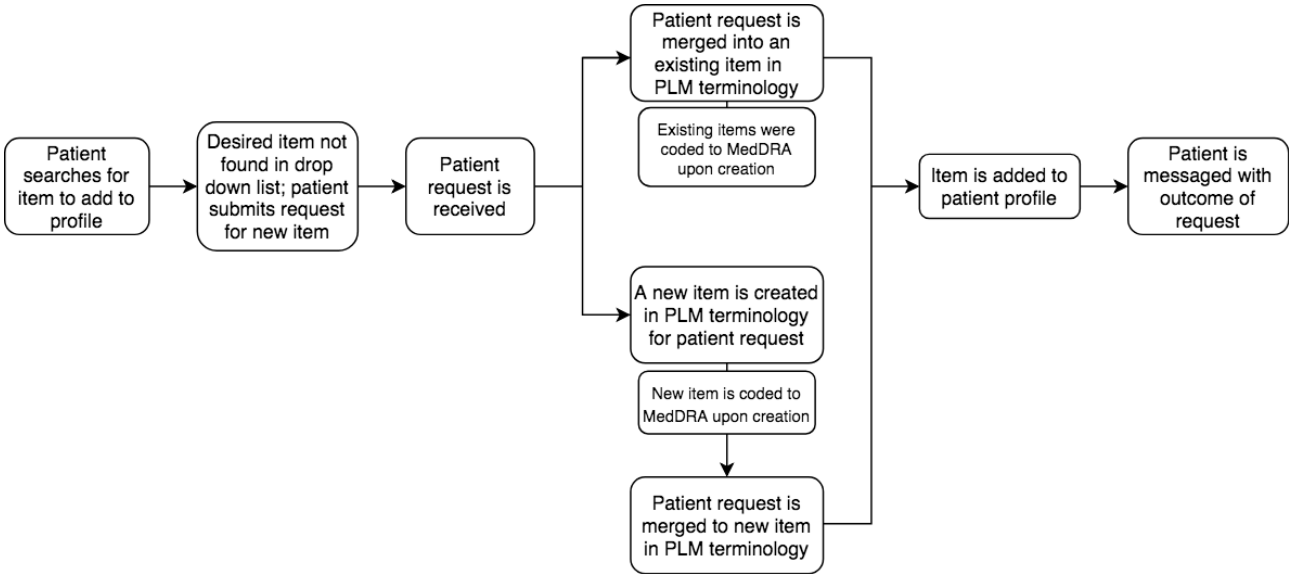
In this study, the FDA reviewer evaluated the appropriateness of the MedDRA term(s) associated with the patients' verbatim text. The FDA reviewer provided written comments for each record indicating one of the following coding results categories:

- MedDRA coding appropriate: Both the FDA and PLM reviewer agreed that the selected MedDRA term was appropriate for the PGHD verbatim.
- Incorrect MedDRA coding: The MedDRA term assigned by PLM was not appropriate.
- Missed concept: A component of the PGHD verbatim entry was not coded to a MedDRA term.
- Outdated MedDRA version: Reviewer recommended a more specific MedDRA term, but it was not available in the MedDRA version used by PLM.
- Duplicate: A unique record was listed more than once in the extracted dataset. These records were not included in the final analysis.
- Unable to assess: PLM's coding decision for these records was based on additional information available as free text on the patient's profile and private message communication between PLM and the patient. Specifically, PLM engages with patients through private messages to learn more about patients' experiences to capture the information as reported accurately; this additional information was not available in the data file provided to the FDA for review. Thus, these records could not be properly evaluated for coding accuracy and were excluded from the final analysis.

Table 1. Coding for data elements of the PatientsLikeMe terminology.

Medical entity type	Examples	Terminology
Condition	Multiple sclerosis, epilepsy, traumatic brain injury, major depressive disorder	Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT), International Classification of Diseases-10 (ICD10), Medical Dictionary for Regulatory Activities (MedDRA)
Symptom	Depressed mood, anxious mood, fatigue, insomnia, pain	SNOMED CT, ICD10, MedDRA, International Classification of Functioning, Disability and Health
Treatment	Gabapentin, vitamin D, physical therapy, cognitive behavioral therapy	RxTerms
Side effect	May be coded to a condition or symptom	See above for Terminology
Treatment purpose	May be coded to a condition or symptom	See above for Terminology
Hospitalization reason	May be coded to a condition, symptom, or treatment	See above for Terminology

Figure 1. Diagram of information flow for patient submissions. MedDRA: Medical Dictionary for Regulatory Activities; PLM: PatientsLikeMe.



For each included record, other than those classified as "MedDRA coding appropriate," the reviewer provided a rationale for disagreement and proposed an alternative MedDRA code. Together, the FDA and PLM reviewers discussed each discordant record, reached consensus on the category, and documented the reasons for discordant coding.

Results

The data file from PLM contained 3349 submissions. A total of 115 items were identified as "duplicates" (n=20) or "unable to assess" (n=95) and were excluded from the final analysis. Examples of entries in this category are: "loss of blood," LLT *Rectal bleeding* (patient clarified the source of blood loss); "systemic nerve overstimulation," LLT *Essential tremor* (patient clarified); "blood pressure," LLT *Blood pressure high* (patient reported high blood pressure just as "blood pressure"); "hose hurts my ears," LLT *Skin irritation* [a patient with chronic obstructive pulmonary disorder on supplemental oxygen therapy].

A total of 3234 MedDRA-coded items remained for the final analysis. The expert reviewer determined that these verbatim terms could be MedDRA-coded as per the patient-reported submission and found that MedDRA coding was appropriate in 97.09% (3140/3234) of cases (Table 2). These reported verbatim terms ranged from specific medical terms ("intercostal neuralgia" and "coccydynia"), to less specific terms ("balance problems" and "blood clots in legs") and personal communications ("just didn't feel right" and "zombie mommy"). Table 3 illustrates examples of differences between the PLM and FDA approach to coding based on MTS:PTC.

In Table 3, example 1 wherein the patient submission of "Pruritis" was merged into the existing PLM term "Itching," demonstrates an instance in which more patient-friendly language is preferred by PLM. In the PLM terminology, the term "itching" encompasses all entries related to "pruritus," "itch," "itchy skin," and "itchiness." After discussion, the FDA reviewer agreed that the coding was appropriate at the PT level, as both LLT *Pruritus* and LLT *Itching* roll up to the same PT *Pruritus*. This example illustrates that the language used by patients can range from informal to highly technical.

Example 2 is an instance of PLM coding an item to more specific MedDRA terms than the FDA. The PLM terminology contains separate terms for a symptom affecting different body area; this approach enables patients to track and monitor a symptom on each body area individually. Thus, PLM chose to split the patient submission "rash on chest & neck" into the individual symptoms "rash on chest" and "rash on neck." "Rash on chest" was mapped to the LLT *Skin rash*, whereas "rash on neck" was coded to the LLT *Neck rash*. However, the FDA coding practice is to code "rash on chest and neck" to a single MedDRA term, LLT *Rash*, and consider it a single event as the term for both "rash on chest" and "rash on neck" roll up to the same PT in the MedDRA hierarchy.

Table 2. Results of the Food and Drug Administration Medical Dictionary for Regulatory Activities (MedDRA) coding review (N=3234[a]).

Category	Records, n (%)
Coding appropriate	3140 (97.09)
Incorrect coding	45 (1.39)
Missed concept	38 (1.18)
Outdated MedDRA version	11 (0.34)

[a]Excludes "duplicates" (n=20) and "unable to assess" (n=95).

Table 3. Examples of Medical Dictionary for Regulatory Activities (MedDRA) coding from the analysis.

#	Patient submission	PLM[a] action	PLM MedDRA coding		FDA[b] reviewer assessment	Outcome
			LLT[c]	PT[d]		
1	Pruritis	Merged into PLM symptom "Itching"	Itching	Pruritus	Coding appropriate	N/A[e]
2	Rash on chest & neck	Merged into PLM symptoms "Rash on chest" and "Rash on neck"	Skin rash; neck rash	Rash	Coding appropriate	N/A
3	Drop foot from surgery	Merged into PLM symptom "Foot drop"	Foot drop	Peroneal nerve palsy	Coding appropriate; however, more specific term is available. Recommend: LLT Peroneal nerve palsy postoperative; PT Peroneal nerve palsy postoperative	Coding was not changed because of the PLM conceptual approach to coding to more general term
4	Sexual dysfunction/no libido	Merged into PLM symptom "Sexual dysfunction"	Sexual dysfunction	Sexual dysfunction	Coding appropriate	N/A
5	Irrational emotions	Merged into PLM symptom "Irrational emotions"	Mixed disturbance of conduct and emotions	Antisocial behavior	Incorrect coding; recommend coding to: LLT Emotional disorder; PT Emotional disorder	Coding updated
6	Cardiac arrhythmia	Merged into PLM symptom "Irregular heartbeat (cardiac arrhythmia)"	Heartbeats irregular	Heart rate irregular	Incorrect coding; recommend coding to: LLT Cardiac Arrhythmia; PT Arrhythmia	Coding updated
7	Increased INR[f]	Merged into PLM symptom "High INR"	INR abnormal	INR abnormal	Incorrect coding; recommend coding to: LLT INR increased; PT INR increased	Coding updated
8	I was stumbling, falling and tripping, my thinking process was very slow and my memory was failing too	Merged into PLM symptoms "Memory problems," "Slowed thinking," and "Tripping and stumbling"	Memory disturbance; slowed thinking; muscular incoordination	Memory impairment; Bradyphrenia; coordination abnormal	Missed concept. Report of "falling" is missing; falls are an important patient safety issue which should be captured. For stumbling and tripping, there is LLT Stumbling and LLT Gait tripping, both under PT Gait disturbance	Coding updated to include additional information
9	Back pain and nausea and vomiting	Merged into PLM symptoms "Nausea and vomiting" and "Back pain"	Vomiting; back pain	Vomiting; back pain	Missed concept (nausea)	PLM symptom "Nausea and vomiting" retired. The separate symptoms "Nausea" and "Vomiting" remain available
10	Gluten sensitivity	Merged into PLM symptom "Gluten intolerance"	Gluten intolerance	Celiac disease	Outdated MedDRA version; coding appropriate for this version of MedDRA, but more appropriate terms available in newer versions. Recommend coding to: LLT Gluten sensitivity; PT Gluten sensitivity	Coding updated after upgrade to more recent MedDRA version
11	Shocked by electricity house	Merged into PLM symptom "Seizures (grand mal or tonic–clonic)"	Tonic-clonic seizures	Grand mal convulsion	Unable to assess. Not clear from information how this could be determined	Communications with patient indicated this was reference to seizures

[a]PLM: PatientsLikeMe.

[b]FDA: Food and Drug Administration.

[c]LLT: lowest-level term.

[d]PT: preferred term.

[e]N/A: not applicable.

[f]INR: international normalized ratio

Example 3 shows that in some other instances, PLM symptoms are intentionally coded into more general MedDRA terms to help connect patients with similar experiences. PLM members reporting "drop foot" are assigned the same symptom in the PLM terminology regardless of the cause. Thus, the patient submission "drop foot from surgery" was merged into "Foot drop," an existing symptom in PLM terminology. "Foot drop" was then coded to the MedDRA LLT *Foot drop*, which is subsumed under the PT *Peroneal nerve palsy.* The FDA reviewer noted that although this was an acceptable choice for the concept, the more specific LLT-PT *Peroneal nerve palsy postoperative* is preferable because it captures the additional information that the foot drop was consequent to a surgery. However, all patients reporting "drop foot" are assigned the same symptom in the PLM terminology regardless of the cause.

Example 4 demonstrates how PLM aggregates experiences related to "sexual dysfunction," even though this likely refers to distinct manifestations for different genders. Patients have the option to add more specific symptoms, which are coded to more specific MedDRA terms when appropriate, such as "impotence" (coded to LLT *Impotence*) or "loss of sex drive" (coded to LLT *Libido loss*).

Examples 5, 6, and 7 illustrate the items in which the PLM-assigned MedDRA terms did not align with the MTS:PTC guide. In example 5, the selected MedDRA term was not medically accurate for the patient submission of "irrational emotions." Although the LLT *Mixed disturbance of conduct and emotions* appears at first to be a reasonable option, it is subsumed under the PT *Antisocial behavior*, which the FDA reviewer determined was not an appropriate code. PLM agreed and updated the coding for this symptom as per the reviewer's recommendation and investigated what may have contributed to the selection of the incorrect term. The likely reason is that only the name of the MedDRA LLT was visible during the data entry process for adding or editing a symptom in PLM terminology. The LLT's association to a PT and higher levels in the MedDRA's hierarchy was not displayed. When adding the new symptom "irrational emotions" to the PLM terminology, the original PLM coder would not have likely selected the LLT *Mixed disturbance of conduct and emotions* if they had been aware of its associated MedDRA PT. Example 6 shows how 2 related medical concepts, irregular heartbeats and cardiac arrhythmias, were considered as a single item in the PLM terminology. PLM codes certain symptoms with both the clinical terminology and more patient-friendly terminology to facilitate patients' tracking their condition and connecting with other PLM patients with similar conditions. However, the MTS:PTC guide states that if both a diagnosis (eg, cardiac arrhythmia) and its characteristic signs or symptoms (eg, irregular heartbeats) are reported, the MedDRA term for the more definitive diagnosis should be selected. PLM has since updated its coding process to reflect this rule. Example 7 was coded incorrectly because it only captured the laboratory result as abnormal, rather than a directional change as specified in the patient submission. In this case, PLM also updated the coding to reflect the increased laboratory value.

Examples 8 and 9 are both instances in which a concept was missed by PLM's coding, although the reasons for missing the concepts are distinct. In example 8, an additional MedDRA term should have been selected. In example 9, the missing concept, "nausea," is captured in the name of the PLM symptom "nausea and vomiting," but the assigned term (vomiting) does not capture this additional information. As a result, the symptom named "nausea and vomiting" was retired from patient search in the PLM terminology; patients can now add "nausea" and "vomiting" as separate and distinct symptoms to their profile.

In example 10, the FDA reviewer identified a more appropriate term. Further investigation of this example and other similar instances revealed that the recommended terms were available only in more recent MedDRA versions. Once PLM integrated the most recent MedDRA version into the platform, this coding was updated.

Example 11 demonstrates 1 of the 95 items that were flagged as "unable to assess" and had been excluded from the final evaluation. In these instances, the record available to the FDA reviewer did not contain all the information PLM had when assigning the MedDRA term, which was necessary to determine if the coding was appropriate.

Discussion

Principal Findings

This examination of coding of PLM PGHD to the MedDRA terminology revealed high concordance (3140/3234, 97.09%) between how PLM PGHD were coded to MedDRA and how the same submissions would be coded to MedDRA based on the MTS:PTC guide. The remaining 2.91% (94/3234) discordant coding instances revealed some important conceptual differences. Namely, the coding for regulatory purposes focuses on capturing the most specific information reported to a postmarketing safety surveillance program for ADEs and medication errors. Coding in the PLM scenario, however, requires first coding PGHD to patient-friendly terms in the curated PLM terminology and then coding the PLM terminology to established medical terminologies such as MedDRA to organize and aggregate medical information. In some instances, PLM codes to a more generalized MedDRA term to facilitate patients with similar symptoms or conditions in more easily finding each other on the PLM platform and sharing their experiences. For example, a patient may report a specific term such as "petit mal seizure," on the PLM platform, but the reported concept would be grouped under a generalized term in the PLM terminology ("seizure," LLT *Seizure*), whereas the same verbatim event ("petit mal seizure") would be coded with specificity in FAERS (LLT *Petit mal*). PGHD data, if they are to serve the dual purposes of facilitating patient discussion and allowing for adverse event detection, need to have sufficient flexibility in coding to achieve the former goal while retaining the general adherence to the medical concepts that underlie coding in the first place. Users of these data need to understand the coding approach to optimize their data retrieval strategy.

This analysis reinforced the importance of several best practices. For example, when selecting a MedDRA term, it is essential to view the LLT-PT association and preferably the entire MedDRA hierarchy for the selected LLT to determine whether the term is, indeed, the most appropriate one. In addition, optimal coding results are achieved when using the latest available MedDRA version. It is important to conduct data coding quality reviews at regularly scheduled intervals.

Limitations

Only a portion of the PLM MedDRA coding terminology was assessed to keep the dataset to a reasonable length. In addition, the PLM platform contains more information than the FDA reviewer had available in the dataset. Free-text information, which may have been private message communications about PGHD or information on the patient profile, was not shared with the FDA reviewer as it could have included personally identifiable information. Information from other structured sections of the profile (such as previously reported ADEs, symptoms, and treatments) was also available to PLM during the process of curating the PGHD but was not included in the data file provided to the FDA reviewer.

Conclusions

This review demonstrates that PGHD consisting of signs, symptoms, and ADE data entered by patients in curated structured fields can be reliably coded to the MedDRA terminology and that the coding of these data by PLM is generally aligned with MTS:PTC principles. Understanding the coding purpose and approach is informative for the optimization of data retrieval strategy. These findings suggest that efficient electronic searching and aggregation of PGHD might be possible when consistent, systematic curation processes are applied to PGHD as they are reported by patients. This standardization makes PGHD more electronically accessible and therefore elevates the visibility and importance of events patients find most significant.

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The MedDRA trademark is owned by the International Federation of Pharmaceutical Manufacturers and Associations on behalf of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Authors' Contributions

SB and DAB designed the research. SB, DAB, MZ, and CC conducted the research and analyzed the data. SB, DAB, MZ, and SO drafted the manuscript. CAP and MH revised it. All authors read, provided feedback, and approved the final manuscript.

Conflicts of Interest

DAB, MZ, CC, and SO are employees of PatientsLikeMe and hold stock options in the company. MH is a former employee of PatientsLikeMe and does not hold stock options in the company. The PatientsLikeMe Research Team has received research funding (including conference support and consulting fees) from AbbVie, Accorda, Actelion, Alexion, Amgen, AstraZeneca, Avanir, Biogen, Boehringer Ingelheim, Celgene, EMD, Genentech, Genzyme, Janssen, Johnson & Johnson, Merck, Neuraltus, Novartis, Otsuka, Permobil, Pfizer, Sanofi, Shire, Takeda, Teva, and UCB. SB and CAP are employees of the US Government. The opinions expressed in this manuscript are those of the authors and not intended to represent the opinions of the United States Food and Drug Administration. MH reports no conflicts of interest.

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Abbreviations

ADE: adverse drug event
FAERS: FDA Adverse Event Reporting System
FDA: Food and Drug Administration
HGLT: high-level group term
HLT: high-level term
ICH: International Council on Harmonisation
INR: international normalized ratio
LLT: lowest-level term
MedDRA: Medical Dictionary for Regulatory Activities
MTS:PTC: MedDRA Term Selection: Points to Consider
PGHD: patient-generated health data
PLM: PatientsLikeMe
PT: preferred term
SOC: system organ class

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Review

Three-Dimensional Portable Document Format (3D PDF) in Clinical Communication and Biomedical Sciences: Systematic Review of Applications, Tools, and Protocols

Axel Newe[1,2], Dipl-Ing (FH), Dr; Linda Becker[3], Dipl-Psych, Dipl-Phys, Dr

[1]Chair of Medical Informatics, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany

[2]NewTec GmbH, Pfaffenhofen an der Roth, Germany

[3]Chair of Health Psychology, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany

Corresponding Author:
Axel Newe, Dipl-Ing (FH), Dr
Chair of Medical Informatics
Friedrich-Alexander University Erlangen-Nürnberg
Wetterkreuz 13
Erlangen, 91058
Germany
Phone: 49 913185 ext 26720
Fax: 49 91318526754
Email: axel.newe@fau.de

Abstract

Background: The Portable Document Format (PDF) is the standard file format for the communication of biomedical information via the internet and for electronic scholarly publishing. Although PDF allows for the embedding of three-dimensional (3D) objects and although this technology has great potential for the communication of such data, it is not broadly used by the scientific community or by clinicians.

Objective: The objective of this review was to provide an overview of existing publications that apply 3D PDF technology and the protocols and tools for the creation of model files and 3D PDFs for scholarly purposes to demonstrate the possibilities and the ways to use this technology.

Methods: A systematic literature review was performed using PubMed and Google Scholar. Articles searched for were in English, peer-reviewed with biomedical reference, published since 2005 in a journal or presented at a conference or scientific meeting. Ineligible articles were removed after screening. The found literature was categorized into articles that (1) applied 3D PDF for visualization, (2) showed ways to use 3D PDF, and (3) provided tools or protocols for the creation of 3D PDFs or necessary models. Finally, the latter category was analyzed in detail to provide an overview of the state of the art.

Results: The search retrieved a total of 902 items. Screening identified 200 in-scope publications, 13 covering the use of 3D PDF for medical purposes. Only one article described a clinical routine use case; all others were pure research articles. The disciplines that were covered beside medicine were many. In most cases, either animal or human anatomies were visualized. A method, protocol, software, library, or other tool for the creation of 3D PDFs or model files was described in 19 articles. Most of these tools required advanced programming skills and/or the installation of further software packages. Only one software application presented an all-in-one solution with a graphical user interface.

Conclusions: The use of 3D PDF for visualization purposes in clinical communication and in biomedical publications is still not in common use, although both the necessary technique and suitable tools are available, and there are many arguments in favor of this technique. The potential of 3D PDF usage should be disseminated in the clinical and biomedical community. Furthermore, easy-to-use, standalone, and free-of-charge software tools for the creation of 3D PDFs should be developed.

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KEYWORDS

3D PDF; 3D visualization; interactive; clinical communication; biomedical science; tools; protocols; apps; online data sharing; scholarly publishing; electronic publishing

Introduction

Background

The best-known and most widely used data format for the exchange of electronic documents is probably the Portable Document Format (PDF), which was standardized by the International Organization for Standardization (ISO) as ISO 32000-2:2017 [1]. Software that can read PDFs is installed on nearly every computer, and most internet browsers and email clients have a built-in PDF renderer. This, in many cases, makes this format the best means for the exchange of electronic documents. However, the PDF offers more features than many people are aware of. Although technically available since 2005, a still lesser-known standard feature of the PDF is the possibility to embed three-dimensional (3D) models, which enables the interactive visualization (eg, zooming, panning, rotating, and selection of components) of such objects with qualified reader software (Figure 1; for an interactive version of this figure, see Multimedia Appendix 1).

A PDF document with embedded 3D objects (3D PDF) has high potential in almost every scenario in which 3D objects should be visualized and exchanged between different platforms (eg, computers with different operating systems). A highly relevant use case is the exchange of medical and biomedical data (eg, the visualization of human anatomy for medical students [2] or clinical data such as the results of surgery planning [3,4]). Therefore, this feature is also considered in the standard AIIM/ASTM BP-01-2008 "Portable Document Format-Healthcare (PDF) A Best Practices Guide" (also known as PDF Healthcare or PDF/H) [5,6]. This standard describes how to use the PDF to exchange and preserve digital health care information in a safe and secure way.

In addition to the exchange between a few persons (eg, a doctor and a patient), 3D PDF offers a very efficient and convenient way for distributing 3D structures through the scientific community by embedding 3D objects into scientific publications.

The primary aim of this review was to investigate the significance of 3D PDF in clinical communication and in scholarly publications in the biomedical sciences. The secondary aim of this review was to provide an overview of the technical possibilities and to present all currently available solutions for creating 3D PDFs and related model files.

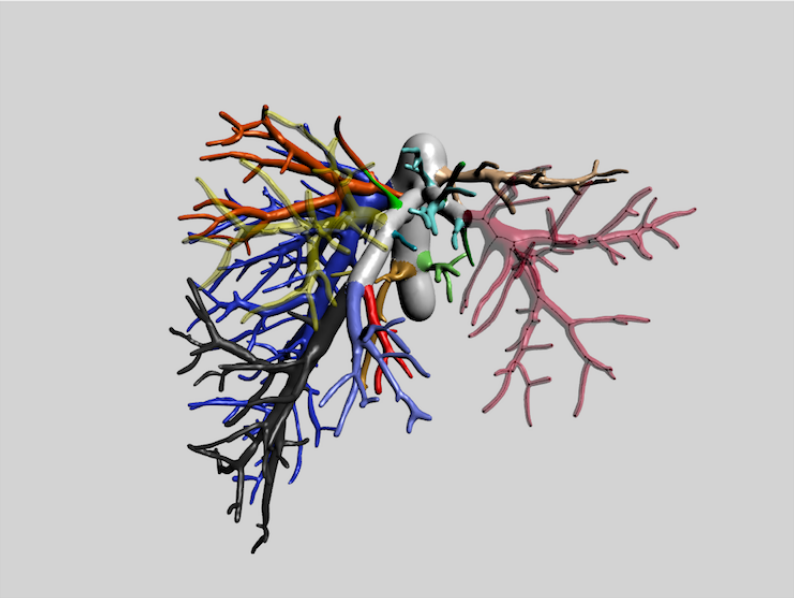
The Portable Document Format

The PDF is a computer file format for the platform-independent definition of electronic documents [1]. It allows for describing electronic documents with preserved fidelity, independently of the software, device, and operating system used to create, display, or print them. Furthermore, PDF is capable of encapsulating all necessary resources (eg, texts, images, or multimedia elements). Along with the open accessibility of the specification, this has led to PDF being the most commonly used file format for the exchange of electronic documents. For example, all scholarly journals allow for an electronic publication of their articles in PDF today.

The PDF was originally developed by Adobe Systems and evolved in the early 1990s from the PostScript page description language for printers. The first specification of PDF was published in 1993; since then, it has been developed further by Adobe until version 1.7 [7], which was released in 2006. This version was given to the ISO, which re-released this specification as ISO standard 32000-1:2008 in July 2008 [8]. The latest version (PDF 2.0) was published in July 2017 [1,9].

The PDF is now the de facto standard for the exchange of electronic documents. The original Adobe Reader software alone has been distributed more than 500 million times around the world [7], and countless other apps for displaying PDF documents are available. For example, Quartz 2D, the native graphics rendering interface for two-dimensional (2D) graphics of the macOS X and iOS operating systems, is based on the PDF specification, (ie, it is an integral part of these operating systems) [10].

Figure 1. Vessel tree of a liver. See Multimedia Appendix 1 for 3D PDF version of this figure and Multimedia Appendix 2 for a 3D PDF version of this entire article.



The Development of the Three-Dimensional Portable Document Format

Version 1.6 of the PDF specification, published in 2004 [11], introduced the capability to embed 3D objects, such as those used by software for computer-aided design, into PDF files. At the time of the introduction of this new feature, the format for the data of 3D objects needed to be Universal 3D (U3D), a file format developed by the 3D Industry Forum (which Adobe was part of) as "a single, common, and open 3D standard" and "JPEG for 3D" [12]. U3D is standardized by the European Computer Manufacturers Association (ECMA) as ECMA-363 [13]. The first software to support 3D Artwork (the PDF term for 3D objects in PDF files) was the Adobe Reader 7 (and Adobe Acrobat 7, respectively), published in January 2005. However, the first software that really allowed for an efficient and convenient working with 3D models in PDF was Acrobat 3D, released in early 2006. This version provided tools for the import and conversion of many 3D formats and a 3D editor [14].

In late 2006, Adobe added the ability to embed 3D models in Product Representation Compact (PRC) format into PDF (PDF BaseVersion 1.7, ExtensionLevel 1 [15]), but this feature has not been integrated into the ISO standard 32000-1 from 2008. It took 11 years until the release of PDF 2.0 (32000-2:2017) in July 2017 to formally integrate PRC as 3D format into the PDF standard. However, the support of editing features for 3D was discontinued in later versions of Adobe Acrobat. Acrobat 9 Pro Extended was the last version to include tools for conversion and editing of 3D models. Instead, this functionality has been outsourced to third-party software and has been sold separately since 2010 [16].

Another feature that is notable in this context is the support of JavaScript. This feature was introduced with PDF 1.3 in July 2000 [17] and allows for executing JavaScript commands within a PDF document (eg, after clicking an embedded button or after activating a 3D model).

Relevance of Three-Dimensional Portable Document Format

Especially in the biomedical domain, the importance of 3D data has grown in recent years (eg, visualization of chemical molecules, anatomy, or vessel systems). With the availability of the necessary technology for the visualization of such 3D data, this technology should consequently be used to avoid a loss of information [18]. This is of particular relevance in scholarly publishing [19]. Furthermore, 3D PDF has a very high potential for the exchange of medical data in clinical communication [3] because it allows for in situ publishing of 3D figures [20].

Objectives

It has tremendously high potential for clinical communication, many scholarly articles would benefit from interactive visualization of 3D data [19], publishers encourage their authors to use 3D PDF technology [21,22], and some journals provide the necessary tools [23], yet it still does not seem to be common use. Thus, the initial motivation for writing this review paper was to test this hypothesis (ie, that using 3D PDF technology is not common in clinical communication or in biomedical publications). Therefore, as the primary goal, an overview was to be created of the dissemination of 3D PDFs in biomedical publications. The scope was not limited to purely clinical use cases to cover as wide a range of possible apps in all fields of medically relevant research. Furthermore, we will investigate in which research areas and use cases 3D PDF has been applied since the advent of this technology.

After the initial hypothesis was confirmed (200 articles were found over a period of 10 years; see Results), we hypothesized three possible reasons:

1. The existence and/or possibilities of 3D PDF might not be well known among the scientific and clinical community.

2. The necessary knowledge that would enable authors and possible users to actually make use of 3D PDFs might be hard to acquire.
3. The creation of appropriate model files and of final PDF documents might be an overly cumbersome process.

Therefore, the secondary goal of this review was to tackle the previous three issues by providing an overview of (1) existing publications that apply 3D PDF technology to demonstrate its possibilities, (2) available protocols for the creation of 3D PDFs to provide the basic knowledge in compressed form, and (3) existing software tools for the creation of model files and 3D PDFs to show ways to simplify the process.

Although the overview of the existing publications that apply 3D PDF technology in this field may elaborate new ideas of how this form of visualization could augment scholarly communication in biomedicine, the presented protocols and tools can probably be applied in other fields as well.

Methods

General Procedure

A systematic literature search was performed in the scientific databases PubMed [24] and Google Scholar [25] to find articles that either applied 3D PDF technology for visualization purposes or articles that generally dealt with the subject of 3D PDF in the context of biomedical sciences.

Because PDF is a vehicle for presenting data rather than an actual research topic, it was likely that a simple database search for this term would not reveal comprehensive coverage of the literature, especially for articles that simply used 3D PDF as a means for visualization. Therefore, a search strategy with two iterations was conceived (see detailed description subsequently). Agreement about this strategy, the inclusion criteria, and the review protocol (see respective sections subsequently) was reached through discussion between all authors.

The first search was performed by AN on March 6, 2017. Three update searches were performed by AN on September 30, 2017, January 1, 2018, and April 30, 2018. The search results were screened and checked for eligibility independently by AN and LB on the basis of predefined inclusion criteria. The remaining articles that were entered into the further analysis were reviewed by means of a predefined review protocol by AN and LB independently.

Search Strategy

As mentioned previously, we conceived a two-tiered search strategy (Figure 2). The first iteration was a PubMed search with the following search term: "(((3d) OR (3-d) OR (three dimensional) OR (interactive) OR (surface model)) AND ((pdf) OR (portable document format))) AND ("2005"[Date-Publication]: "3000"[Date-Publication])".

The goal of this initial search was to reveal all biomedical publications that mentioned 3D PDFs without the most common unwanted meanings for "PDF." It was limited to articles published after 2004 because 3D PDF technology was not available before 2005.

The results of this first iteration were then screened to exclude articles that did not fulfill the inclusion criteria. The remainders, which will subsequently be referred to as "primary results," were then analyzed to identify articles that were cited as a source of 3D PDF creation (referred to as "tool articles;" see a more detailed explanation subsequently). Next, both PubMed and Google Scholar were searched for articles that cited these tool articles to identify more articles that applied or mentioned 3D PDF and that could not be found via the initial PubMed search. The results of this second iteration were then also screened for the inclusion criteria and the remaining articles (referred to as "secondary results") went into the review process along with the primary results and the tool articles.

Finally, a small number of additional articles that were known to us to be eligible, but which were not discovered by the systematic search, were included as well. Further details about the search strategy, the search results, and the screening results are available in Multimedia Appendix 3.

Inclusion Criteria

The general inclusion criteria for this review were defined as follows: (1) articles from the biomedical domain that applied 3D PDF for visualization or articles that presented protocols or tools for the creation of 3D PDFs or for the creation of 3D PDF-specific, intermediate file formats (U3D or PRC); (2) articles in English language only; and (3) peer-reviewed articles only.

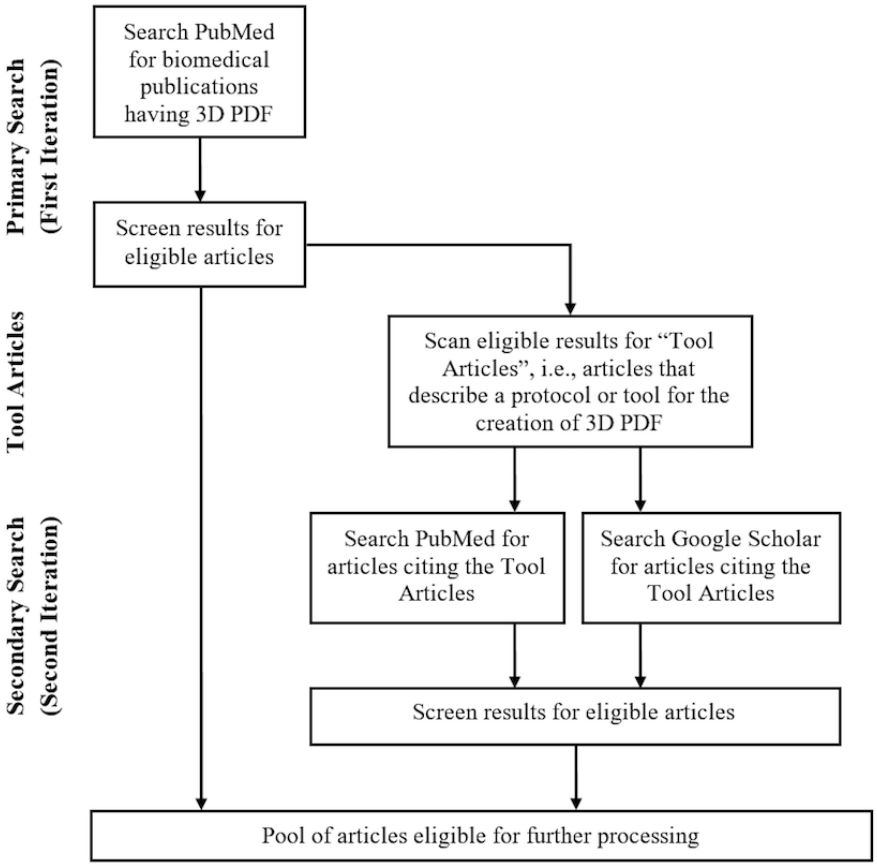
Review Protocol

To fulfill all these objectives, all eligible articles were first classified into article types using four categories:

1. Application: articles that applied 3D PDF technology for visualization.
2. Descriptive: articles that described a way, method, or idea how to use or to utilize 3D PDF technology.
3. Tool: articles that described a method, protocol, software, library, or other means for the creation of 3D PDFs or model files.
4. Mentioning only: articles that only mentioned the possibility of using 3D PDF (without further details).

The assignment to more than one category (eg, descriptive and application) was allowed.

Figure 2. Search strategy.



All articles of the type "application" were then further analyzed for the 3D features used, for the availability of the 3D PDF documents, and for the file size. The following 3D PDF features were considered:

1. Geometry only: articles that only presented the geometry of the 3D model without further features.
2. Multiple colors and transparency: articles that had transparent/colored models.
3. Product Manufacturing Information (PMI)/markup: articles that used PMI features or markup for labeling objects.
4. Scripting: articles that used JavaScript for advanced interactive features.
5. Texture: articles that used textured models.
6. Animation: articles that use animations.

The availability of the 3D PDFs was classified into:

1. Embedded: articles that directly embedded 3D models into the PDF version.
2. Supplement: articles that provided supplemental information files with 3D PDFs.
3. Link to external resources: articles that provided the URL or mail address for accessing the referred 3D PDFs.

Finally, all articles were classified into a scientific discipline (eg, "medicine," "embryology," or "human anatomy"; for a full list see Multimedia Appendix 4) and the clinically relevant articles were analyzed further.

Results

Search Results

The initial PubMed search retrieved 123 publications; after the third update search, a total of 237 publications were found. After screening these PubMed results, 109 articles were excluded because "PDF" was not used as an acronym for "Portable Document Format," one was excluded because it was not in English language, one was excluded because it did not cover a biomedical topic, and eight were excluded because they were an erratum only (ie, not a peer-reviewed article). During the full-text eligibility assessment, 65 more articles were excluded because they had no content relevant for 3D PDF. The initial analysis of the remaining 53 primary results revealed 19 tool articles, with 15 of them being duplicates (ie, four new tool articles were identified).

The second iteration (ie, the search for articles citing the tool articles) retrieved a total of 128 articles from PubMed and 537 articles from Google Scholar after the third update. After removing 356 duplicates, 366 articles were screened. Of those, 22 were excluded because they were not in the English language and 43 were excluded because they were not peer reviewed. During the full-text eligibility assessment, 48 articles were excluded because they did not fall into the biomedical domain and 63 more articles were excluded because they had no content relevant for 3D PDF. That resulted in 133 articles from the second iteration. Together with the 53 articles of the first iteration, the four additional tool articles, and 10 articles that were included due to our knowledge, 200 articles were included

in the final analysis, which is shown in a modified Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram [26] in Figure 3.

Overall Analysis Results

Of the total 200 articles, the simple possibility of using 3D PDF (without providing further details) was mentioned in 13 articles (6.5%) [27-39]. Another 18 (9.0%) [2,3,23,40-54] articles described a way, method, or idea how to use or to utilize 3D PDF technology and 19 articles (9.5%) [20,40,55-71] described a method, protocol, software, library, or other means for the creation of 3D PDFs or model files.

In 156 (78.0%) articles, 3D PDF technology was actually applied for the visualization of research results. In 11 (7.1%) more articles, it was claimed that 3D PDF should be available, but no 3D model could be found [58,72-81]. Of the 156 articles with applied 3D PDF technology, 34 (21.8%) [40,55-57,61,64,68,82-108] had the 3D content directly embedded into the PDF of the article, 94 (60.3%) [20,48,59,60,63,66,67,109-195] articles provided the 3D content as supplementary material, and 28 (17.9%) [4,41,62,196-220] referred to an external resource. The 34 articles in which the 3D objects were embedded directly into PDF of the main article were published in 25 different journals.

Different features of 3D PDF were used. In seven articles (4.5%), only the basic geometry was displayed, but in a majority of articles (146/156, 93.6%), at least multiple colors or transparencies were used. More advanced features such as PMI/markup (11/156, 7.1%), scripting (29/156, 18.6%), or textures (28/156, 17.9%) were used rarely. Only one article (0.6%) made use of the animation feature [67].

The disciplines were manifold. In most cases either animal (86/200 total article, 43.0%) or human (33/200, 16.5%) anatomies were visualized. The other fields were general science (34/200, 17.0%), biochemistry (14/200, 7.0%), embryology (14/200, 7.0%), clinical/medicine (13/200, 6.5%), biology (3/200, 1.5%), statistics (1/200, 0.5%), bioinformatics (1/200, 0.5%), and astronomy (1/200, 0.5%).

The file size ranged between 0.2 and 429 mebibyte (MiB) (mean 29.9, SD 59.9 MiB). An analysis by year of publication is provided in Table 1; a detailed analysis for each publication is available in Multimedia Appendix 4.

Three-Dimensional Portable Document Format in Clinical Use Cases

We found 13 publications covering the use of 3D PDF for medical purposes. Eight of them could be assigned to the clinical field, whereas the other five were studies about the value of 3D PDF as educational material for students of medicine. Only one article described a use case from a clinical routine operation: the distribution of results from computer-aided planning for liver surgery [3]. The evaluation of the acceptance and the user experience in this study turned out to be very good. This confirms that the usage of 3D PDF for clinical communication in telemedicine is practicable and highly accepted by the users, and that it has many advantages over 2D technology. The method described there has been used for research as well [221].

Figure 3. Modified PRISMA flowchart.

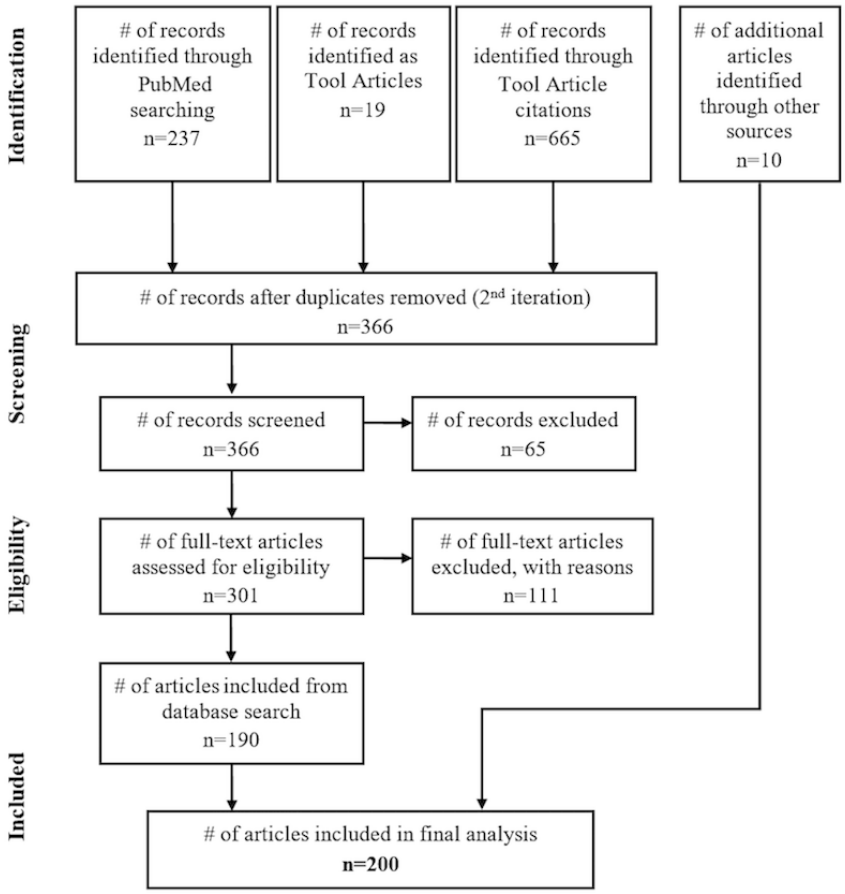


Table 1. Number of publications dealing with 3D PDF by type (assignment to more than one article type was possible).

Year	Article type, n				Total, n
	Tool	Application	Descriptive	Mentioning	
2008	3	5	—	—	5
2009	—	6	1	—	7
2010	2	9	—	1	13
2011	3	13	1	1	18
2012	2	13	2	1	18
2013	4	20	1	2	24
2014	1	23	5	2	28
2015	1	31	2	—	34
2016	1	18	3	1	25
2017	1	12	2	4	19
2018 (until April)	1	6	—	1	9

All other publications with clinical applications of 3D PDF reported pure research work. Day and colleagues [109] demonstrated that preoperative 3D modeling of magnetic resonance imaging data of fistula-in-ano can reduce confusion and ambiguity among surgeons when interpreting 3D PDF reports instead of complex textual reports. The benefit of 3D PDF for the simulation of surgical procedures was described by Mavar-Haramija and colleagues [4,41] for endoscopic endonasal interventions. Husch and colleagues [192] demonstrated how automatically generated 3D PDF reports can be used to visualize and assess the spatial relationships between electrodes and brain structures and to detect misplaced electrodes in a postoperative deep brain stimulation setting. Finally, the findings of Elbashti and colleagues [54] emphasized the value of 3D PDF for clinical communication with their study on the use of 3D PDF for the documentation of maxillofacial prostheses.

Another area where 3D PDF has proven valuable is patient education. Both the telemedicine study on liver surgery mentioned previously [3] and another study by Prats-Galino and colleagues [197] pointed out that 3D PDF can make it much easier to convey the necessary understanding of a planned procedure, its risks, and future consequences to a patient.

Several other studies showed that 3D PDF is a good means to help students understand anatomy [2,27,42,198] or surgical procedures [199].

Interim Summary

Overall, within the investigated period of 10 years, only 200 articles were found that used or described the usage of 3D PDFs in biomedical science, with 13 of them covering clinical topics. Compared to the importance of 3D data in the biomedical domain and thus to a presumed number of several thousand publications containing 3D data in some form, this is a tiny fraction. Therefore, we hypothesized about possible reasons for this. We assumed that the lack of 3D PDF usage might be due to one of the following reasons (see Introduction): (1) the existence and/or possibilities of 3D PDF might not be well known among the scientific community, (2) the necessary knowledge that would enable authors to actually make use of 3D PDF might be hard to acquire, and (3) the creation of appropriate model files and of final PDF documents might be an overly cumbersome process.

A verification of these hypotheses would be out of scope of this review. However, assuming these are true, it is possible to mitigate the causes of these hypothesized problems on the basis of the publications that were already collected: hypothesis 1 might be mitigated by the pure existence of this review in general, and both hypotheses 2 and 3 might be mitigated by providing an overview of the protocols and software for creating PDFs that have been published so far.

Protocols and Software for Creating Three-Dimensional Portable Document Format

Of the total of 200 articles, the tool articles (ie, articles that described a method, protocol, software, library, or other means for the creation of 3D PDFs or model files) accounted for 19 articles (9.5%) [20,40,55-71] (Tables 2 and 3; a combined table is available in Multimedia Appendix 5). These tools can be classified into two groups: (1) protocols that described all necessary artifacts and steps for a creation workflow, and (2) software libraries or software apps that could produce 3D PDFs or necessary intermediate file formats (U3D or PRC).

The following is a description of all these tools (software and protocols) that have been published in the biomedical field. It is intended to be used as a reference for authors that are interested in using 3D PDF technology for their publications or for applied medical use (eg, as demonstrated in [3]). However, especially the older protocols rely on software that is no longer available and that has no successor with the same functionality. For a quick overview, see Tables 2 and 3, and see Multimedia Appendix 5 for a more detailed analysis.

The first protocol that described the workflow for the creation of a 3D PDF was presented by Kumar and colleagues [55] in 2008 and required a minimum of four steps as well as the usage of commercial software and three intermediate file formats. It is based mainly on Adobe Acrobat 3D, which is no longer available today. Another very simple protocol was presented by Barnes and Fluke [222] in 2008: along with their S2PLOT [223] library for the programming languages C, C++, and Fortran, only the Adobe Acrobat 3D software was needed. The S2PLOT library was later extended to provide additional features for creating PRC files (described subsequently). At around the same time, Ruthensteiner and Heß [57] published their protocol for the creation of 3D PDFs of biological specimens. It consisted of 11 steps, including four related to the processing of the sample itself. This protocol relied on commercial software as well: Adobe Acrobat 3D and Adobe 3D Toolkit, both of which are no longer available today.

Approximately two years later, Kumar and colleagues [58] presented a protocol for the generation of 3D PDFs of molecules that required a minimum of four steps. Although this protocol was generally based on commercial software, which in part is no longer available, it also shows an alternative way by using the well-known document preparation system LaTeX [224] in combination with the movie15 package [225]. However, the use of LaTeX requires a model file in U3D format, which needs to be created with other software.

Two months later, Ruthensteiner and colleagues [59] presented an update of the 2008 article that included the S2PLOT library and that focused on virtual volume rendering in PDF documents. This protocol included for the first time the scripting feature of PDF. The need for commercial software, however, had still not been eliminated. At the beginning of 2012, de Boer and colleagues [60] published a very detailed protocol for the creation of 3D PDFs that described all necessary steps for a basic process and an advanced process on seven pages. It also relied on commercial software (Amira, Adobe Acrobat 9 Pro Extended, Adobe Illustrator), but for the first time it allowed for embedding custom control elements for selecting structures of predefined views of the 3D figure. One month later, Ziegler and colleagues [40] demonstrated how to incorporate a variety of multimedia elements into PDF, including a textured 3D figure (an interactive model of a human face). This publication also mentioned the possibility of using LaTeX to create the final PDF. In August 2011, Danz and Katsaros [61] published their protocol, which was based on a combination of free software (for model generation) and commercial software (for PDF creation). One year later, Shin and colleagues [62] also released a protocol that was still purely based on commercial software; 4 months later, Phelps and colleagues [63] presented another solution that combined a workflow of 22 steps using commercial and noncommercial software. Finally, Lautenschlager [64] published in 2013 another protocol that required a wide range of commercial and noncommercial software.

Table 2. Overview of requirements, restrictions, and possible output of the tools presented in the tool articles. For features, see Table 3.

Article	Software needed		Output	Programming needed[a]
	Commercial	Free		
Articles presenting a protocol				
Kumar et al [55]	Adobe Acrobat 3D[b], Adobe Acrobat 3D Toolkit[c], Adobe Photoshop, Adobe Illustrator		Model file, final PDF	No
Barnes & Fluke [56]	Adobe Acrobat 3D[b]	S2PLOT	Final PDF	Yes
Ruthensteiner & Heß [57]	Amira, Adobe Acrobat 3D Toolkit[b], Adobe Acrobat 3D[b]		Model file, final PDF	No
Kumar et al [58]	Adobe Acrobat 9 Pro Extended[d], Adobe Acrobat 3D Reviewer[b]	LaTeX, MeshLab	Model file, final PDF	No
de Boer et al [60]	Amira, Adobe Acrobat 9 Pro Extended[d], Adobe Illustrator		Final PDF	No
Ziegler et al [40]	Adobe Acrobat 9 Pro Extended[c,d]	LaTeX	Final PDF	No
Danz & Katsaros [61]	Adobe Acrobat X Pro[d], Tetra 4D 3D PDF Converter plug-in for Acrobat	MeshLab, DAZ Studio		No
Shin et al [62]	Mimics, Autodesk Maya, Deep Exploration[d], Adobe Acrobat 9 Pro Extended[d]		Final PDF	No
Phelps et al [63]	Microsoft PowerPoint, Adobe Acrobat	MeshLab	Model file, final PDF	No
Lautenschlager [64]	Amira, Mimics, Adobe Acrobat 8 Pro[b]/9 Pro Extended[d], Adobe Acrobat 3D Reviewer[b], Adobe Acrobat 3D Toolkit[b], Tetra 4D 3D PDF Converter plug-in for Acrobat, GeoMagic Studio[c], Abaqus FEA[c], Avizo[c], VG Studio Max[c], Autodesk Maya[c]	MeshLab, LaTeX, Drishti[d], SPIERSedit[d], Blender[d], DAZ Studio[d]	Model file, final PDF	No
Mavar-Haramija et al [65]	Amira, Adobe Acrobat 9 Pro Extended[d], Adobe Acrobat 3D Reviewer[b], Tetra 4D 3D PDF Converter plug-in for Acrobat		Model file, final PDF	No
van de Kamp et al [67]	Amira or Avizo, Cinema 4D, Deep Exploration[d], Adobe Acrobat 9 Pro Extended[d]		Model file, final PDF	No
Zhang et al [70]		libHaru	Model file, final PDF	Yes
Articles presenting a protocol and a library				
Ruthensteiner et al [59]	Deep Exploration[d], Adobe Acrobat 9 Pro Extended[d]	Amira, S2PLOT, ImageMagick,	Model file, final PDF	Yes
Barnes et al [20]		Asymptote, S2PLOT, LaTeX, libHaru	Model file, final PDF	Yes
Articles presenting a software app				
Newe & Ganslandt [66]		MevisLab	Model file	No
Newe [68]		MevisLab	Model file	No
Newe [69]		MevisLab	Model file, final PDF	No
Brandner et al [71]		MevisLab	Model file, final PDF	No

[a]Solution requires the creation of individually tailored software code. Usage of LaTeX is not considered as "programming."

[b]Software is no longer available.

[c]Optional.

[d]Software is no longer available, but a successor which provides the same functionality is available.

Table 3. Overview of features of the tools presented in the tool articles (PDF: Portable Document Format).

Article	Supported geometry type			Supported 3D PDF features					
	Mesh	Polyline	Point cloud	Multiple colors	PMI/markup	Scripting	Texture	Animation	Poster image
Articles presenting a protocol									
Kumar et al [55]	x	x	x	x		x	x	x	x
Barnes & Fluke [56]	x	x	x	x		x	x		
Ruthensteiner & Heß [57]	x	x	x	x		x	x	x	x
Kumar et al [58]	x			x		x			
de Boer et al [60]	x			x	x	x	x		
Ziegler et al [40]	x	x	x	x	x	x	x		
Danz & Katsaros [61]	x								
Shin et al [62]	x			x			x		
Phelps et al [63]	x			x					
Lautenschlager [64]	x			x			x	x	x
Mavar-Haramija et al [65]	x	x	x	x		x			
van de Kamp et al [67]	x			x				x	
Zhang et al [70]	x	x	x	x					
Articles presenting a protocol and a library									
Ruthensteiner et al [59]	x	x	x	x	x	x	x		x
Barnes et al [20]	x	x	x	x	x	x	x	x	
Articles presenting a software app									
Newe & Ganslandt [66]	x			x					
Newe [68]	x	x	x	x					
Newe [69]	x	x	x	x					x
Brandner et al [71]	x	x	x	x			x		x

The first solution that could be used without any commercial software was presented by Barnes and colleagues [20] in September 2013 (ie, 5 years after the first appearance of 3D PDF in biomedical publications). It was based on a number of free software tools and libraries (Asymptote [226]; S2PLOT; LaTeX, libHaru [227]). Although this solution could be used to create both model files and final PDFs, and it could be used free of charge, it had a major drawback: it required writing a program (ie, a certain set of programming skills was necessary to apply this protocol). On the other hand, this gave the user greater flexibility because the program code could be adapted exactly to their needs and to the specific-use case.

Only 2 months later, two more articles with tools for the creation of 3D PDFs were published. Mavar-Haramija and colleagues [4] presented another commercial software-based protocol that focused on control elements for a more sophisticated interaction with the 3D model. At the same time, Newe and Ganslandt [66] presented a noncommercial solution for the creation of model files of surface meshes in U3D format that did not require programming skills. The final PDF could not be created with that solution, but it reduced the number of steps for the creation of such model files and provided a convenient graphical user interface. However, this solution required the installation of the third-party biomedical-imaging framework, MeVisLab [228,229].

In September 2014, a previously unregarded feature of 3D PDF emerged through a new protocol: animation. Van de Kamp and colleagues [67] for the first time demonstrated the feasibility and the usefulness of animated 3D figures in electronic publications. Eight months later, Newe [68] presented an update to his previous publication that provided an advanced user interface for more flexibility. Furthermore, it provided the possibility to embed both point clouds and line sets into the interactive 3D figures. Previous publications usually only considered objects that consisted of surface meshes. However, it was still limited to the creation of model files. The creation of final PDFs was not possible.

The first all-in-one solution for the creation of both model files and the final PDF that did not require any programming was also presented by Newe [69]. The Scientific3DFigurePDFApp provided a graphical user interface for the assembly of 3D models (meshes, line set, point clouds) and included an editor for predefined views. It was also capable of producing one-paged PDF files with the embedded 3D figure that could

directly be used as supplementary figures for scientific publications.

The latest complete protocol was published by Zhang and colleagues [70] in November 2017. Although it did not require commercial software, it was also based on the libHaru library (ie, it required the writing of program code). However, this publication featured a deep insight into the U3D file format.

Finally, Brandner and colleagues [71] presented an extension to the toolbox described in [69], which added the support of textures.

Discussion

Summary of Main Findings

With this systematic review, we give an overview of the usage of 3D PDF in the biomedical domain with a special focus on clinical applications. Furthermore, we investigate which protocols and software tools for 3D PDF creation have been published so far. In addition, we hypothesize about possible barriers that might be responsible for the low dissemination of 3D PDF in clinical communication and biomedical sciences. Our primary search revealed 19 tool articles that can be considered as the roots of 3D PDF in biomedical publishing. For these articles, the scope has intentionally not been limited to the biomedical domain, because many biomedical publications seem to be inspired by the Barnes [56] publication (ie, an astronomy publication). Excluding this paper would have left several in-scope biomedical articles unrevealed (eg, [73,88,121,128,131]).

After the secondary search, in which we searched for articles that cited these tool articles, 200 articles were found overall that fulfilled the inclusion criteria and entered into further analysis. This is a very small number with respect to the fact that in the last 10 years (January 1, 2008 to January 1, 2018) a total number of 9,705,959 articles were indexed by PubMed. Even if only 1% of these articles touched the subject of 3D data, 200 articles is still a tiny fraction.

Within these 200 articles, actual 3D PDF figures were available in 156 articles (78.0%). However, the 3D content was embedded directly into the PDF version of the articles in 34 cases only. One reason for this might have been that the journals did not support the direct embedding. This matches the experience of the authors. Even some modern, online-only journals are not capable (and, in some cases, not willing) to provide the possibility to embed 3D figures directly into the PDF versions of their articles.

Possible Reasons for the Low Dissemination of Three-Dimensional Portable Document Format in Medicine and Biomedical Research

As mentioned previously, one reason might be that the journals do not support 3D PDFs. However, a further—and probably more serious reason—might be that most clinicians and scientists do not know about this feature. Although this hypothesis could not be investigated with our systematic review and it should be investigated in future research, the pure existence of this review article might help to draw attention to this technology and help to overcome this threshold.

A further reason might be that the potential target audience—although they know about 3D PDF in principle—do not know how to create 3D PDFs or that they do not have appropriate technical skills. In our systematic review, we reported the protocols and software tools that were used in the 156 articles that apply 3D technology in PDFs. Unfortunately, many of them are based on software packages that are no longer available. Furthermore, the usage of most of the reported protocols or tools needed either programming skills, advanced technical knowledge, and/or expensive, highly specialized, commercial software. Although this gives the user great flexibility because the program code can be adapted exactly to the needs and to the specific-use case, we conclude that the threshold for creating 3D PDFs is still too high and that easy-to-use, standalone software tools are needed to facilitate 3D PDF creation. Of all the software tools analyzed in this review, the solution presented by Newe [69] comes closest to this requirement because it is an all-in-one solution for the creation of both model files and final PDFs, which is operated via a graphical user interface. The major drawback of this solution is the need for the software MeVisLab, which also requires some basic training.

Potential of Three-Dimensional Portable Document Format and Future Research

Although it is not widely disseminated yet, the first approaches are very promising and show that 3D PDF has a high potential in clinical communication, in biomedical research, and in research in general. 3D PDF offers the possibility to simply distribute atlases of, for example, human or animal anatomy as demonstrated in the 3D Atlas of Human Embryology [110,200,230] or in the Visible Korean anatomy database [62,231]. It is, therefore, an alternative to traditional 2D atlases in which much of information gets lost because of the projection of a 3D object to a 2D plane [18]. Furthermore, 3D PDFs can easily be distributed via the internet or shared via emails, making it unnecessary to travel to museums all around the world, for example.

Future research should mainly focus on the development of software tools that can be used easily by everyone and without charge. Furthermore, it should be investigated (eg, by means of surveys) how well-known 3D PDF is in the biomedical and clinical community. Besides, simple instruction manuals for the existing tools are needed and should be disseminated further. Additionally, the routine usage of 3D PDF in clinical applications should be further promoted and evaluated for other disciplines than liver surgery planning. Finally, future research could also consider other domains than the biomedical one.

Limitations

Our review is subject to some limitations. First, an unknown number of articles that would fulfill the inclusion criteria may not have been found. The most probable reason for missing such an article might be that authors developed the 3D PDF on their own (without any of the tool articles) and that the availability of a 3D PDF was not necessarily pointed out in the

abstract or in the available full text. Another reason might be that a tool article was used, but not properly cited. However, 200 articles can be considered a solid basis for a review.

Based on our expertise and the high relevance of 3D PDFs in the investigated domain, the scope of this review was intentionally limited to biomedical publications. Other scientific disciplines are known to use 3D PDF as well (eg, astronomy [232], paleontology [233,234], and chemistry [235]) and may yield different results.

Second, as already mentioned, many of the protocols presented previously are based on commercial software that is no longer available and that has no successor providing the same functionality. To cover all available articles, they are still presented, but the use of the more modern protocols is recommended.

Third, a systematic review is not a suitable method to investigate the personal reasons for researchers not using 3D PDF. Other methods such as surveys are needed for this.

Conclusions

The use of 3D PDF for visualization purposes in real medical use cases or in biomedical publications is not yet fully accepted, although the necessary technique is available and there are many arguments in favor of 3D PDF. In this review paper, a wide range of examples for applied 3D PDF technology and a variety of protocols and software tools for the creation of relevant documents and files are presented. It aims to draw attention to this valuable technology, to demonstrate the possibilities, to help interested readers find a suitable solution, and lower the threshold for its use.

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Authors' Contributions

AN and LB conceived the study. AN performed the literature search. AN and LB screened the search results. AN and LB analyzed the search results. AN and LB drafted and wrote the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

3D PDF version of Figure 1.

[PDF File (Adobe PDF File), 3MB - medinform_v6i3e10295_app1.pdf]

Multimedia Appendix 2

3D PDF version of this article (best viewed with Adobe Reader 9 or later).

[PDF File (Adobe PDF File), 3MB - medinform_v6i3e10295_app2.pdf]

Multimedia Appendix 3

Overview over the search strategy and all articles that were found and processed.

[XLSX File (Microsoft Excel File), 143KB - medinform_v6i3e10295_app3.xlsx]

Multimedia Appendix 4

Detailed analysis of all eligible articles.

[XLSX File (Microsoft Excel File), 68KB - medinform_v6i3e10295_app4.xlsx]

Multimedia Appendix 5

Detailed analysis of articles that present a protocol or a software for 3D PDF creation.

[XLSX File (Microsoft Excel File), 16KB - medinform_v6i3e10295_app5.xlsx]

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Abbreviations

2D: two-dimensional
3D: three-dimensional
ECMA: European Computer Manufacturers Association
ISO: International Organization for Standardization
MiB: mebibyte, (binary) megabytes
PDF: Portable Document Format
PMI: product manufacturing information
PRC: Product Representation Compact
U3D: Universal 3D

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