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Health Informatics Journal

Original Article

A prediction model of blood pressure for telemedicine

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Abstract

This paper presents a new study based on a machine learning technique, specifically an artificial neural network, for predicting systolic blood pressure through the correlation of variables (age, BMI, exercise level, alcohol consumption level, smoking status, stress level, and salt intake level). The study was carried out using a database containing a variety of variables/factors. Each database of raw data was split into two parts: one part for training the neural network and the remaining part for testing the performance of the network. Two neural network algorithms, back-propagation and radial basis function, were used to construct and validate the prediction system. According to the experiment, the accuracy of our predictions of systolic blood pressure values exceeded 90%. Our experimental results show that artificial neural networks are suitable for modeling and predicting systolic blood pressure. This new method of predicting systolic blood pressure helps to give an early warning to adults, who may not get regular blood pressure measurements that their blood pressure might be at an unhealthy level. Also, because an isolated measurement of blood pressure is not always very accurate due to daily fluctuations, our predictor can provide the predicted value as another figure for medical staff to refer to.

Keywords

artificial neural network, hypertension, machine learning, prediction, systolic blood pressure, telemedicine

Introduction

Hypertension is a major global public health issue. According to the National Institutes of Health (NIH), around one in three adults in the United States has hypertension.[1] It is a chronic medical condition characterized by persistent high blood pressure (BP) with systolic blood pressure (SBP) and diastolic BP readings of higher than 140 and 90 mmHg, respectively.[2]

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Health consequences

Untreated high BP or hypertension may damage major organs of the body, including the heart, kidneys, and brain. Recent studies have shown that hypertension is related to many diseases, such as stroke, loss of consciousness, memory loss, heart disease, cardiovascular disease, and damage to eyes and kidneys.[3–8] Another study has also shown that people who have consistent high blood pressure in their 20s are more likely to develop atherosclerosis by the time they reach middle age.[9] Most people with high blood pressure or hypertension often have no signs or symptoms, even if their blood pressure readings have already reached an emergent level. Thus, they may notice nothing for years, even as their heart, blood vessels, kidneys, brain, or other body parts are damaged by high blood pressure. The early detection or prediction of consistently high blood pressure to minimize the risk of hypertension and its complications is the first step in hypertension care. However, the fact is that many people, especially young and middle-aged adults, do not undergo regular monitoring of their blood pressure in order to prevent hypertension.

Factors associated with high BP

According to the World Health Organization,[1] high blood pressure is very often associated with health factors such as old age, tobacco use, stress, a lack of physical activity, the harmful use of alcohol, and obesity. The following is a discussion of the factors associated with high blood pressure.

Age. Sparrow et al.[10] used multiple linear regression analyses to show that the SBP of a person aged over 50 years increases more rapidly than that of someone between the ages of 20 and 39 years.

Male/female. According to a survey,[11] the blood pressure of men is usually higher than that of women of the same age. In fact, men are at a higher risk of developing hypertension and cardiovascular disease than premenopausal women of the same age.

Body mass index. Obesity, as indicated by body mass index (BMI), has become a serious public health issue all over the world. Golino et al.[12] carried out a study to predict blood pressure by the machine learning method and concluded that BMI, waist circumference, and waist–hip ratio have a relationship of correlation with heart diseases such as hypertension, shock, and cardiovascular diseases.

Alcohol consumption. According to Criqui et al.,[13] alcohol consumption seems to be significantly related to SBP and diastolic blood pressure for both men and women. Hartung et al.[14] obtained a similar result, concluding that both males and females' blood pressure readings are related to alcohol consumption. They also found that the blood pressure of a regular consumer of medium quantities of alcohol is much lower than that of one who drinks excessive amounts daily, which shows that the relationship between blood pressure and alcohol intake quantity is not a linear one.

Exercise level. Many studies[14] have shown that a person's blood pressure drops in response to heightened physical activity. A lack of physical activity also increases a person's risk of becoming overweight, raising the likelihood that the individual will develop hypertension.

Stress level. The American Heart Association (AHA) has pointed out that although stress is not a confirmed risk factor for high blood pressure, many studies on the subject are currently being carried out. In a stressful situation, people's bodies react by releasing stress hormones into the blood, which raises their blood pressure.[15]

Salt intake level. A study by Denton et al.[16] showed that eating too much salt contributes to a significant rise in both SBP and diastolic blood pressure.

Smoke status. Tobacco and exposure to secondhand smoke have a significant effect on blood pressure. Experiments have shown that a person's blood pressure will temporarily increase a few minutes after that person starts smoking.[17,18]

Model to predict blood pressure

In this article, a new model for predicting blood pressure is presented. It will allow health service providers to predict a person's blood pressure based on that person's health-related information. This prediction model is not meant for patients who are undergoing treatment, as such patients would already be having their blood pressure measured using standard equipment. The model is designed for people who are not getting regular blood pressure measurements. For example, in a telemedicine consultation, the doctor may want to predict whether a person is at risk of high blood pressure. The information on that person, together with this model, would provide a prediction of that person's blood pressure before an actual measurement is made. In another situation, a person may want to review his or her health status using an online computer program such as an expert system. The expert system would gather all of the relevant data and health-related information on that person under consultation and give predictions on the person's potential risk of developing various conditions, including high blood pressure. The model in this article would be a valuable tool for such predictions, as it provides a preliminary assessment of a person's blood pressure.

Some studies[19,20] have indicated that there are people who are at risk of developing hypertension, yet do not get their blood pressure checked regularly. Therefore, it is desirable to develop a method that can predict blood pressure using factors relating to a person's age and lifestyle (BMI, exercise level, alcohol consumption level, smoking status, stress level, and salt intake level). The method discussed in this article is a method for predicting the SBP of a person when given factors associated with blood pressure. It is not intended to replace actual measurements, but simply to provide an early warning of an individual's risk of developing hypertension and cardiovascular diseases.

Literature review

This article proposes a new model that will allow health personnel or doctors to know the predicted value of an individual's blood pressure based on that person's health-related information, obtained through the use of a neural network. Conway et al.[7] proposed a blood plasma model to evaluate the relationship between the magnesium ions present in a person's blood plasma and that person's SBP using an artificial neural network (ANN). Their result showed that the neural network can uncover the complexity of the relationship between the input variables and help the researcher to understand the role of magnesium in SBP and glucose. However, the objective of their study was to determine the relationship between the magnesium ions in blood plasma and SBP, which differs from the aim in our article.

Golino et al.[12] carried out a study to predict a person's blood pressure using a classification tree, which is a machine learning technique. The variables used for the prediction were physical conditions, such as BMI, waist and hip circumference, and waist-to-hip ratio. The machine learning technique that they used differs from the technique used in this article, which is the ANN. Also, they only used the physical condition of a person to predict that person's blood pressure, whereas we also apply some health-related information of a person (e.g. age, stress, and exercise levels) in the prediction.

Kupusinac et al.[21] presented a study using an ANN to estimate a person's cardio-metabolic risk (CMR), with the aim of achieving early prevention of atherosclerosis and cardiovascular diseases. No prediction of blood pressure was carried out. They used gender, age, waist-to-height ratio, BMI, and blood pressure as the primary risk factors and high-density lipoprotein (HDL)-, low-density lipoprotein (LDL)-, and total cholesterol levels; triglycerides; glycemia; fibrinogen; and uric acid as the secondary risk factors. The output CMR-coefficient is a relative measure of CMR in the interval [0, 1]. They obtained a result by estimating CMR with a best accuracy of 82.76 percent after analyzing different parameters of the ANN. In their experiment, they tested the trained ANN using a training dataset and an unknown dataset. However, the goal of their research was to estimate a value that would indicate a person's risk of developing cardio-metabolic disease, which is different from the objective in this article of predicting the SBP.

A review of the impact of telemonitoring blood pressure on hypertension outcomes was given in AbuDagga et al.[19] Directly measuring BP at home or in the office is crucial for controlling and managing BP. For patients with diabetes, monitoring blood pressure and blood glucose at home is mandatory for self-managing the disease.[20] As discussed in Koopman et al.,[20] this may appear to be a simple process in daily life, but in practice there could be all kinds of obstacles and complications involved in uploading the readings from the measurement device. However, this article focuses on the indirect gathering of information on BP by predictions based on other physical attributes of the patient.

A thorough review indicated that no studies have been carried out based on the same idea as that in our model. Hence, the concept presented in this article is a new one in the field of telemedicine. As a tool for predicting blood pressure, it can be used as a component of an expert system related to medical consultations.

Clinical relevance

It must be noted that a person's normal blood pressure range should correspond to that person's age group.[10] It is well known that blood pressure has a daily pattern that can vary across several BP readings within a day. Blood pressure is usually lower when a person is asleep, rising during the day and reaching a peak in mid-afternoon. Blood pressure values then begin to drop again and during sleep can be 20 percent lower than during the day.

The clinical relevance of the method developed in this article is explained as follows. Suppose the blood pressure of a person is not available or the person is at a remote location. Figure 1 shows an ANN that can be used to predict the SBP of a person based on a database used in this study. In this example, the person has to input some values related to age, gender, height, weight, stress, and exercise levels. The neural network will give a prediction of that person's SBP. Assuming that the predicted value is larger than the hypertension alarm value, the user should be given a warning. For example, if the predicted value is 150 mmHg, which is more than the SBP of 142 mmHg for a person aged 52 years, the user should receive an alert.

Another scenario on the usefulness of the blood pressure predictor is as follows. A person provides all of the relevant information for the neural-network-based blood pressure predictor, and his blood pressure measurement is also taken (Figure 2). Suppose that the measured value seems normal, but the predicted value is alarming. A recommendation would then be given to the person to double-check his blood pressure. For example, if the measured value was 138 mmHg for a person aged 52 years but the predictor gives a value of 150 mmHg, the relatively low value of his SBP

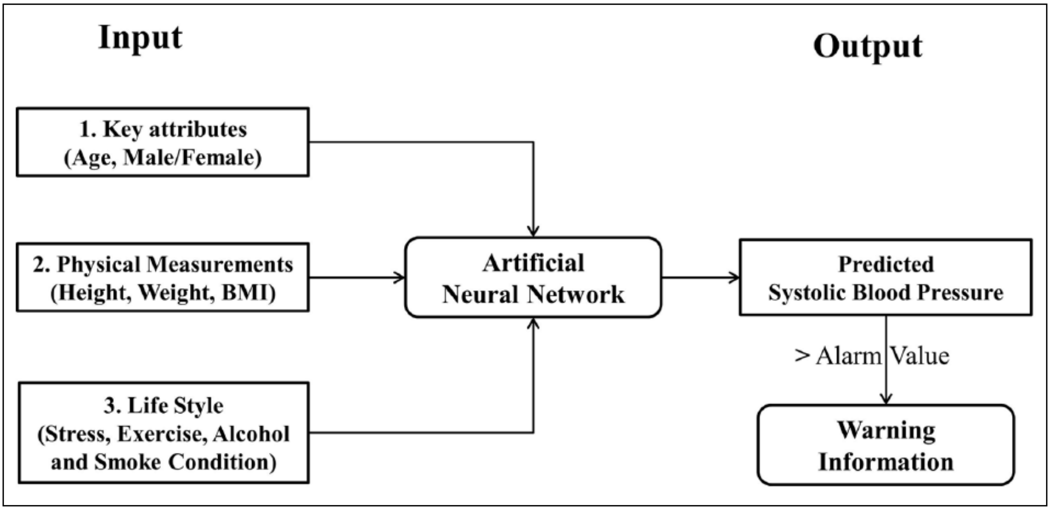

Figure 1. Predicting without measuring.

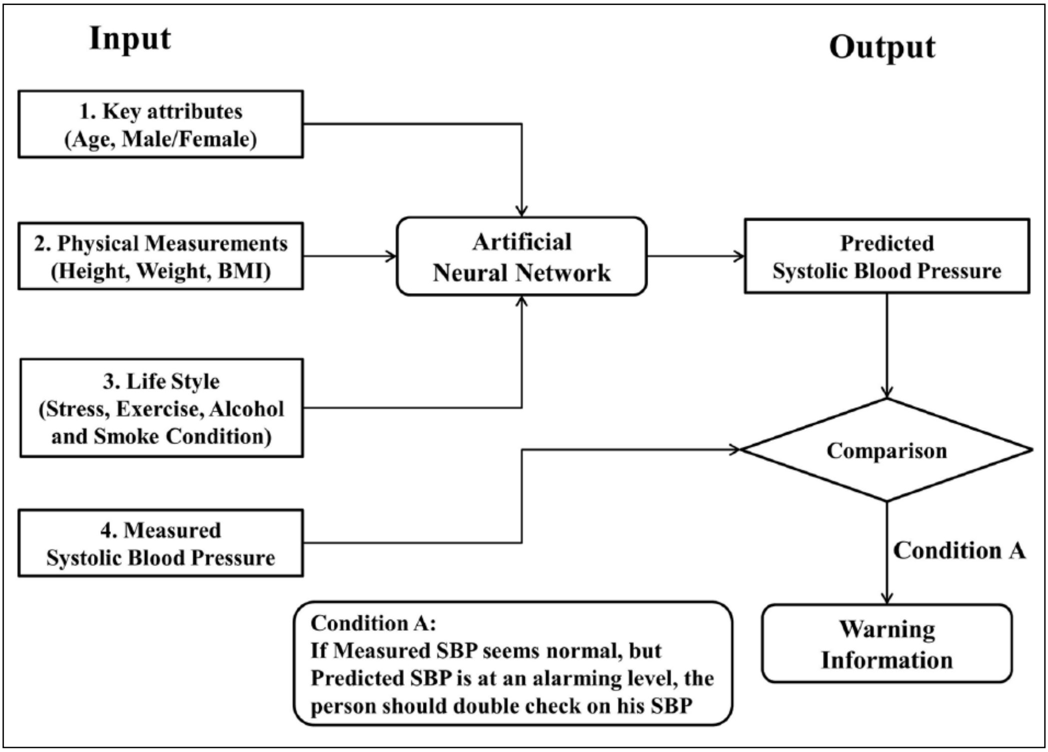

Figure 2. Predicting with measurement.

measurement could be inaccurate. In such a situation, the person is advised to have further measurements of his blood pressure taken.

In this article, the machine learning method of an ANN is used to determine the relationship between the correlated variables (age, gender, BMI, stress level, exercise level, alcohol consumption level, smoking status, and salt intake level) and the SBP value. A trained neural network would then be used to predict the SBP when the input variables are provided.

Materials and methods

ANN

The ANN is based on an intelligent computational model and uses a computer network system to simulate the biological neural network. It consists of an input layer of source information, at least one middle or hidden layer of computational neurons and an output layer of computational neurons.[22–24] The ANN has the ability to discover the existence of a nonlinear relationship between its inputs and outputs. It has played a major role in many scientific and industrial applications, such as time series prediction, pattern recognition, decision making, load forecasting, and event prediction.[19,25–29] In this article, we aim to use neural networks to determine the correlation between the input variables and the output, which is SBP. Essentially, we would like to use an ANN as a tool to predict the value of a person's blood pressure, given some health-related measurements and personal data.

For example, Figure 3 shows ANN structures using different databases in this study. Based on the database, an ANN structure with seven inputs (age, BMI, stress level, exercise level, alcohol consumption level, smoking status, and salt intake level) and four hidden nodes is shown in Figure 3. The common objective of this structure is to predict SBP based on the different input variables.

The strength of a neural network is its learning capability. A problem can be solved by first training the neural network using some training examples or instances of input–output pairs. Two well-known algorithms for the training of neural networks are the Back Propagation algorithm and the radial basis function (RBF) network. The interconnection weights between the different layers in an ANN will be obtained at the end of the training session.

Back-propagation neural network. The Back Propagation neural network is a typical architecture of a multi-layered feed-forward neural network.[22,23,30–32] A typical Back Propagation neural network usually consists of layers of neurons, and the objective is to train the network weights so as to minimize the mean-square error of the network output. Figure 3 shows the architecture of a typical Back Propagation neural network with seven inputs, one hidden layer with four hidden nodes, and one output value.

RBF neural network. Our RBF neural network is composed of one hidden layer.[33,34] In an RBF network, the hidden layer can implement better nonlinear mapping from the data space to the feature space. The most common basis function chosen is a Gaussian function, which means that the closer the input is to the center of the Gaussian function, the larger will be the response of the node. In stage 1 of the training of the RBF network, the self-organizing feature map (SOFM) was used as a clustering algorithm to determine the weights between the input and the hidden layer. At each hidden node, the basis function used was a Gaussian function. In the second stage, the weights between the hidden and output layer were determined by a least-mean-square (LMS) algorithm.

Statistics

The data were collected from the health and body conditions of 498 people and included SBP, gender, age, BMI, smoking status, exercise level, alcohol consumption level, stress level, and salt intake

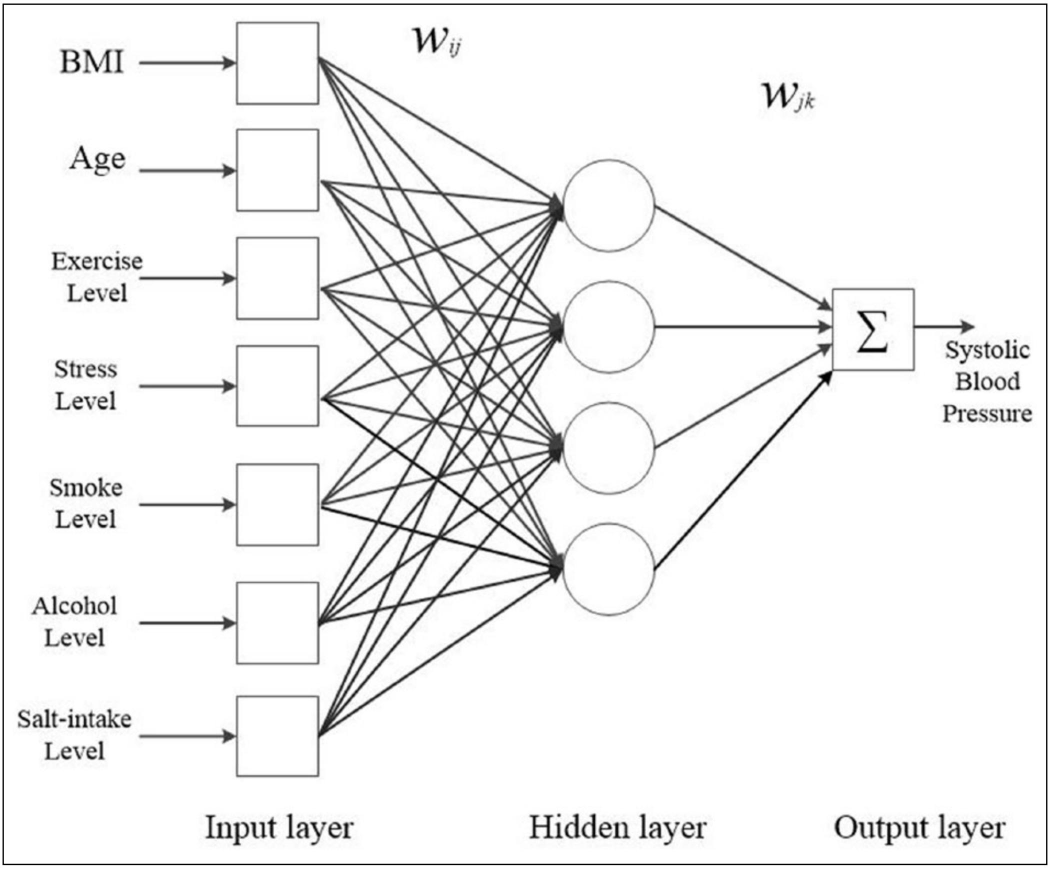

Figure 3. Structure of an artificial neural network.

Table 1. Description of the variables.

Variable	Description
Systolic blood pressure (SBP)	Continuous variable (mmHg)
Gender	Binary variable (M—male; F—female)
Age	Continuous variable (year)
Body mass index (BMI)	Continuous variable (kg/m^2)
Smoking status	Binary variable (yes, no)
Exercise level	Categorical variable (low, medium, high)
Stress level	Categorical variable (low, medium, high)
Alcohol level	Categorical variable (low, medium, high)
Salt intake level	Categorical variable (low, medium, high)

level.[35] These variables are believed to be correlated with a person's blood pressure reading. The descriptions of the variables are shown in Table 1. Among the 498 cases, 236 were male, accounting for 47 percent of the data, while the remaining 262 cases were female. Due to the obvious influence of gender difference, the author split the data into male and female sets, respectively.

Results

The experiments were carried out by two different algorithms of ANNs: Back Propagation and RBF. The Back Propagation algorithm was first used for the training of an ANN. The output was the predicted value of the SBP. The inputs were the factors used for the prediction (age, gender, BMI, stress level, exercise level, alcohol consumption level, smoking status, salt intake level), and the number of hidden nodes varied from 1 to 10.

The RBF algorithm was also used for the training of an ANN, which mapped the relationships between SBP and the input variables belonging to different clusters. The number of naturally formed clusters was determined, and these then provided the weights between the input and hidden layers. The maximum number of clusters varied from 1 to 10. In the second stage, the weights were determined by an iterative LMS algorithm.

The flowchart of the algorithm is shown in Figure 4. The experiment was carried out and repeated 50 times for each problem instance, and the average value of the results was presented. To evaluate the ANN with different hidden nodes/clusters, the algorithm varied the number of nodes/clusters from 1 to 10.

It is very important to emphasize that the testing data were kept separate from the training data. A certain percentage (60%, 70%, 80%, or 90%) of the data from the database was used for training, and the rest was used for testing the performance of the trained neural network. The predicted SBP value from the neural network was compared with the value in the database. The average accuracy, defined below, was recorded, and the standard deviation was also obtained

$$\text{Accuracy} = 1 - \frac{|\text{Predicted Value} - \text{Measured Value}|}{\text{Measured Value}} \times 100\%$$

The blood pressure prediction model was coded in MATLAB R2014b and run on an Intel Core 2 Quad 2.83 GHz PC with 8 GB of RAM. The computation times of the experiments are presented in the following parts.

Back-propagation ANN

In our experiment, we have already investigated the parameters relating to the performance of the neural network, such as different hidden neurons of ANN and different proportions for training and testing. The experiment was repeated 50 times, and the average of the results on accuracy and standard deviation was obtained. The trained neural network was tested by two sets of data: the first set was the data used to train the ANN, and the second set was the data reserved for testing. The experiment was carried out using the MATLAB neural network toolbox. The algorithm of the toolbox was set to trainlm, and the learning rate of toolbox was defined as 0.3. One hidden layer of neurons was used initially in the Back Propagation algorithm, and an architecture of two hidden layers was also examined later. We examined the issue of the maximum number of iterations in the training of the Back Propagation network. We found that the training settled down within 200 iterations. Two typical performance graphs are shown in Figure 5. In our experiment, we allowed the maximum number of iterations to reach 200.

Results based on males. The ANN used one hidden layer at the beginning of this experiment. Different percentages of the database were used for the training of the Back Propagation ANN. As shown in Figure 6, lines of different color stand for different proportions (60–40, 70–30, 80–20, and 90–10) of training and testing from the dataset. Based on the testing data, it is obvious that the best result was obtained when 80 percent was used for training and the remaining 20 percent for testing the performance of the ANN. As the number of hidden nodes increased (from 1 to 10), the

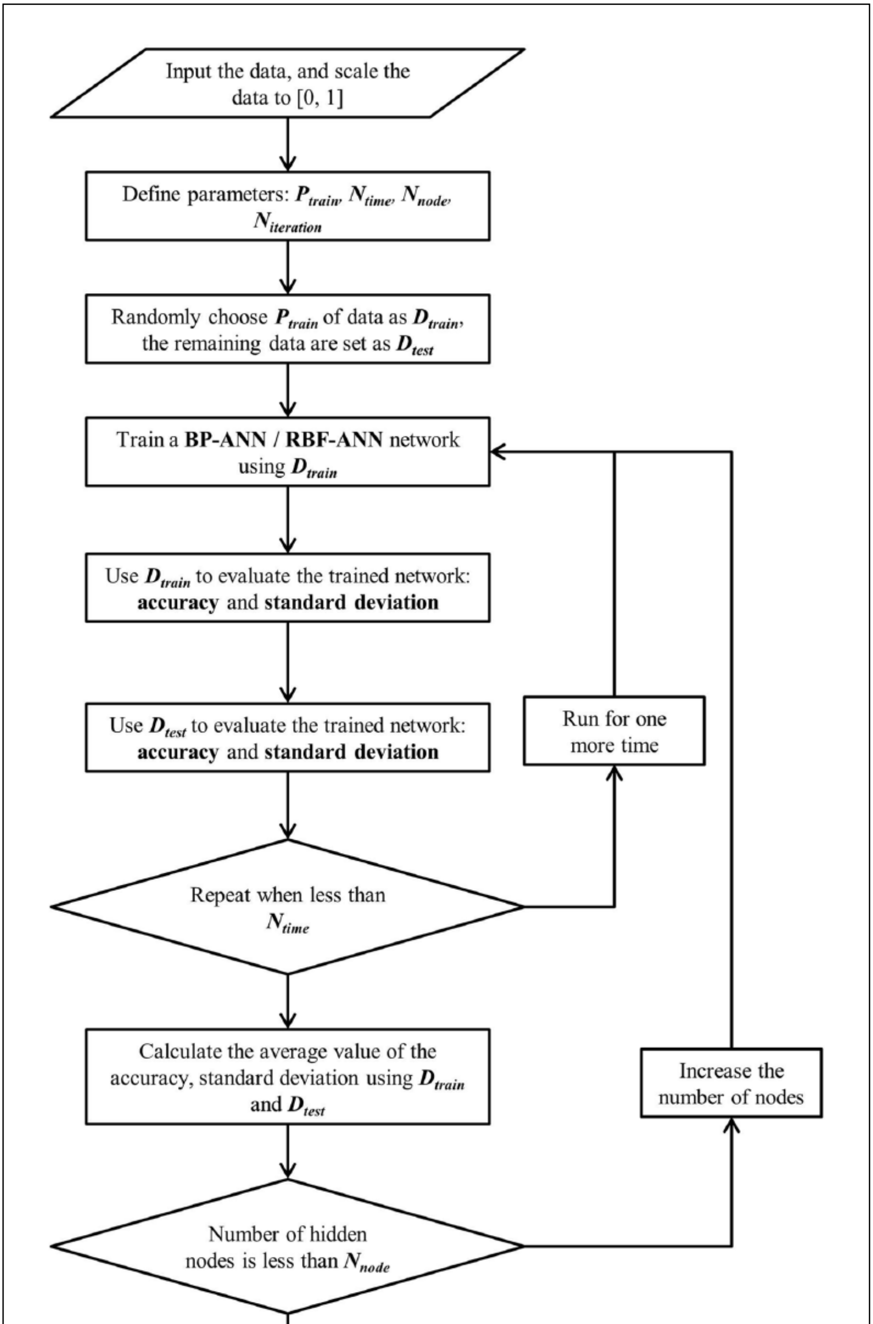

Figure 4. Flowchart of the ANN algorithm.
BP: back propagation; ANN: artificial neural network; RBF: radial basis function.

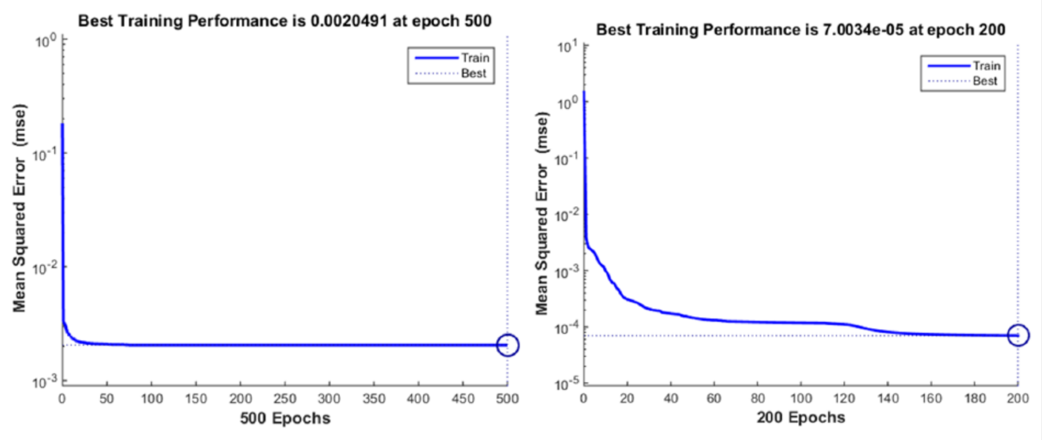

Figure 5. Two performance graphs of convergence obtained by Back Propagation ANN.

performance achieved using the training data kept improving, while the results based on the testing data got worse. This is because when the number of hidden nodes increased, the neural network had a greater degree of freedom to learn the relationship between the inputs and the output based on the training data. Hence, the accuracies based on the training data improved as the number of hidden nodes increased. On the other hand, the use of more hidden nodes decreased the generalization capability of the neural network. When the unseen testing data was presented to the neural network, the prediction accuracies appeared to decrease as the number of hidden nodes increased. Taking the two graphs on accuracy into consideration, we found that using four hidden nodes gives the best overall result when their averages are calculated.

Results based on females. A similar experiment was carried out for the female cases in the dataset. Referring to the different proportions on the use of data (Figure 7), and on the accuracy of predictions using the testing data, the use of 80 percent data for training gave the "best" result. Again, it seemed that more hidden nodes would give better results when using the training data, which means that the ANN had already learned the corresponding relationship of the training data well. However, the trained ANN with more hidden nodes did not perform well when using the testing data. Taking the average of the two results into consideration, the use of four hidden nodes gave the best result.

Results based on both genders. A case combining the male and female datasets was carried out in this section. The experiment was run and repeated 50 times, after which the average accuracy was calculated. The number of hidden nodes varied from 2 to 10. In the case combining both genders, the gender information of each sample was defined as another input in the ANN. In Table 2, the performance of this case was compared with those of cases of datasets separated by gender. The last row shows that the prediction accuracy with a combined gender dataset is lower than that with male cases.

Results based on two hidden layers. In this part, a Back Propagation ANN with two hidden layers was used to obtain the prediction value of the blood pressure. To test the performance of the network, the results were compared with the experiment using male data with one hidden layer. In this test, 80 percent of the data were used for training, with the remainder being used for testing. Each experiment was also repeated 50 times, and then, the average result was calculated. In the network with two hidden layers, the number of hidden nodes for each layer varied from 2 to 10. As shown in Table 3,

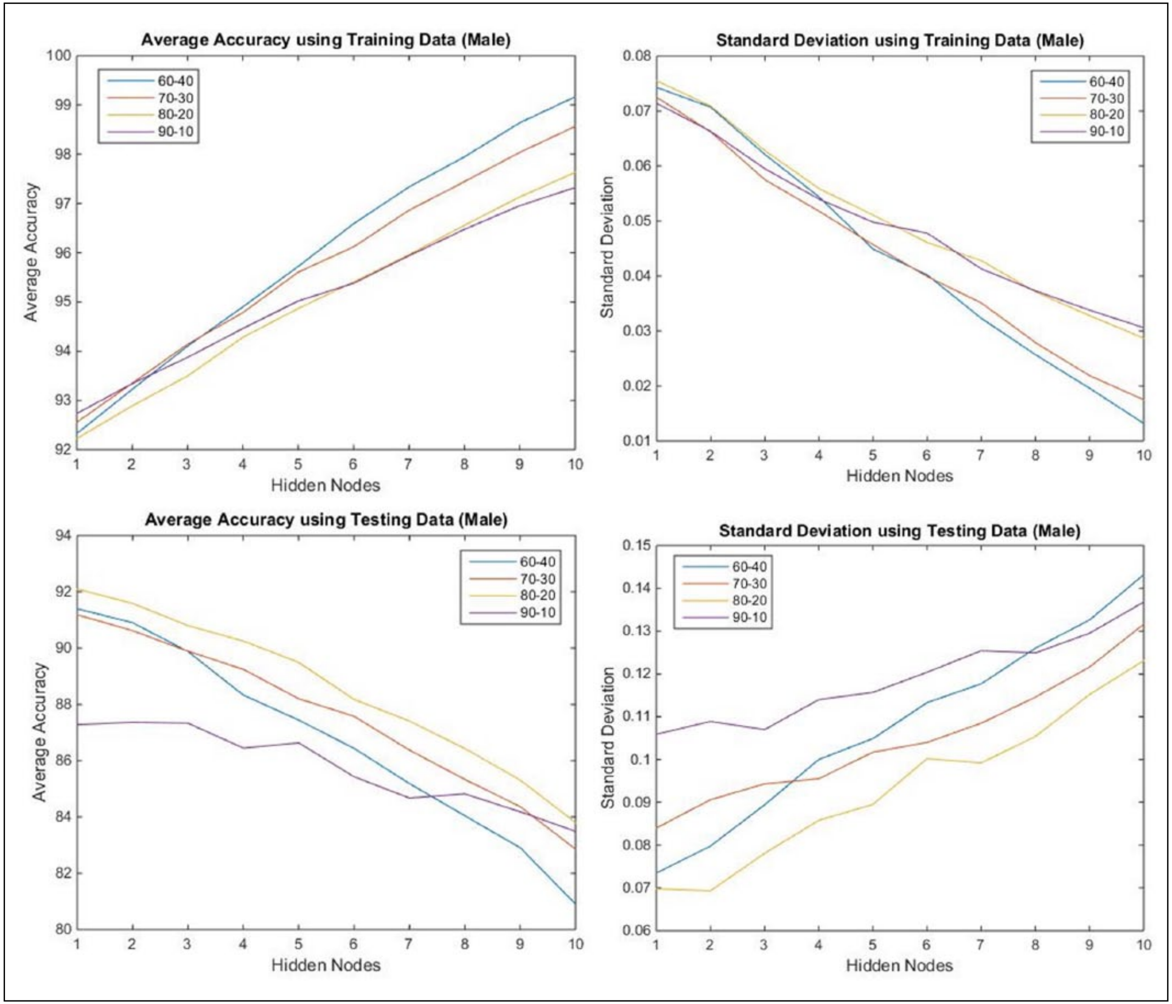

Figure 6. Performance of trained Back Propagation ANN using the male data (one hidden layer).

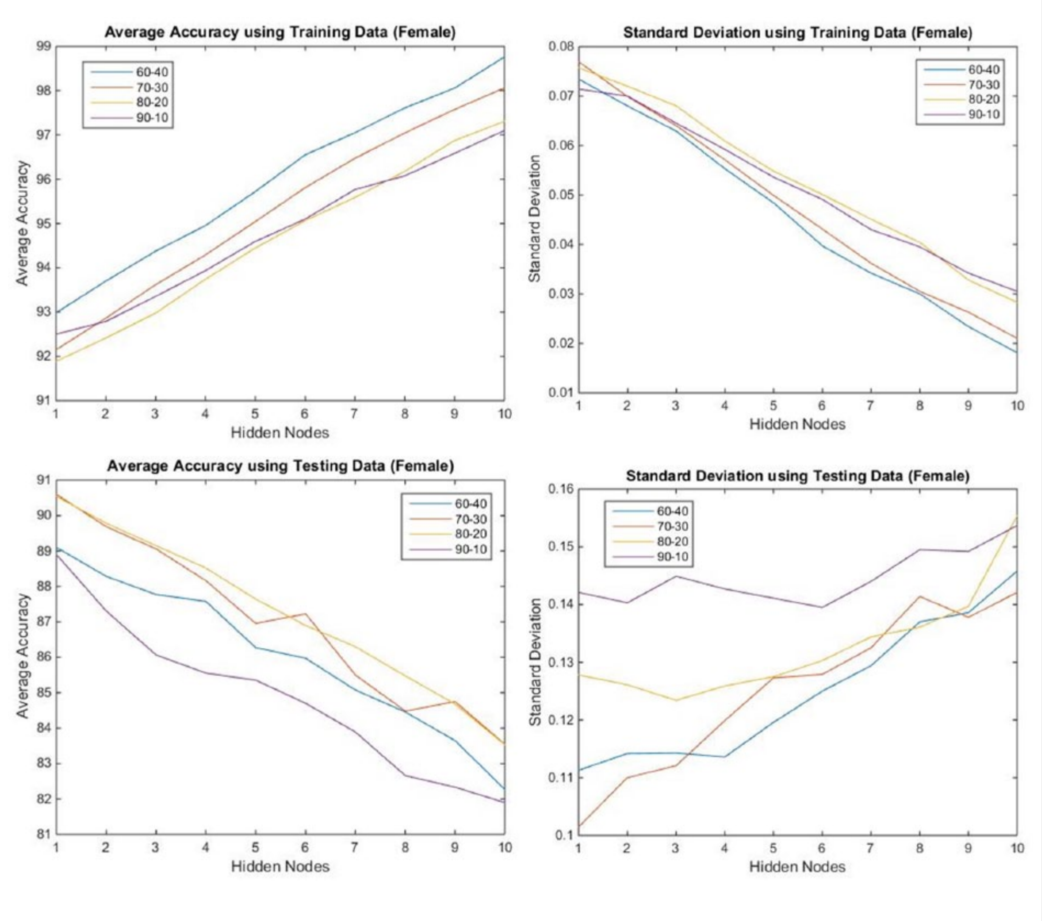

Figure 7. Performance of trained Back Propagation ANN using the female data.

Table 2. Comparison of the performances of the combined and separated datasets.

Number of hidden nodes	2	3	4	5	6	7	8	9	10
Male	91.66%	91.69%	91.59%	91.62%	91.40%	91.22%	91.13%	90.94%	90.47%
Combined	90.86%	90.97%	91.02%	91.08%	91.12%	91.15%	91.13%	91.19%	91.14%

the average accuracy using the network with one hidden layer was always higher than the network with two hidden layers. Hence, having two hidden layers did not help the Back Propagation ANN to obtain a predicted blood pressure value in this problem.

RBF network

In this experiment, some related parameters were investigated to test the performance of the RBF neural network. As shown in Figure 3, the RBF network in this article is a two-layer network

Table 3. Comparison of the performances of one and two hidden layers.

Number of nodes on each layer	2	3	4	5	6	7	8	9	10
One hidden layer	91.66%	91.69%	91.59%	91.62%	91.40%	91.22%	91.13%	90.94%	90.47%
Two hidden layers	89.84%	89.05%	88.04%	85.94%	84.48%	82.57%	81.36%	81.20%	80.91%

whose output forms a linear combination of the basis function computed by the hidden units. The basis functions in the hidden layer produce a localized response to the input, and each hidden unit has a localized receptive field.

Let X and Y be the set of the input and output data, respectively. Let (x_i, y_i), $i = 1, 2, 3, \ldots, NumT$ be such a training sample, where $NumT$ is the number of training data. Let C be the set of centers/clusters. The algorithm of the RBF network used in this article is summarized into three steps:

Step 1: weight initialization. The weights in the hidden layer are determined by a clustering algorithm, and the weights in the output layer are initialized to small random values.

Step 2: calculation of activation. The activation level h_j of the hidden unit j is calculated by

$$h_j = \exp\left[-\frac{(X-C_j)^T \cdot (X-C_j)}{2\sigma^2}\right]$$

The activation level n_j of an output unit is determined by

$$n_j = \Sigma W_{ij} h_i$$

Step 3: weight calculations. In the hidden layer, the SOFM clustering algorithm is used to update the weights. In the output layer, the weight is learned by a LMS algorithm. The weights are adjusted by

$$W_{ij}(t+1) = W_{ij}(t) + \Delta W_{ij}$$

where $W_{ij}(t)$ is the weight from the unit i to unit j at the tth iteration and ΔW_{ij} is the weight adjustment.

The weight change is computed by

$$\Delta W_{ij} = \eta \delta_j h_i$$

where η is a trial-independent learning rate and δ_j is the error at the unit j

$$\delta_j = d_j - n_j$$

where d_j is the desired output activation and n_j is the actual output at the output unit j.

Similar to the Back Propagation ANN, different proportions were used for training and different numbers of clusters were carried out in the experiment. However, the RBF helps the kernel function of ANN rather than the optimization algorithm. The experiment was repeated 50 times, and the average of the results in terms of accuracy and standard deviation was calculated. Again, the trained

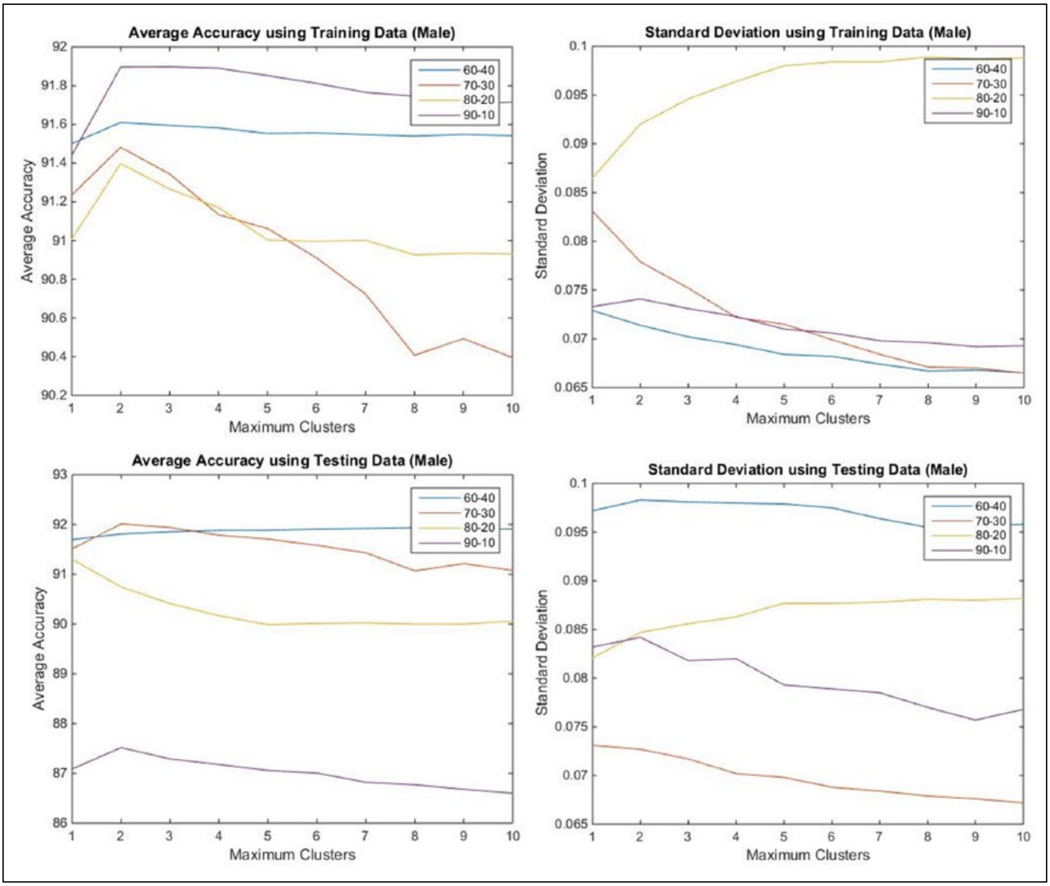

Figure 8. Performance of trained RBF ANN using the male data.

network was tested based on two sets of data: data used to train the ANN and data reserved for testing. The learning rate of this algorithm was set to 0.3 and the maximum iteration was set to 100. The network had already settled down with 100 iterations, and there was no advantage to having more iterations.

Results based on males. In this case of RBF NN, Figure 8 shows that having more clusters did nothing to improve performance. Our experiment found that five clusters were enough for the problem. Different percentages of the database were used for the training of the RBF ANN. In Figure 8, lines of different colors stand for different proportions (60–40, 70–30, 80–20, and 90–10) of training and testing data from the dataset. Based on the testing data, it seems that the best result was obtained when 70 percent was used for training and the remaining 30 percent for testing the performance of the ANN.

Results based on females. A similar experiment was carried out for the female cases as shown in Figure 9. Again different percentages (60%, 70%, 80%, and 90%) of the database were used for the training of the RBF ANN. Based on the testing data, it seems that the best result is obtained when 90 percent is used for training and the remaining 10 percent for testing the performance of the ANN.

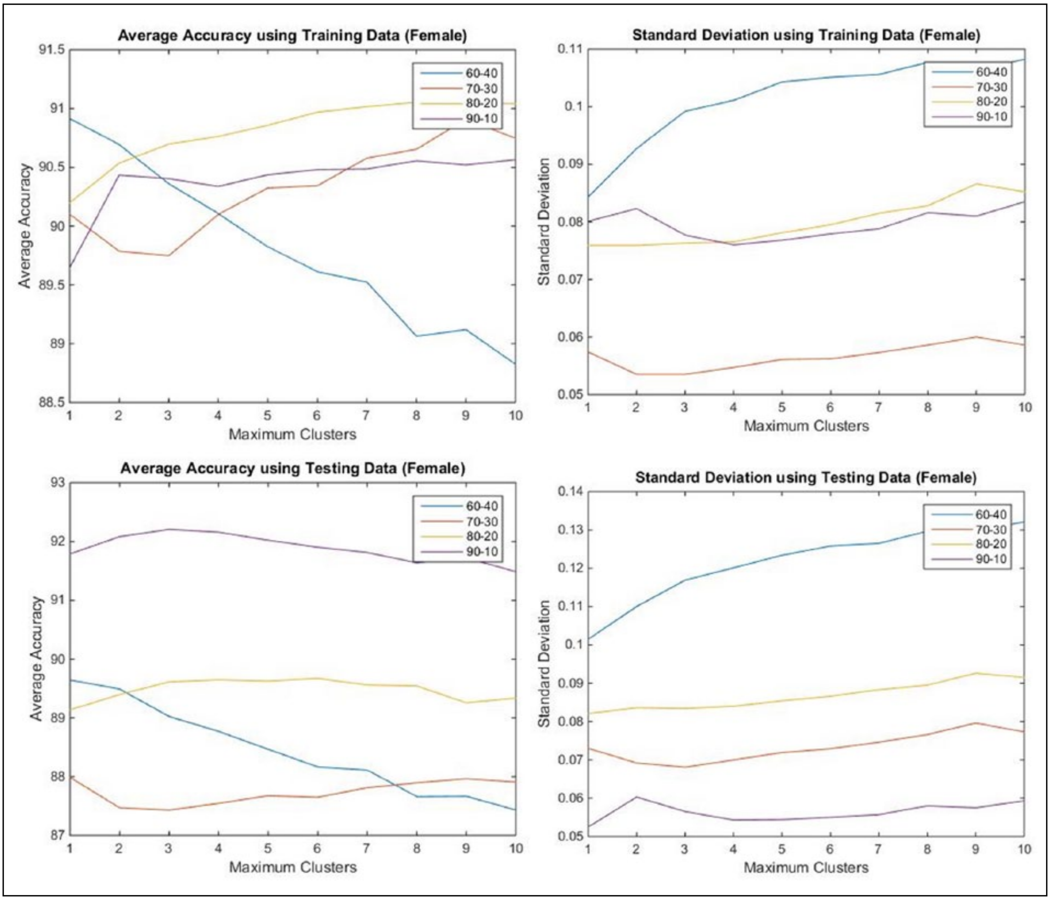

Figure 9. Performance of trained RBF ANN using the female data.

Summary of the results

The computation times of the experiments are summarized in Table 4. In the experiment, the neural network was tested by the number of hidden nodes/clusters from 1 to 10. Also, each case of experiment was run 50 times to calculate the average accuracy. The average computation time of the ANN was calculated with different proportions of training and testing data. The results showed that the RBF ANN runs faster than the Back Propagation ANN in obtaining the predicted BP value.

A summary of the major results is shown in Table 5. It can be seen that the accuracy was around 90 percent for both male and female cases. The number of nodes used in the middle layer of the neural network was also comparable.

Discussion

Gender is the only constant factor among the input variables. Other variables, such as BMI and smoking status, change according to a person's lifestyle. Also, using a separated ANN for male cases was shown to lead to better results than using a combined dataset. The database showed that the subjects ranged in age from 18 to 64 years, with 236 male and 262 female cases. Many of the results have been presented in the previous section. The reliability of the proposed approach was

Table 4. Average computation time.

Algorithm of ANN	Dataset	Proportion (90/10)	Proportion (80/20)	Proportion (70/30)	Proportion (60/40)
BP ANN	Male	2.14 s	2.10 s	2.02 s	1.94 s
	Female	2.10 s	2.04 s	1.94 s	1.94 s
RBF ANN	Male	0.99 s	0.86 s	0.68 s	0.57 s
	Female	1.12 s	0.94 s	0.74 s	0.69 s

BP: back propagation; ANN: artificial neural network; RBF: radial basis function.

Table 5. Experimental results.

Algorithm of ANN	Dataset	Number of hidden nodes	Proportion (training/testing)	Accuracy using trained data	Standard deviation using trained data	Accuracy using testing data	Standard deviation using testing data
BP ANN	Male	4	80/20	90.25%	0.0858	94.28%	0.0559
	Female	4	80/20	88.52%	0.1259	93.74%	0.0609
RBF ANN	Male	5	70/30	91.71%	0.0698	91.06%	0.0715
	Female	5	90/10	92.02%	0.0544	90.44%	0.0768

BP: back propagation; ANN: artificial neural network; RBF: radial basis function.

evaluated by comparing the ANN-predicted SBP value against the data used for both training and testing. The main criterion for evaluation should be the result obtained based on the testing data, and accuracy of over 90 percent was obtained.

Both of the ANNs studied in this article had a structure with only one hidden layer. In fact, the use of two hidden layers did not produce better results than the use of one hidden layer. It is also understood in the field of ANN that one hidden layer is sufficient to represent any nonlinear function, provided that enough hidden nodes are used.

We also found that using four hidden nodes in the Back Propagation ANN was sufficient for good performance. We attempted to use more hidden nodes in the training of both the Back Propagation and RBF networks, but the performance of the prediction was no better than when just a few hidden nodes were used. This observation is not surprising, as it is well known that using more hidden nodes merely introduces more parameters into the predictor (ANN). The neural network tries to "memorize" the training cases rather than to generalize and strengthen its learning capability. This issue of over-training should be avoided; the use of just a few hidden nodes has verified that our approach is correct.

The results suggest that the Back Propagation and RBF networks in the current study are comparable. The Back Propagation structure provides a default ANN configuration, and the learning effort goes into the training to find the interconnection weights between the layers. However, the RBF is a more refined structure, and the neural network is trying to turn the training data into clusters. In general, the time required for training is faster for an RBF network than for a Back Propagation network.

Limitations of the study

This study has several limitations. First, the size of the database used in the experiments was not very large. In order to obtain better predictions, the database should contain more samples for the training of ANN. Second, some attributes provided in the database, such as stress, exercise, alcohol, and smoking status, were subjective values without detailed and clearer information. With the use of telemedicine technology,[36] many attributes and health-related data, including the patient's

BP, can be gathered online. These would form a valuable database for predicting BP. To conclude, further studies using a larger database should be carried out, along with the use of more input variables for the neural network.

Conclusion

This article has proposed a machine learning method to predict SBP using the back-propagation (Back Propagation) neural network and the RBF network. The results from this article indicate that a blood pressure predictor can be developed based on the ANN models that were proposed. The average accuracy of the prediction is over 90 percent. The results obtained from the Back Propagation neural network and RBF network are in agreement.

Our results indicate that the machine learning technique can be an efficient tool for analyzing the relationship between a person's SBP and his age and lifestyle factors (BMI, exercise level, alcohol consumption level, smoking status, stress level, and salt intake level). It must be emphasized that this method does not aim to replace the direct measurement of a person's blood pressure. However, the method provides an estimated value in a telemedicine or expert system consultation. It also provides a reference value to compare with the measured value if a measurement is taken. This can contribute to the development of an SBP predictor, which can provide early warnings of the risks of hypertension and cardiovascular disease.

Declaration of Conflicting Interests

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Cost-effectiveness of telemonitoring of diabetic foot ulcer patients

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Abstract

This study compared the cost-effectiveness of telemonitoring with standard monitoring for patients with diabetic foot ulcers. The economic evaluation was nested within a pragmatic randomised controlled trial. A total of 374 patients were randomised to either telemonitoring or standard monitoring. Telemonitoring consisted of two tele-consultations in the patient's own home and one consultation at the outpatient clinic; standard monitoring consisted of three outpatient clinic consultations. Total healthcare costs were estimated over a 6-month period at individual patient level, from a healthcare sector perspective. The bootstrap method was used to calculate the incremental cost-effectiveness ratio, and one-way sensitivity analyses were performed. Telemonitoring costs were found to be €2039 less per patient compared to standard monitoring; however, this difference was not statistically significant. Amputation rate was similar in the two groups. In conclusion, a telemonitoring service in this form had similar costs and effects as standard monitoring.

Keywords
cost-effectiveness analysis, diabetes, foot ulcers, randomised controlled trial, telemedicine

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Introduction

The prevalence of foot ulcers among individuals with diabetes mellitus in Denmark is estimated to be at least 22,000 and the annual incidence is 3000 based on cases treated in a hospital setting.[1] Approximately 15% of patients with diabetes will have at least one diabetes-related foot ulcer during their lifetime,[1] and 40%–60% of ulcers will recur within 5 years.[2–4] Diabetes is associated with ischaemia, neuropathy and deformities that lead to a particularly high risk of developing foot ulcers and a low likelihood of ulcer healing.[5] These ulcers cause considerable physical discomfort and affect the patient's mobility and quality of life.[1] The total annual direct economic cost of diagnosing and treating individuals with incident diabetic foot ulcers in Denmark has been estimated at 793 million Danish Kroner (DKK) (€106 million) per year.[5]

Wound monitoring via telemedicine is currently being implemented in Denmark, also for diabetic foot ulcers, under a National Action Plan for the deployment of telemedicine and is expected to be available in all regions and municipalities by 2017.[1,5,6] However, there is little evidence that telemedicine in the monitoring of diabetic foot ulcers improves ulcer healing or patient outcome in general.[1,7] An optimistic so-called 'business case' was published in support of the National Action Plan, but no high-quality studies are available that consider the economic aspects of the use of telemedicine for ulcer monitoring.[6,8]

As a consequence, a large Danish pragmatic randomised controlled trial (RCT) of telemedicine consultations in the monitoring of diabetic foot ulcers was undertaken in the Region of Southern Denmark.[8] The clinical and organisational results have been published elsewhere,[9,10] and the current article reports the economic evaluation. The main purpose of the trial was to generate information for the decision-making process regarding the national introduction of telemedicine consultations in the monitoring of patients with diabetic foot ulcers. The RCT was part of the RENEWING HEALTH[11] project in which nine European regions examined the effect of telemedicine in a broad, interdisciplinary perspective in patients with chronic diseases, including diabetes mellitus.[11,12]

Aim and objectives

The aim of this study was to perform an economic analysis, piggybacked on an RCT, to compare the costs and effects of telemonitoring (TM) with standard monitoring (SM) in individuals with diabetic foot ulcers. The following three steps were performed:

1. Descriptive statistics and calculation of average use of resources, average costs and average effects;
2. Cost-effectiveness analysis (CEA) and calculation of incremental cost-effectiveness ratio (ICER) for amputations;
3. Sensitivity analysis:
   a. Bias corrected bootstrap analyses on 5000 re-samples to evaluate the overall uncertainty of the estimated ICER;
   b. One-way sensitivity analyses to assess the robustness of the study results.

Methods

A recent publication by the European Wound Management Association has recommended using the Model for ASsessment of Telemedicine (MAST) when evaluating telemedicine in wound care.[13] MAST advocates the use of a multidisciplinary assessment comprising seven different domains.[14] This article uses the MAST approach and focuses on the fifth domain of economic aspects. The economic evaluation follows international guidelines for the conduct of health economic evaluation of health interventions as stated by CHEERS – Consolidated Health Economic Evaluation Reporting Standards.[15]

The clinical study

The RCT was conducted in 2010–2014 at seven departments and outpatient clinics of five hospitals and included all 22 municipalities in the Region of Southern Denmark.[8] A pragmatic study design was applied, and patients diagnosed with a diabetic foot ulcer starting treatment in one of the specialised ulcer outpatient clinics were eligible for the clinical study. The aim of the clinical trial was to investigate, whether a telemedicine approach to ulcer treatment could be used as an alternative to conventional monitoring at the outpatient clinic.[16] The participants were assessed for comorbidity and the need for surgical intervention prior to randomisation. The per protocol telemedical monitoring consisted of two tele-consultations in the patient's own home and one consultation at the outpatient clinic. SM comprised three outpatient clinic visits. The three-visit cycle continued until the study endpoint, that is, patients stayed in the study until one of the following endpoints occurred: ulcer healing, amputation, patient withdrawal of consent, patient moving to a hospital department not using telemedicine monitoring of diabetic foot ulcers, death, or 1 year (365 days) without healing (i.e. the ulcers were considered chronic).

The telemedical consultations were conducted by telephone or online written consultations between the specialised municipal nurse and doctors at the outpatient clinic. These consultations were supplemented by an uploaded screen image of the ulcer and a detailed written assessment via the online database.[17] If needed, the treatment strategy was revised, and the next consultation was carried out as required (i.e. telemedical or outpatient consultation), and the indication for further images was agreed between the nurse and physician. Patients randomised to standard care followed the usual practice and treatment provided by the outpatient clinic, where all consultations took place in the outpatient clinic. In both groups, municipal nurses provided standard daily care to the study participants in their own home under supervision of a municipality nurse specialised in ulcer care. Home care was delivered after an algorithm determined by clinical judgment, usually twice or three times a week. The healthcare professionals received training in use of the telemedicine system,[17] and diabetic foot ulcer management competencies were upgraded among the involved municipality nursing staff.

Cost estimation and prices

Healthcare sector resource use and costs were estimated using a variety of sources. The following elements were included: (1) admissions, (2) outpatient visits at hospitals, (3) emergency department visits, (4) all visits to general practitioner, (5) staff training, (6) investment and running costs of the telemedicine equipment, (7) time used by home care nurse on ulcer consultations and transport and (8) patient time used on transport to hospital for ulcer consultations. Elements 5–8 were based on questionnaires and interviews from the RCT, whereas elements 1–4 were identified for individual patients from national health administrative databases. Also, time used by staff regarding the wound-related outpatient visits in element 2 was recorded in the RCT.

Table 1 presents 2012 unit costs used in the analysis. DKK were converted to EURO (€) using the exchange rate €1 = 7.5 DKK. As the magnitude of the investment costs were minor compared to the other cost components in the CEA (see Table 3), minimal efforts were put into estimating these with great precision in accordance with the recommendations.[18] Investment costs covered

Table 1. Unit costs (€, 2012 prices).

Cost type	Total annual price[a]
Investment and running costs	
Technical infrastructure	€13,454
Project management, evaluation activities, meetings, administration	€12,770
Staff training in wound management	€8966
Meetings, project activities for hospital staff, producing guideline material	€5112
Running cost – licence for running the TM service	€23,333
Running cost – local system integrations[b]	
Running cost – education/IT support	€9705
	Price per hour/unit
Time used by staff	
Doctors	€68.63
Nurses	€33.93
Podiatrist	€30.26
Secretarial	€33.43
Other hospital staff	€41.56
Municipal home care nurses (consultations)	€33.93
Patient time (saved transportation)[c]	€26.45
Telemedicine device – mobile phone	€14.77 per patient treated
Effects on patient use of healthcare	
Admissions (DRG-value in TM/SM group)[d]	€6100 and €6322 per admission
TM outpatient visit (DAGS-value)	€16.60 per visit
General practitioner visits/contacts to emergency doctor	€8.31 average per visit

IT: information technology; TM: telemonitoring; SM: standard monitoring; DRG: diagnosis-related group; DAGS: Danish Ambulatory Grouping System.

[a] Investment/running costs are the total annual cost for running the TM service the first year for 204 patients (the annual number of patients receiving the service at Odense University Hospital – not the number of RCT patients).

[b] It is uncertain whether extra costs for this component may apply.

[c] 28.5% of patients were in the workforce and thus incurred lost productivity.

[d] The corresponding median values were €0 and €89 per admission, indicating skewed data.

staff training, establishing the service infrastructure and project management. Investment costs were based on staff knowledge and details from an internal Odense University Hospital[19] document containing an overview of the budget for national implementation of telemedicine.

Hospital staff completed questionnaires about the type of consultation and the time used. Average salaries from the university hospital were used for valuing staff time, under the assumption of 1481 effective work hours per year. The number of home care consultations and the time used on consultations and transportation were recorded in questionnaires filled out by the home care nurses. The patient's distance to hospital was recorded by hospital staff when the patient was enrolled in the study. The value of patient time used was estimated from the average national income from Statistics Denmark, under the assumption of 1481 effective work hours. Furthermore, the RCT study show that 28.5% of the patients were in the workforce, and thus had costs related to lost productivity.[20]

The Equivalent Annual Cost (EAC) method[18] was used to handle hardware investments and establishment costs by converting them to an annual cost, assuming a 2-year life span for mobile phones and IT equipment and a 5-year life span for establishment costs. The above calculation assumed that 204 foot ulcers were treated at Odense University Hospital annually, based on estimates from the clinical department regarding the annual expected number of patients. Cost and effectiveness outcomes were not discounted as the analysis was limited to 6 months.

Information about patient use of healthcare services (e.g. inpatient and outpatient activity, general practitioner visits) was drawn from the Danish National Patient Register[21] that records every healthcare encounter for all Danish citizens. Each healthcare service was assigned a standardised cost (reimbursement), so that cost estimates were based on the number of encounters recorded in the Danish National Patient Register multiplied by the ascribed standardised DRG/DAGS rate[22] and fee-for-service rates for general practitioner activities reflecting average costs.

Analysis

Handling of missing data. In the main CEA analysis, missing values were handled by mean imputation conditional on the assigned group, that is, replacing a missing value with the mean value of the available cases in either the TM or the SM group.[23]

The economic evaluation. The primary outcome for the CEA was incremental cost per 1% change in amputation rate. Follow-up for amputations was approximately 6 months and for costs 6 months after study inclusion. In the data analysis, differences in the average use of resources, costs and effects per patient in the intervention and control groups were calculated. Differences in costs and number of amputations were compared in the two groups and combined in a CEA. The ICER, which is the additional cost per additional health outcome, that is, amputation, was then calculated according to the standard formula: $ICER = (C1-C2)/(E1-E2)$, where C1 and E1 were the cost and effect in the intervention group, and C2 and E2 were the cost and effect in the control group.

Data handling, sensitivity analysis, statistical methods and assumptions. It was intended to keep all patients in the analysis in order to analyse data by the intention-to-treat principle (ITT). According to ITT, all randomised patients in a study should be analysed regardless of whether they have completed the study or not or received the treatment. The full ITT principle is only applicable when complete measurements on the primary outcomes for all randomised patients exist.[24] In this case, no measurements on the primary outcomes exist for the dropout patients, and it is further considered unethical to use data from patients who have withdrawn their consent, and hence ITT is not performed.

Data were entered into EpiData version 3.1[25] before transfer to the statistical package Stata version 12 for analysis. The two patient groups were compared using appropriate statistical tests for testing differences in costs and effects, that is, t-test for normally distributed continuous data, χ^2-test for categorical data and the non-parametric Mann–Whitney test for non-normally distributed data. Statistical significance was set at $p < 0.05$. The analyses were performed on means for all variables included in the economic evaluation. The overall uncertainty of the estimated ICER was evaluated through probabilistic sensitivity analysis in terms of a 5000 bootstrap re-sample with a 95% confidence interval. A cost-effectiveness plane was used to illustrate the 5000 bootstrap re-sample of ICER.

Results

The data and descriptive statistics

Data for 24 patients were not included in the economic (and clinical) evaluation; 2 patients withdrew consent after randomisation, 8 had participated before, 3 did not have an ulcer on the foot and

11 had insufficient data and were excluded for a variety of reasons.[10] Hence, the CEA was carried out on individual data from a total of 374 patients (181 in the SM group and 193 in the TM group). Most variables were 100% complete, and imputed values were used for three elements in the CEA (home care visits were 63% complete while total outpatient visits and distance from patient's home to hospital were 95% complete).

The patients in the two groups had no significant differences at baseline on demographic and clinical characteristics, that is, age, gender, height, weight, body mass index, smoking, comorbidities and years with diabetes. A statistically significant difference in mortality rate in the two groups was observed; see the clinical study for a discussion of this result.[10] Average costs per patient 6 months *before* inclusion in the study were calculated based on admissions, outpatient visits, emergency department visits and general practitioner visits and showed no statistically significant differences in the two groups. Hence, no adjustments for baseline values were made in the following analyses.

Average resource use and average costs

Table 2 shows a statistically significant difference in total staff time used on outpatient consultations (156 min for the TM group compared with 266 min for the SM group). This is expected, given the study design. Furthermore, the total time used by staff on telemedicine consultations was 68 min for the TM group. The between-group differences in staff time used for telephone consultations and other outpatient visits were not statistically significant, but the number of telephone contacts was significantly higher in the TM group (0.3 contacts vs. 0.2 contacts). Again, this is expected given the study design. Total staff time (time spent on the four consultation types combined) was statistically significantly higher in the SM group (306 min) than the TM group (255 min), due to fewer outpatient visits in the TM group and less time used by nurses and podiatrists.

The number of total hospital consultations was fairly similar in the TM and SM groups (6.9 vs. 6.2), but the TM group had more municipal home care consultations (40 contacts vs. 35 contacts), and hence higher staff time. On average, a TM patient used less time than an SM patient on transport for outpatient visits (122 vs. 273 min). The TM group had fewer hospital admissions. As Table 2 shows, only four resource elements showed a statistically significant difference.

Unit costs were multiplied by the quantities to calculate total costs. Table 3 shows that from a broad healthcare sector perspective, the total costs of TM were €2039 lower per patient treated than in the SM group. This was mainly due to fewer admissions and lower outpatient costs in the 6-month follow-up period. This difference was not statistically significant, however.

The distribution of total cost per patient in the two groups 6 months after study inclusion is shown in Figure 1. As noted by Drummond,[18] cost data are often non-normally distributed with a skewed and heavy right-hand tail of individuals who make frequent use of healthcare services. This was also the case in our data. The mean total cost in the TM and SM groups was €12,356 and €14,395, respectively; the corresponding median numbers were €6503 and €7677. One TM patient and one SM patient had a total cost above €100,000; this difference is explored in more detail in the sensitivity analysis.

Incremental cost-effectiveness ratio

No statistically significant difference could be detected between the TM and SM groups in the primary outcome, that is, amputations, but there was an absolute difference in the primary outcome. The following results of the CEA should thus be interpreted with great caution.

Table 2. Average use of resources *per* patient in the TM and SM group.

Type of costs	Mean use *per* patient (6 month follow-up)				p-value
	TM group, N = 193		SM group, N = 181		
Patients' use of hospital consultations recorded in the clinical study					
(A) Staff time used on tele-consultations	67.6 min	CI: 52.72–82.47	–	–	–
(B) Staff time used on outpatient consultations	156.3 min	CI: 135.63–177.03	265.6 min	CI: 232.33–298.86	0.00*
(C) Staff time used on telephone consultations	3.4 min	CI: 2.00–4.90	2.6 min	CI: 1.00–4.20	0.44
(D) Staff time used on other* consultations	27.7 min	CI: 21.62–33.88	37.7 min	CI: 29.44–46.04	0.06
(E) Total hospital staff time used on consultations (A+B+C+D)	255.1 min	CI: 227.92–282.33	305.9 min	CI: 271.27–340.60	0.02*
Total hospital time used on consultations according to staff-type					
Doctors	71.4 min	CI: 63.46–79.36	72.3 min	CI: 64.01–80.69	
Nurses	136.1 min	CI: 120.60–151.65	172.7 min	CI: 149.04–196.26	
Podiatrist	37.3 min	CI: 29.75–44.85	50.3 min	CI: 40.85–59.74	
Secretary	9.4 min	CI: 6.73–12.17	9.7 min	CI: 6.94–12.48	
Other staff	0.9 min	CI: 0.03–1.69	1.8 min	CI: 0.25–3.28	
Total hospital consultations according to type					
(F) Number of tele-consultations	3.0	CI: 2.55–3.47	–	–	–
(G) Number of outpatient visit	2.8	CI: 2.46–3.20	5.4	CI: 4.76–6.04	0.00*
(H) Number of telephone contacts	0.3	CI: 0.22–0.43	0.2	CI: 0.09–0.25	0.02*
(I) Number of other contacts[a]	0.7	CI: 0.54–0.91	0.7	CI: 0.51–0.83	0.68
(J) Total number of hospital consultations (F+G+H+I)	6.9	CI: 6.12–7.66	6.2	CI: 5.50–6.99	0.24
Use of home care resources recorded in the clinical study					
Number of home care consultations	39.8	CI: 34.05–45.64	34.8	CI: 28.45–41.07	0.25
Time used by home care nurse (consultations + transport)	1163.6 min	CI: 972.92–1354.29	893.6 min	CI: 695.56–1091.60	0.06
Patients' use of other resources					
Number of emergency room visits	0.3		0.4		0.38
Number of other outpatient visit[b]	10.1		9.1		0.16
Time used by patients (transport to hospital outpatient consultations, i.e. B)	121.8 min		273.2 min		
Number of admissions	1.16		1.35		0.33
Number of contacts to general practitioner or emergency doctor	28.7	CI: 24.01–33.39	24.1	CI: 19.93–28.29	0.15

CI: confidence interval; TM: telemonitoring; SM: standard monitoring; RCT: randomised controlled trial.

[a] Other contact/consultations = type of visit was unknown (coded either as missing or other).

[b] To avoid double-counting, the number of other outpatient visits was the residual calculated as: number of visits (DAGS-activity for 6 months) – total number of outpatient contacts from the RCT study.

Table 3. Average treatment costs per patient in the telemedicine (TM) and standard monitoring (SM) groups (€, 2012 prices).

Type of costs	Mean cost per patient (6 months follow-up)				p-value
	TM group, N = 193		SM group, N = 181		
Investment in TM[a]					
Technical infrastructure	66		–		
Project management, evaluation activities, meetings and administration	63		–		
Staff training	44		–		
Meetings and project activities for hospital staff + producing guideline material	25		–		
(*A*) *Total investment costs*	198		–		
Running costs:					
TM service licence[a]	114		–		
Education/IT support for TM[a]	48		–		
Staff hospital – all consultations (element E in Figure 2)	183	CI: 165–202	212	CI: 190–234	0.02*
Telemedicine devices – mobile phone	15		–		
Admissions (DRG-value of inpatient activity)	7080	CI: 5354–8805	9243	CI: 6212–12,274	0.19
Other outpatient visits (DAGS-value)	3781	CI: 3346–4216	4151	CI: 3704–4598	0.24
Home care nurse (consultations + transport)	658	CI: 538–685	505	CI: 375–471	0.00*
Emergency room visits	15	CI: 9–21	21	CI: 10–33	0.30
General practitioners visits	243	CI: 213–274	214	CI: 184–244	0.18
(*B*) *Total running costs* €	12,137		14,345		0.27
Time costs (*lost productivity*)					
Transport time for patients[b]	21.44		48.42		
(*C*) *Total time costs*	21.44		48.42		
Total costs (*A* + *B* + *C*)	12,356	CI: 10,402–14,310	14,395	CI: 11,295–17,495	0.42

CI: confidence interval; DRG: diagnosis-related group; RCT: randomised controlled trial.

Differences in costs were tested with Mann–Whitney test.

[a] These elements are the total cost for running the TM service and are divided by the total number of expected patients receiving the service in a year at Odense University Hospital – not just the number of RCT patients.

[b] 28.5% of patients were in the workforce and thus incurred lost productivity.

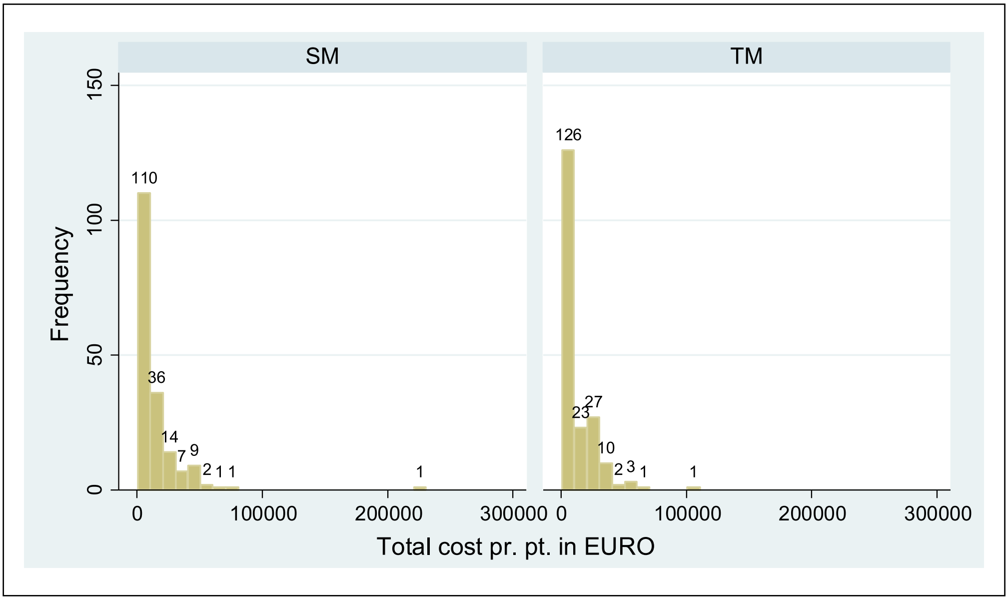

Figure 1. Histogram of total costs per patient in the telemonitoring group and the standard monitoring group.

Based on data from 374 patients, we calculated the ICER as the cost per avoided amputation. Table 4 indicates that on average, a patient in the TM group cost €2039 less than an SM patient. Furthermore, 11% and 14% of patients had amputations in the TM and SM groups, respectively. Combining the above information, the result was a mean saving of approximately €67,973 to avoid one amputation.

Figure 2 shows that most of the 5000 replications were in the fourth quadrant of the figure, indicating that TM was less expensive and associated with fewer amputations than SM, that is, TM was dominant. It should be noted that this observed result in Table 4 and Figure 2 may be due to chance alone (due to no statistically significant differences in cost or amputation rate).

Sensitivity analysis

Table 5 presents four different sensitivity analyses, S1–S4 (the first row, S0, is the results from the main analysis reported above, for comparison).

As the clinical analysis found a significant difference in mortality between the TM and SM groups,[10] we tested whether the difference in total cost between the two groups was due to this difference in mortality rate. In S1, we excluded from the economic analysis all patients who died during the study period, but this did not change the overall results. S2 investigated whether the average total costs per patient changed over time in the two groups. The results indicated that costs in the TM group appeared robust over time, with little change from the first half of patients included in the RCT to the second half. A different pattern was observed in the SM group, where the second half of the patients included in the RCT were less costly to treat, with a mean cost of €10,395 compared to the first half patients with a mean cost of €19,014.

In S3, we first excluded one patient with the highest total cost and subsequently patients with a total cost of more than €100,000 (one in each group). The result was highly sensitive to this change.

Table 4. Incremental cost-effectiveness ratio (ICER) for amputations in the telemedicine (TM) and standard monitoring (SM) groups.

Type of element	TM group, N=193	Confidence interval	SM group, N=181	Confidence interval	Difference between groups
Mean cost per patient (6 months follow-up)	€ 12,356	10,413–14,299	€ 14,395	11,311–17,479	€ –2,039
Mean effect i.e. amputation rate (N) per patient (6 months follow-up)	0.11 (22)	0.06–0.15	0.14 (26)	0.09–0.19	0.03
Mean ICER	€ –67,973				

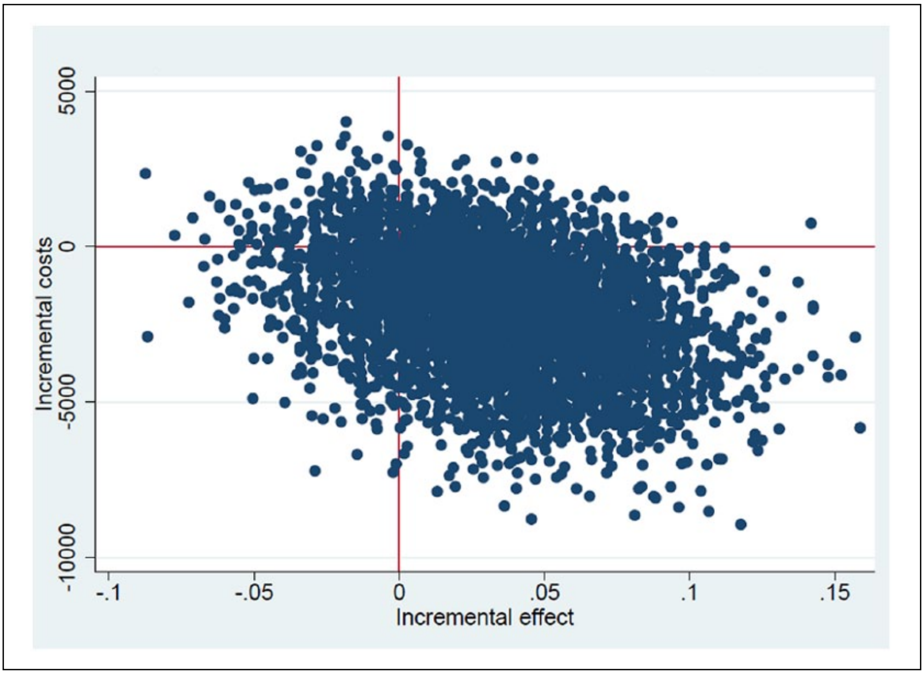

Figure 2. Cost-effectiveness plane.

Excluding one patient lowered the average total cost by approximately €1100 in the SM group, while excluding two patients resulted in a lower total cost of approximately €500 per patient in the TM group and €1200 in the SM group.

Finally, the difference in hospital resource use was explored in more detail. As can be seen from the average total costs in the main analysis in Table 3, the difference in total costs was primarily due to differences in number of admissions and outpatient visits in the two groups. S5 investigated this difference further by subdividing hospital costs (admissions, outpatient and emergency) into ulcer-related or non-ulcer-related costs. This categorisation was done by two doctors with extensive wound care experience using the departmental codes for hospital visits. The results of S5 show that SM patients had higher ulcer-related and non-ulcer-related costs, suggesting that the overall

Table 5. Four one-way sensitivity analyses on total costs per patient in the telemedicine (TM) and standard monitoring (SM) groups.

	Subgroup	*Mean cost per patient in TM group €*	N	*Mean cost per patient in SM group €*	N
S0	CEA base-case	12,356	193	14,395	181
S1	Excluding patients who died in the study period (n = 9)	12,083	185	14,384	180
S2	First half of patients in the RCT	12,177	103	19,014	84
	Second half of patients in the RCT	12,561	90	10,395	97
S3	Excluding most expensive patient (n = 1)	12,356	193	13,221	180
	Excluding patients with total costs > €100,000 (n = 2)	11,891	192	13,221	180
S4	1. Admissions, ulcer-related	4608	193	6360	181
	2. Admissions, non-ulcer-related	2472	193	2883	181
	3. Outpatient visits, ulcer-related	2523	193	2747	181
	4. Outpatient visits, non-ulcer-related	1258	193	1404	181
	5. Emergency room visits, ulcer-related	4	193	10	181
	6. Emergency room visits, non-ulcer-related	11	193	11	181
	Total ulcer-related hospital costs (1+3+5)	7135	193	9117	181
	Total non-ulcer-related hospital costs (2+4+6)	3741	193	4298	181

RCT: randomised controlled trial; CEA: Cost-effectiveness analysis.

cost difference between a TM and an SM patient was robust. On the other hand, because the same pattern was seen for both ulcer and non-ulcer elements, it is unlikely that the difference was due to the TM consultations for treatment of diabetic foot ulcers.

Discussion

This CEA comparing TM and SM for individuals with diabetic foot ulcers found that TM cost is €2039 less per patient treated than SM; however, this difference was not statistically significant. Cost savings were due to differences in the number of admissions and outpatient visits, and TM remained less expensive in all sensitivity analyses. The amputation rates were similar in the two groups, and the incremental cost-effectiveness ratio showed a mean saving of approximately €67,973 to avoid one amputation. On the basis of these results, we conclude that a telemonitoring service in this form has similar costs and effects as standard outpatient monitoring. Cost savings by providing TM care for individuals with diabetic foot ulcers are thus uncertain.

This study is the first RCT-based economic evaluation of TM in individuals with diabetic foot ulcers. A few other studies have addressed the costs of telemedicine in wound care, but none addressed cost-effectiveness in accordance with international guidelines on economic evaluation alongside a trial.[10,26] A Swedish study by Tennvall et al. concluded that inpatient costs for foot complications cannot be accurately estimated from the Inpatient Registry when based exclusively on the primary diagnosis. However, they concluded that fairly good estimates can be made with a combination of foot-related diagnoses together with codes for diabetes.[27] We have taken this observation by Tennvall et al. into account and have used clinical expert opinion in performing sensitivity analysis on costs to investigate whether admission, outpatient and emergency visits are ulcer-related.

The conclusion that the costs and effects of TM are comparable to those of SM may seem counter-intuitive given the non-significant major difference in total costs in absolute terms.

However, our findings may reflect that the study was powered after the clinical study to detect a change in number of emergency department visits, and not differences in the costs of outpatient or inpatient visits. Hence, the chosen study design in the clinical study poses a key limitation to the economic study because emergency department visits are only a very small element in the total costs. The data variability is likely to be much higher for total costs than for the number of emergency department visits reducing the possibility of identifying statistically significant changes. Thus, we cannot expect to find a statistically significant difference in the overall costs – even if such a difference was present.

Conversely, some evidence challenges that the absolute difference in costs was due to use of TM. Sensitivity analysis was used to investigate the difference between the two groups in admissions and outpatient visits. When hospital costs (admissions, outpatient and emergency) were subdivided into ulcer- or non-ulcer-related costs, the same reduction in costs was observed in both groups (ulcer- or non-ulcer-related costs). Excluding the most expensive patient from the analysis and the difference in total costs decreased substantially. These findings suggest that the absolute difference in costs may not be ulcer-related (and thus TM-related) and that the potential for future cost savings with TM may be limited.

Originally, a cost-utility analysis was planned as the main analytical framework, but results from this analysis are omitted due to incomplete data. First, we had a very low completion rate on the SF-36 questionnaires, and quality-adjusted life years (QALYs) could be calculated for only 65 patients. Second, the representativeness of these 65 patients was low compared to that of the 274 patients in the cost-effectiveness analyses. Overall, the use of randomised design in economic evaluation of telemedicine is a matter of dispute. On one hand, a small-scale test of telemedicine within one or few hospitals having a positive attitude towards telemedicine and an un-blinded staff and patients may result in positive bias. On the other hand, optimal use of telemedicine may require major organisational changes that a hospital testing a new intervention in a small-scale study is not ready to make. In addition, implementation of telemedicine may require large investment in training and IT equipment, and this may result in higher costs compared to a large-scale implementation. A possible solution to this could be observational studies estimating the costs per patient before and after a hospital or country implemented telemedicine on a large scale. However, one should not forget the value of pragmatic randomised trials which are quite distinct from traditional RCT and better suited for the changing environment of telemedicine interventions and the complex nature of the intervention.[28,29]

Regarding transferability of results, it can be argued that some of the included costs may be overestimated and avoidable if the service was implemented in a different setting or in a day-to-day running of the telemedicine service, that is, not protocol-driven. For example, the cross-sectorial collaboration between hospital and municipal health services is essential and an important aspect of the TM.[16] Consequently, some of the investment costs in the economic analysis cover more than a narrow implementation of telemedicine ulcer treatment (e.g. staff training in general wound care, project management, establishing an infrastructure for the service and evaluation activities), and there is an argument for leaving some of these components out of the CEA. Costs related to project management and evaluation activities may be avoidable in a day-to-day running of a telemedicine service, but since they constitute less than 1% of the total costs per patient not influencing the overall results, we decided to keep them in the analysis. When assessing total cost differences between the two groups in the long term, it is more fair to omit investment costs altogether.

Furthermore, the results reported here are based on experiences from a research trial. In routine clinical use, it may be possible to optimise the telemedicine consultations to make them faster and thus less costly. Also, the time used for patient transportation is rather low reflecting that on an average, a TM patient has 18 km to the hospital and an SM patient has 21 km. This is valid in an urbanised area like Denmark, but in a typical rural environment, distances are likely to be much longer making TM more cost-effective. The cost for home care nurses may also be higher in a more rural setting due to longer distances. Thus, the average treatment cost per patient in the TM group may be even lower.

Despite the above-mentioned weaknesses, the study brings new evidence to an area with little previous research and is the first with a methodologically strong economic evaluation of TM for individuals with diabetic foot ulcers.[18]

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Popular apps on the medical category targeting patients and the general public in the United Kingdom: Do they conform to the Health On the Net Foundation principles?

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Abstract

Smartphones with their rising popularity and versatile software ‘apps’ have great potential for revolutionising healthcare services. However, this was soon overshadowed by concerns highlighted by many studies over quality. These were subject and/or discipline specific and mostly evaluated compliance with a limited number of information portrayal standards originally devised for health websites. Hence, this study aimed to take a broader approach by evaluating the most popular apps categorised as medical in the United Kingdom for compliance with all of those standards systematically using the Health On the Net (HON) Foundation principles.

The study evaluated top 50 free and paid apps of the ‘medical’ category on both iTunes and Google stores for evidence of compliance with an app-adapted version of the HON Foundation code of conduct. The sample included 64 apps, 34/64 (53%) were on Google Play and 36/64 (56%) were free. None of the apps managed to comply with the entire eight principles. Compliance with seven principles was achieved by only one app (1.6%), and the rest were compliant with three, two, and one (14.7%, 27%, and 38%, respectively).

In conclusion, this study demonstrated that most popular apps on the medical category that are available in the United Kingdom do not meet the standards for presenting health information to the public, and this is consistent with earlier studies. Improving the situation would require raising the public awareness, providing tools that would assist in quality evaluation, encouraging developers to use robust development process, and facilitating collaboration and engagement among the stakeholders.

Keywords

apps, ehealth, medical apps, mobile applications, quality, quality control, quality standards, Smartphones

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Introduction

Healthcare services are facing monumental challenges, ranging from increasing costs, budget cuts, rising ageing population, and increasing burden of chronic illness to issues with health service inequality and pressures for improving the quality of care.[1] The situation has even reached apparent crisis proportions, as what was revealed in the Francis report,[2] where among the various recommendations made, 'information' was identified as key to improving services. This was subsequently followed by guidance from the Academy of Royal Colleges, outlining how information technology (IT) could be harnessed by healthcare services to improve access, efficiency, and quality.[3] The concept of using IT solutions in healthcare though is not new, and such solutions often faced various implementation obstacles, such as customisation issues, the lack of advocacy by healthcare professionals, and accessibility problems.[4]

In this context, smartphones with their rising popularity[5] and versatile portable software known as 'apps' have great potential for overcoming these hurdles[6] and could be a game changer. Nevertheless, the hype was soon overshadowed by negative reports of apps providing the wrong information,[7] making false claims,[8] content plagiarism accusations,[9] and potential for security and privacy breaches.[10]

Moreover, studies that evaluated various aspects of medical apps directed towards healthcare professionals and the public were found to be of variable quality and mostly poor.[8,11–22] The majority of these evaluated compliance with a limited number of information portrayal standards originally devised for health websites, namely, authorship,[14–16,18–21] consistency with professional guidelines,[11,19] source attribution,[15,23] purpose,[23] content currency,[19,24] security, and privacy.[12] The only study that managed to systemically evaluate all of those principles was a study by Huckvale et al.[17] on 'asthma' apps where he utilised the Health On the Net (HON) Foundation principles. The HON Foundation is an international, not-for-profit health website accreditation initiative based in Geneva.[25] Its principles have objective standards that are easy to use and widely applicable.[26] The value of evaluating adherence to information portrayal standards lies in that they are based on widely accepted ethical principles, they help reduce misunderstanding by clarifying the context, and they empower users to validate and select suitable information for themselves.[27]

This study, hence, aimed to take a broader approach by evaluating the most popular apps categorised as medical in the United Kingdom for compliance with all of those standards systematically by using the HON Foundation principles.

Previous studies on the quality of medical apps quality

Studies that evaluated the quality of medical were subject and/or discipline specific. Topics covered were smoking cessation,[11] colorectal surgery,[18] dermatology,[8,16] cardiothoracic surgery,[14] asthma,[17] opioid conversion,[15] alcohol consumption,[22] infectious disease,[24] microbiology,[21] medication self-management,[13] pain self-management,[19,20] insulin dose calculation,[23] and medical app security.[12]

Quality aspects evaluated were authorship,[14–21] consistency with professional guidelines,[11,17,19] source attribution,[15,17,23] purpose,[17,23] functionality testing,[8,15,19,22,23] content currency,[17,19,24] download popularity,[11,19,23] user feedback,[13,19,22] confidentiality,[12,17] and compliance with principles of the HON Foundation, which encompasses authorship, attribution, purpose, content justifiability, confidentiality, and currency.[17]

Healthcare professional input in app creation ranged from 14 per cent of all apps surveyed[20] to 48 per cent.[15] Huckvale et al.[23] showed that 59 per cent of apps in their study had a clinical disclaimer. Frequency of citing references in apps, on the other hand, ranged from 25 per cent of all apps surveyed in the study by Huckvale et al.[17] to 52 per cent by Haffey et al.[15] Moreover, compliance with HON Foundation principles was found to be poor, with 55 per cent of apps had their developer contact details available, 18 per cent provided disclosure of their funding source, and 17 per cent had a confidentiality policy.[17] Furthermore, Albrecht et al.[12] highlighted serious security and privacy issues in their study, where half of the apps lacked encryption or anonymity, data transfer was performed without user acknowledgement, and the content of privacy statements were ambiguous.

Methodology and study design

This was an observational cross-sectional study and entailed three stages. The first was capturing the top 50 free and paid smartphone apps on the 'medical' category of Apple iTunes (Apple Inc, Cupertino, CA) and Google Play (Google, Mountain View, CA) UK stores on a personal computer using the print screen function and subsequently selecting the sample after applying the inclusion and exclusion criteria (Box 1). The second stage entailed obtaining characteristic descriptive information from the promotional page of selected apps (Box 2). The third stage involved evaluating the app promotional page, developer website if available, and the app itself after installation for evidence of compliance with an app-adapted version of the HON Foundation principles used previously by Huckvale et al.[17] (Box 3).

Box 1. Inclusion and exclusion criteria.

Inclusion criteria
- Apps on Google Play and iTunes smartphone app stores
- Among the top 50 free and paid apps on the medical category
- In English language
- Aimed at patients and the lay public
- Provide medical or health information
- Cost £10 or less

Exclusion criteria
- Duplicates
  - Already evaluated
  - Lite versions of apps already evaluated
  - Being cheaper on the other store and meeting the inclusion criteria
- Electronic versions of printed books
- Veterinary apps
- Require subscription or verified registration for access
- Do not provide medical or health information and/or do not make any medical or health claims
  - Diary, logbook, and recording apps that provide no information or advice
  - Provide locations of healthcare services
  - Pill reminders
  - Irrelevant apps
- Not examined because of technical reasons

Box 2. Generic variables collected.

A. General description:

1. App name
2. Operating system (iOs/Android)
3. Price (in British Pounds)
3. Version
4. Presence of free 'lite' version (if applicable)
5. Download size (in megabytes)
6. Date of last update
7. Number of downloads (if available)
8. Number of ratings (if available)
9. Average user rating (if available)
10. Overall purpose (as claimed by market description)
11. Target audience

B. Developer information:

1. Developer/s
2. Individual or team?
3. What is their profession/background?
4. Have they worked with clinicians/experts if not already part of the team?
5. What other applications they have they created?
6. Developer website present?

Adapted from Reynoldson et al.[19]

Box 3. Modified HON Foundation principles.

1. *Information must be authoritative*:
    - All medical information presented by (and/or calculations performed by an app) must be attributed to an author and his/her training in the field must be mentioned.
2. *Purpose (of the app)*:
    - A statement clearly declaring that the (app) is not meant to replace the advice of a health professional has to be provided.
    - A brief description of the (app)'s mission, purpose, and intended audience is necessary. Another brief description of the organisation behind the (app), its mission, and its purpose is also necessary.
3. *Confidentiality*:
    - The (app publisher) must describe its privacy policy regarding how you treat confidential, private, or semi-private information such as email addresses and the content of emails received from or sent to (its users).
4. *Information must be documented, referenced and dated*:
    - All medical content (including calculations and formulae) must have a specific date of creation and a last modification date.
5. *Justification of claims*:
    - All information about the benefits or performance of any treatment (medical and/or surgical), commercial product, or service are considered as claims. All claims have to be backed up with scientific evidence (medical journals, reports, or others).

Box 3. (Continued)

6. *(App) contact details*:

- The (app) must be operational and the information must be accessible and clearly presented.
- There must be a way to contact the (app publisher), such as a working email address or contact form, for visitors who would like to have more details or support.

7. *Funding*:

- (The app publisher) must include a statement declaring its sources of funding.

8. *Editorial and advertising policy*:

- Conflicts of interest and external influences which could affect the objectivity of the editorial content must be clearly stated in the disclaimer.
- All (apps) displaying paying banners must have an advertising policy. This policy must explain how the (publisher) distinguishes between editorial and advertising content and which advertisements are accepted. Any conflict of interest has to be explained.

Adapted for apps by Huckvale et al.[17]

Methods

Sampling method

The apps of interest were obtained from Apple iTunes and Google Play UK stores, as these are the two most dominant worldwide smartphone platforms.[28] App stores accessed were in the United Kingdom, as this was the geographical location of the study. Sampling was purposeful, as the aim was to curate apps with particular characteristics.[29] The sample included free and paid apps to ensure fair representation of both types. The ‘medical’ category of both stores was chosen with the assumption that it would contain apps taken more seriously. It is worth noting though that the ‘medical’ category also contains non-relevant apps,[30] and this is due to the loose regulation of categorisation within app stores, as developers often list their apps in multiple categories to reach wider audiences.[10,24,30,31]

Selecting the apps among the top 50 was to ensure that those sampled were the ones most in demand. To be among the top 50 apps in the US iTunes store, for example, a free app would require at least 23,000 downloads a day, while a paid app would require 950.[32] Additionally, since most app users today are becoming less willing to pay,[33] an arbitrary £10 cap was made. Furthermore, the target audience for sampled apps were patients and the lay public, with the assumption that those two groups are the more vulnerable for false information compared with healthcare professionals.

Funding and ethical approval

This study was self-funded, and purchased apps were subsequently uninstalled and refunded after evaluation. Apps are commercially available and therefore constitute data available in the public domain, hence no ethical approval was required.

Quality assessment standard

Apps selected had their store promotional page and developer website if available, and the app itself checked for evidence of content compliance with an app-adapted version of the HON Foundation principles used by Huckvale et al.[17] (Box 3).

It is worth noting that the final decision on principle compliance is ultimately decided by HON Foundation experts prior to accreditation,[34] and there is currently no information on the validity and reliability of any HON assessment tools used for websites[35,36] or apps. However, the Foundation encourages developers and users to be aware of their standards and has even designated an online form to assist with compliance assessment,[37] thus one could reasonably argue that evaluating compliance with the HON Foundation standards does have face validity.

Compliance was checked by the author who is a health informatics master's degree student at Swansea University. An app was deemed non-compliant with a given HON Foundation principle if the promotional page, developer website, and the app content itself do not fulfil all the applicable criteria. Moreover, in case of doubt or the lack of clarity on whether an app is compliant, the app was designated as non-compliant.

Data collection and analysis

Free access to the app stores was obtained using a personal computer with Microsoft Windows 7 operating system (Microsoft, Inc., Redmond, WA) via the Apple iTunes portal software (version 12.1.2) and the Google Play website portrayed on a Google Chrome browser (version 43.0.2357.81 m). Screenshots of the app store sections containing the required sample were captured on 27 May 2015. The eligibility criteria were applied and the generic information of the selected apps was gathered from the promotional page on the store. Compliance was recorded on Microsoft Excel 2013 spreadsheet table in dichotomous form (yes/no) for each one of the eight principles, akin to the study by Huckvale et al.[17]

The apps were downloaded and installed on two personally owned devices. The iPhone apps from Apple iTunes were installed on an Apple iPad 2 tablet computer operated by an iOS version 7.1 operating system, whereas Google Play smartphone apps were tested on Samsung Galaxy Note 3 device (Samsung Electronics Co., Suwon, Korea) operated by Google Android Lollipop operating system version 5.0.

Statistics

Summary statistics were performed using Microsoft Excel 2013 with an Analysis ToolPak add-in. Fisher's exact and Spearman's rank tests were performed using IBM SPSS Statistics 22 (IBM, Inc., Armonk, NY).

Results

The study sample comprised 64 apps, 34/64 (53%) were from Google Play and 36/64 (56%) were free (Figure 1). The median price was £2.74 (range, 0.62–7.61; Figure 2), and the median download size was 7.15 MB (range, 0.594–333; Figure 3). Last update dates ranged from November 2008 to June 2015. The number of ratings received ranged from 2 to 54,093, and the median individual app rating was 4.1/5 (range, 1–5; Figures 4 and 5).

Most topic themes were on women's health (24/64 (38%)) and mental health (8/64 (13%); Figure 6). The majority of app utilisations were providing medical or health information to the public (study inclusion criteria) (64/64 (100%)), calendars and diaries (23/64 (36%)), calculators (12/64 (19%)), self-diagnosis (8/64 (13%)), and hypnotherapy (8/64 (13%); Figure 7). Most apps were developed by a team (38/64 (59%)), 2/64 (3%) were developed by an individual, and 24/64 (38%) had no developer information.

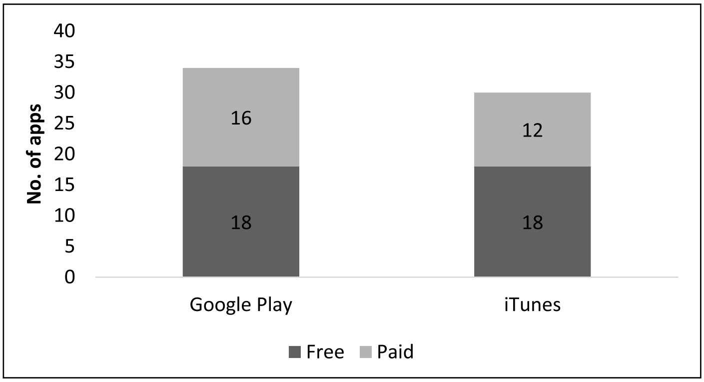

Figure 1. App sample (n = 64).

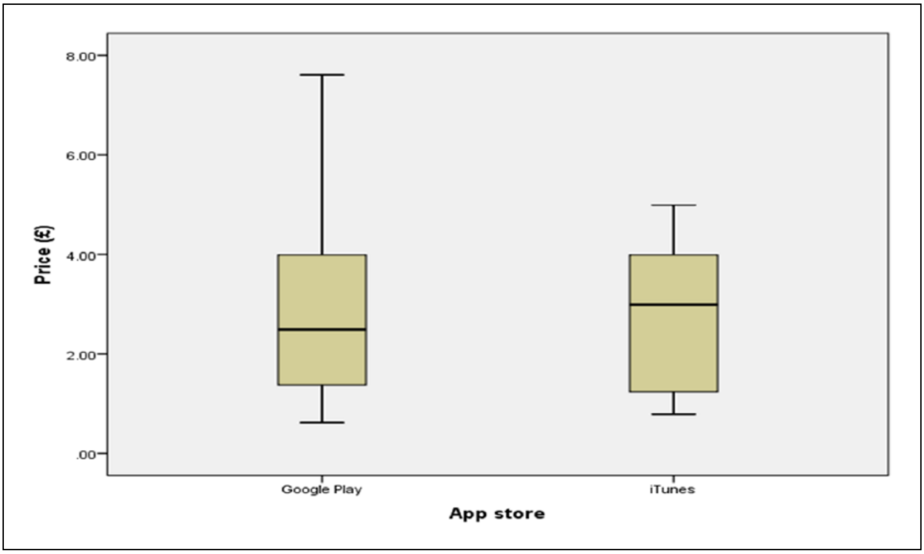

Figure 2. App prices.

None of the apps within the sample managed to fully comply with the entire eight HON Foundation principles. Compliance with seven principles was achieved by only one app (1.6%) titled ‘Drugs.com Medication Guide’. This was an app rendering a HON Foundation certified website, and the only principle it failed to comply with was ‘attribution/currency’, as the date of when the information was first created was not clear. The rest of the apps were mostly compliant with one, two, or three principles (38%, 27%, and 14.7%, respectively; Figures 8 and 9). Most complied with principles were ‘transparency’, ‘purpose’, and ‘confidentiality’ (97%, 53%, and 43%, respectively), while the least complied with were ‘attribution/currency’, ‘authoritative’, and the ‘advertising and editorial policy’ (2%, 9%, and 12%, respectively; Figures 10 and 11).

Apps on iTunes had better compliance with ‘authoritative’ (10% vs 8.8%), ‘purpose’ (60% vs 47.1%), ‘confidentiality’ (56.7% vs 35.3%), ‘financial disclosure’ (26.7% vs 5.9%), and ‘advertising

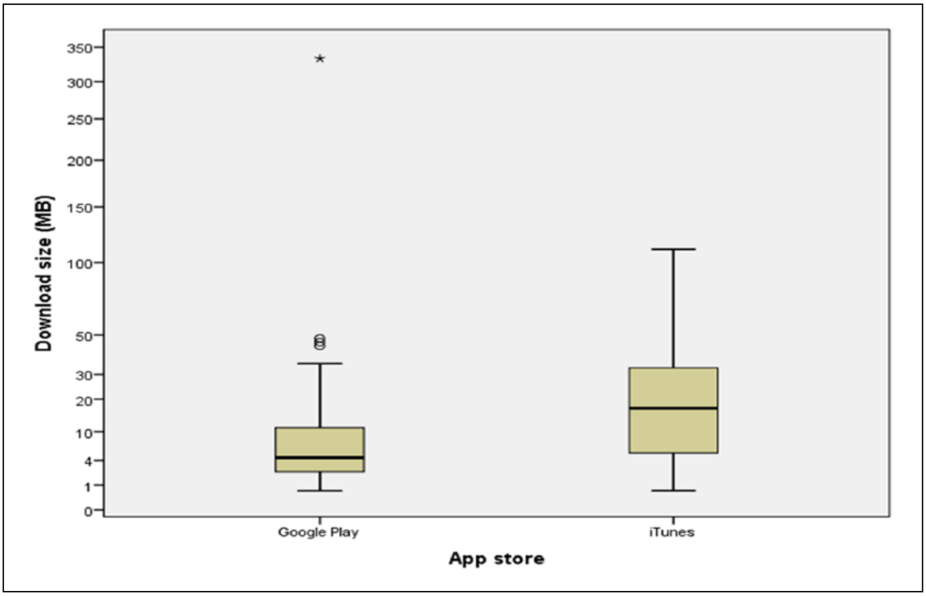

Figure 3. Download sizes.

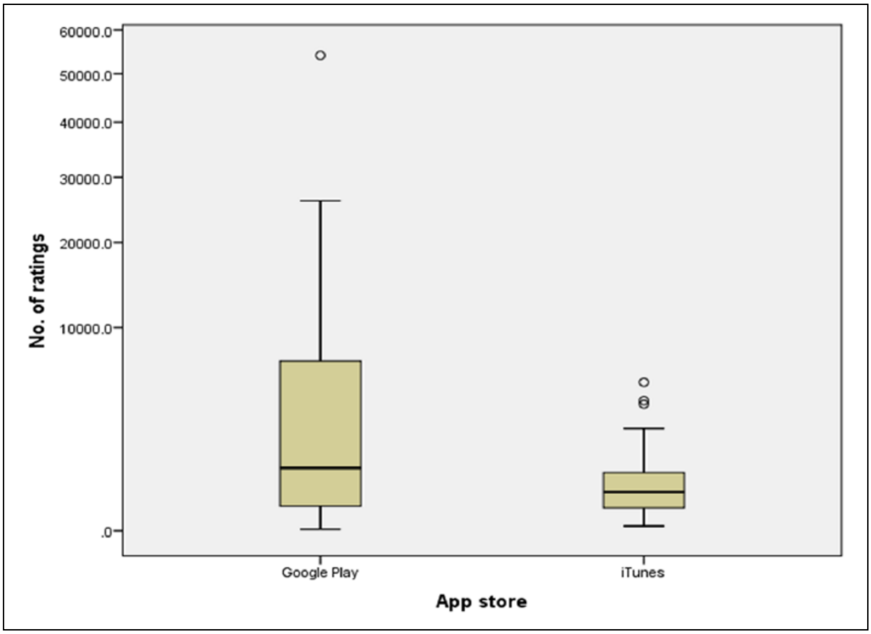

Figure 4. Number of ratings.

and editorial policy' (16.7% vs 8.8%) principles. Google Play apps, on the other hand, had better compliance in regard to 'attribution/currency' (2.9% vs 0%), 'justifiability' (14.7% vs 13.3%), and 'transparency' (100% vs 93.3%) principles. There was no significant statistical difference in

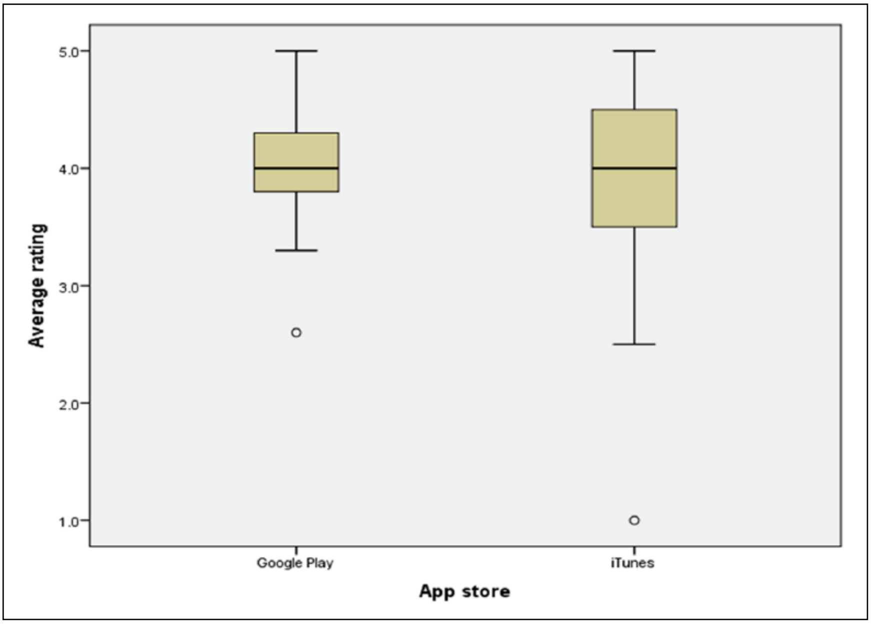

Figure 5. Average rating.

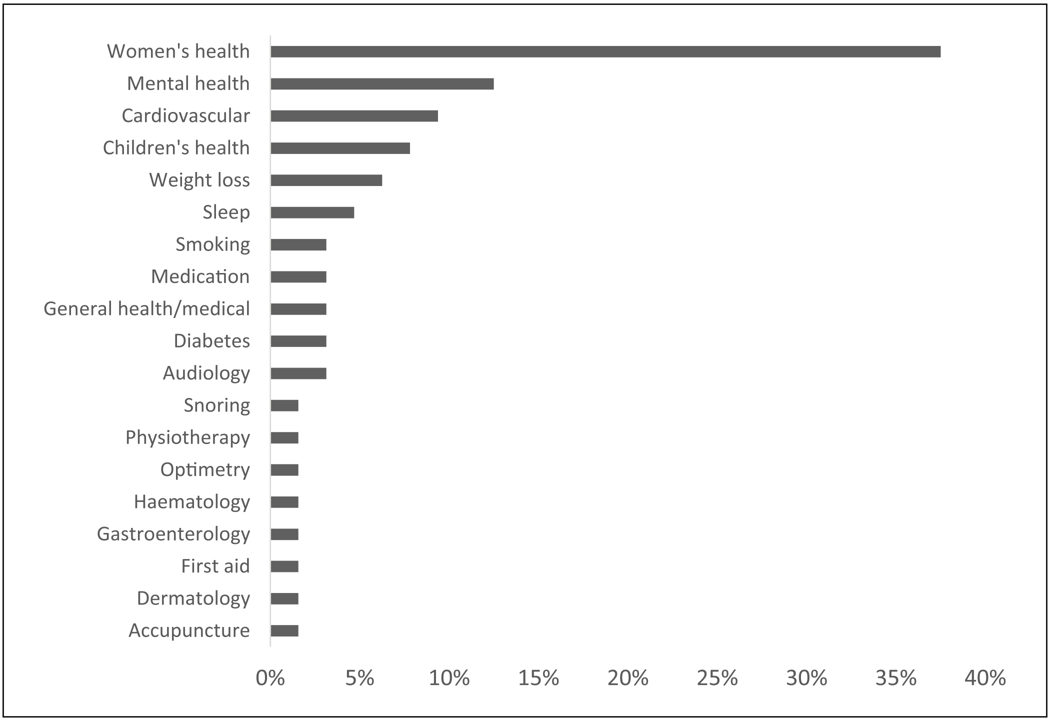

Figure 6. App themes.

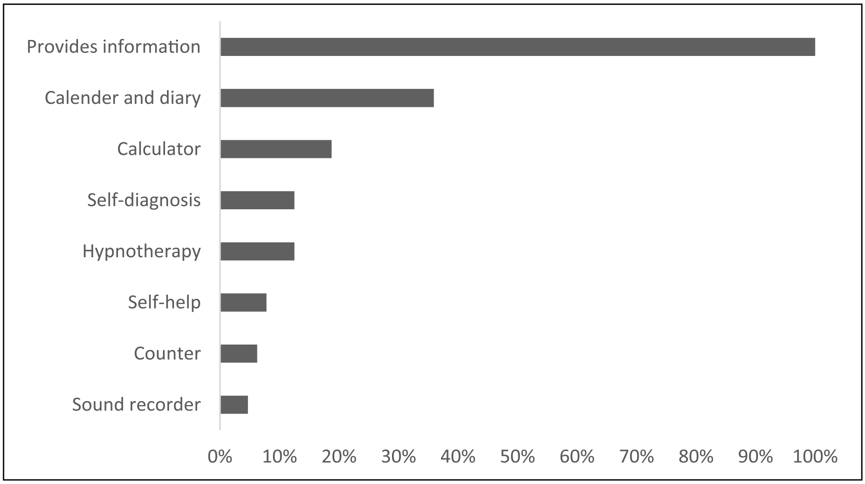

Figure 7. App functions.

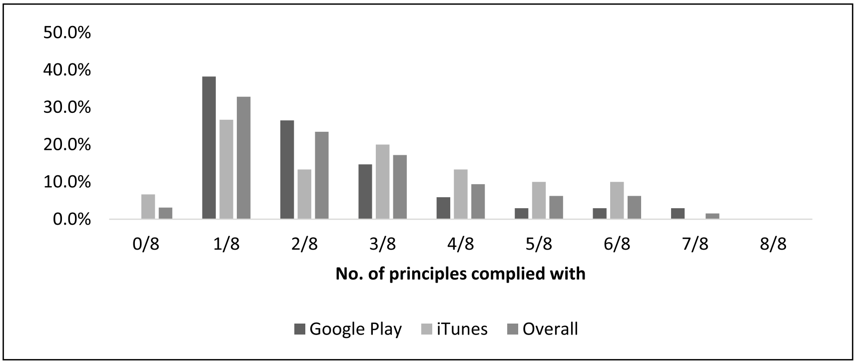

Figure 8. Number of HON Foundation principles complied with (by store).

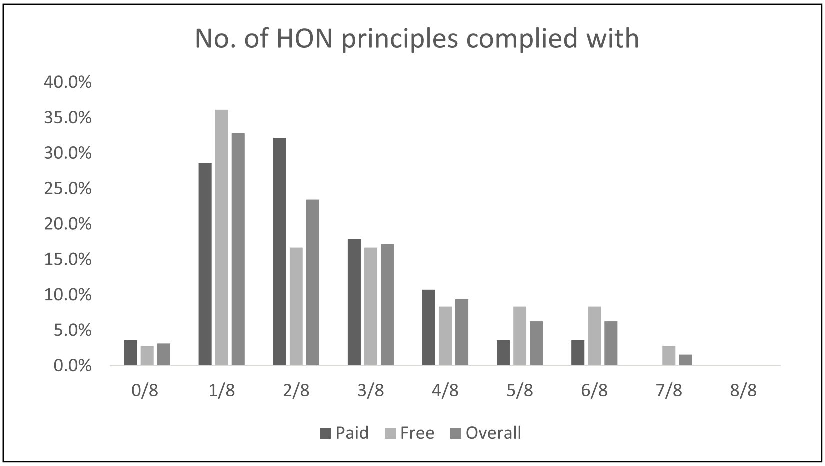

Figure 9. Number of HON Foundation principles complied with (by cost).

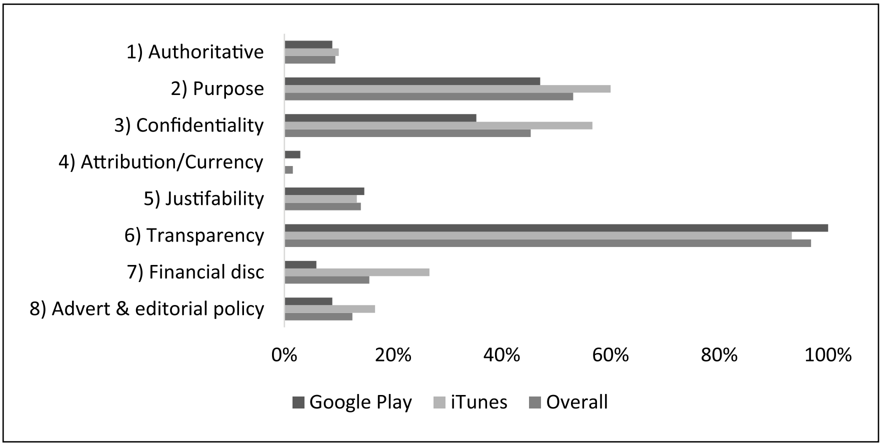

Figure 10. HON Foundation principle compliance percentage (by store).

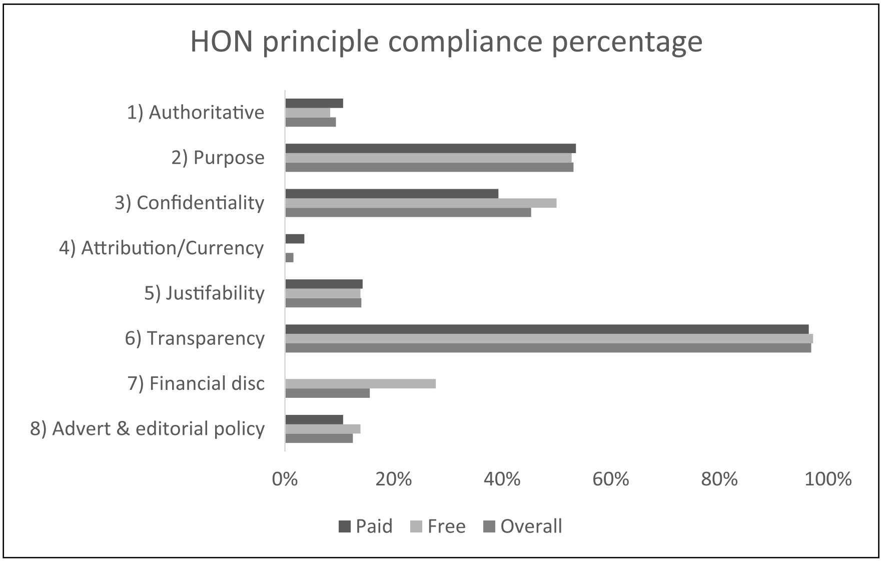

Figure 11. HON Foundation principle compliance percentage (by cost).

compliance between the two app stores or between free and paid apps, with the exception of compliance with the principle financial disclosure where the results were significant at $p < 0.05$ (Table 1).

The study also showed that apps compliant with ‘purpose’, ‘confidentiality’, or ‘financial disclosure’ principles tend to correlate strongly with compliance with higher number of HON Foundation principles (rS 0.817, 0.771, and 0.607, respectively; $p < 0.01$*) (Table 2). Additionally, healthcare professional involvement in app creation was also found to correlate strongly with ‘authoritative’ and ‘justifiability’ principle compliance (rS 0.918 and 0.722, respectively; $p < 0.01$*), as well as adherence to five or more HON Foundation principles (rS 0.722; $p < 0.01$*) (Table 3). However, the generalisability of these associations and correlations is questionable given the small sample size.

Table 1. Fisher's exact tests.

Principle compliance	Frequency by platform				Frequency by cost			
	Google Play (n = 34)	iTunes (n = 30)	Overall (n = 64)	p value, FET (two-sided)	Free (n = 36)	Paid (n = 28)	Overall (n = 64)	p value, FET (two-sided)
1. Authoritative	3 (9%)	3 (10%)	6 (9%)	1.000	3 (8%)	3 (11%)	6 (9%)	1.000
2. Purpose	16 (47%)	18 (60%)	34 (53%)	1.000	19 (53%)	15 (54%)	34 (53%)	0.327
3. Confidentiality	12 (35%)	17 (57%)	29 (45%)	0.454	18 (50%)	11 (39%)	29 (45%)	0.131
4. Attribution/ currency	1 (3%)	0 (0%)	1 (2%)	0.438	0 (0%)	1 (3.6%)	1 (2%)	1.000
5. Justifiability	5 (15%)	4 (13%)	9 (14%)	1.000	5 (14%)	4 (14%)	9 (14%)	1.000
6. Transparency	34 (100%)	28 (93%)	62 (97%)	1.000	35 (97%)	27 (96%)	62 (97%)	0.216
7. Financial disclosure	2 (6%)	8 (27%)	10 (16%)	0.003*	10 (28%)	0 (0%)	10 (16%)	0.036*
8. Advert and editorial policy	3 (9%)	5 (17%)	8 (13%)	1.000	5 (14%)	3 (11%)	8 (13%)	0.458

FET: Fisher's exact test.
*Fisher's exact test (two-sided) is significant at $p < 0.05$.

Table 2. Spearman rank test 1.

	Number of HON Foundation principles complied with	
	rS	p (two-tailed)
Purpose	0.817	<0.01*
Confidentiality	0.771	<0.01*
Financial disclosure	0.607	<0.01*

HON: Health On the Net.
*Correlation is significant at the 0.01 level (2-tailed).

Table 3. Spearman rank test 2.

	Healthcare professional involvement in app creation	
	rS	p (two-tailed)
Authoritative	0.918	<0.01*
Justifiability	0.722	<0.01*
Adherence to five or more HON Foundation principles	0.722	<0.01*

HON: Health On the Net.
*Correlation is significant at the 0.01 level (2-tailed).

Discussion

Compared to the best results in the literature, this study had better figures in regard to overall app compliance with transparency and confidentiality principles (97% vs 55%[17] and 45% vs 17%,[17] respectively) and worse figures in regard to 'purpose', 'financial disclosure', 'authoritative', and 'attribution/currency' compliance (53% vs 59%,[23] 16% vs 18%,[17] 9% vs 48%,[15] and 2% vs 52%,[15] respectively).

The better compliance with the ‘transparency’ principle result is unexplained, as there is no evidence to suggest that providing developer contact information for users is currently being required by app stores. On the other hand, better compliance with ‘confidentiality’ might have been influenced by the new mandatory privacy policy for apps involved in the transmission of data containing personal information by Apple,[38] though this is currently only a recommendation by Google.[39] It is worth mentioning that the HON Foundation mandates a privacy policy even when no personal data are being transmitted.[40]

The overall poor compliance with the HON Foundation principles revealed in this study is not surprising, as it is comparable to earlier studies on apps evaluating partial and full app compliance. It also indicates that the quality issues with medical apps targeting patients and the lay public are both ongoing and widespread. More needs to be done to reassure users.

The scene on regulating medical apps was initially shrouded with uncertainty over whether they should be regarded as medical devices, and the position of regulatory agencies in Europe and the United States is still developing. However, some consensus has emerged in regard to considering certain apps that meet specified criteria as medical devices, though there are still differences among various agencies, and the situation still leaves wide range of apps outside their realm, such as electronic versions of reference materials, educational tools, and apps that patients use to obtain information.[41]

Some have argued that the responsibility for overseeing the quality of these apps should lie with the big app vendors such as Apple and Google.[42] It is worth noting that apps submitted to both stores are subjected to various degrees of scrutiny prior to release, though their content is unlikely to be thoroughly evaluated.[43] However, there are little incentives for these big companies to undertake such role, especially that medical apps are not a major source of revenue, unlike other categories such as Games,[10] though the situation might change in view of the optimistic growth forecasts of the mobile health market.[44] Conversely, while the involvement of Apple and Google in medical app regulation might be desirable, this would also bring up their conflict of interest into question should they become involved.[42]

Various initiatives have since emerged to assist users with identifying high-quality medical apps, such as peer-review,[45] certification,[46,47] professional review,[48] and user feedback.[49] The scene, though, is still evolving with new emerging proposals such as the utilisation of an app synopsis that could be incorporated into a search engine[50] and self-certification based on standards of health information portrayal akin to the HON Foundation scheme,[51] while others have been discontinued such as Haptique.[52] Moreover, a recent guidance by Royal College of Physicians of London[53] recommended against using apps in healthcare unless they have been registered as a medical device and to exercise professional judgement when using apps in any clinical settings. The college also declared that while they have no intentions of recommending apps to doctors, they are collaborating with other organisations and agencies on developing quality criteria.

Not surprisingly, the current issues with medical app quality seem to mirror earlier problems and debates on health websites,[27,54–61] which are still ongoing.[26,62–64] These are relevant within the realm of medical apps as both are media for providing information, and their use could involve the collection and transmission of personal data. Furthermore, Internet accessibility is enhanced by smartphones, and websites could be rendered in a compressed format on smartphones known as ‘web apps’. Hence, valuable lessons could be learnt.

Views on health website content quality evaluation and regulation are diverse. Some regarded it as an impossible task and that the responsibility should be left with the users, akin to other information media outlets.[62,65] Delamothe,[66] on the other hand, argued that no omniscient non-biased observer exists that would be able to evaluate contents of websites through the eyes of medical professionals, patients, and lay people at the same time. While others proposed and established initiatives and tools with the purpose of assisting users in identifying high-quality websites, such as codes of conduct, self-applied quality labels, user guidance systems, filtering, third-party accreditation for a fee,[60] and curation of useful sites in lists.[55] These took a downstream regulatory approach given the decentralised nature of the Internet[57] and were not without their limitations.

Lone codes of conduct without enforcement mechanisms, for example, were found not to be effective.[67] User guidance tools, on the other hand, could be burdensome as the evaluation process can be time consuming and subjective,[59] while filtering and curation lists require costly continuous updates.[55,60] Moreover, third-party accreditation schemes do put up huge costs for participating website providers[60] and self-applied quality labels, such as the HON Foundation scheme, and certify only health information presentation, thus placing some burden on users by requiring them to be aware of the principles while evaluating the content[68] and on website developers in terms of compliance.[60]

Given the above, Fahy et al.[26] have hence suggested that perhaps the best approach would be through utilising multiple methods. This is interestingly consistent, in a way, with the conclusion of a landmark market research in the 1980s on consumer preferences, which showed that there was no such thing as a single perfect set of product characteristics, but rather a variety of characteristic sets that would appeal to consumers with different preferences.[69]

Recommendations and implications for further research

It would be reasonable to extrapolate that within the realm of medical apps, various quality initiatives and approaches might be needed in order to assist users with different degrees of willingness and abilities in regard to accepting the evaluative burden. This would also help in offsetting the limitations of each method and allows the consideration of various views held by app stakeholders. Therefore, a self-certification scheme similar to that of the HON Foundation, as suggested by Lewis,[51] would be a useful addition to other approaches in use today. This could also be utilised as a first level of a multi-tier app certification system, after which an app could undergo further comprehensive evaluation[50] and risk assessment.[70] However, further research is needed in determining the reliability and validity of the HON Foundation compliance tools within the realm of apps.

Additionally, raising awareness of the wide prevalence of poor quality among medical apps, explaining the potential risks associated, emphasising the importance of evaluating the content critically, and guiding them towards tools that could assist them in the process would help raise consumer expectations and could pressurise developers into raising standards. Developers of medical apps are currently strongly advised to adopt robust quality development processes,[10,41] such as the ‘Clarify, Design, and Evaluate’ approach devised by the Imperial College of London.[71]

Furthermore, bringing and engaging the stakeholders under a collaborative non-profit organisation, such as HANDI[72] in the United Kingdom, would greatly facilitate app development process through disseminating best practices and providing a great medium for networking and discussions.

Limitations

This study was restricted to Apple iTunes and Google Play stores, as these were the platforms with the biggest share of the market and meet the objective of evaluating most popular apps. Only the UK stores were evaluated as this was the geographical location of the study, though inferences could still be extrapolated to other developed countries. The sampling process was purposeful, and this was intentional as the aim was to obtain apps relevant to the scope of the study and was performed according to a predetermined explicit inclusion and exclusion criteria. The study sample was small due to the lack of funding and time constraints, and this had an impact on the ability to generalise the significance of group comparisons. Further research with a larger sample would provide useful insights.

On the other hand, compliance with the HON Foundation principles was evaluated by a single evaluator who is the study author. Although the Foundation does encourage developers and users to evaluate compliance using its explicit list of principles and criteria, this is ultimately formally assessed by experts prior to certification. This is additionally compounded by the lack of information in regard to the validity and reliability of any available HON assessment tools. Further research is needed to establish this for apps and take it beyond mere face validity.

Moreover, compliance evaluation by a single assessor increases the potential for bias. In an attempt to minimise this, a systematic evaluative methodology was adopted and was performed according to an explicit strict study protocol. Accordingly, an app was only deemed compliant with a given principle when it unequivocally fulfils all the applicable criteria. One would acknowledge though that this has set the bar high and likely to have contributed towards lowering app compliance results in our study.

Conclusion

This study demonstrated that most popular apps on the medical category that are available to the public do not meet the standards for presenting health information to the public, and this is consistent with earlier reports and studies on medical apps.

Our experience from websites tells us that multiple user guidance initiatives are needed to suit people with various differences and preferences. Thus, having a scheme akin to that of the HON Foundation would be a useful addition to the existing initiatives that aim to guide the users towards high-quality apps. This could also be utilised as a first-level stage within a multi-tier certification system.

Moreover, improving the current situation would require raising the public awareness, providing tools that would assist in quality evaluation, encouraging developers to use robust development process, and facilitating collaboration and engagement among stakeholders.

Declaration of Conflicting Interests

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The use of mobile technology in waiting rooms to leverage women's empowerment: A conceptual context

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Abstract

This article focuses on a conceptual framework that can be applied to the use of mobile technology in the waiting room with the goal of empowering women recently diagnosed with abnormal Pap test results. It further describes trends which indicate a need for improved and timely information dissemination. Genecology practice outpatients report a predominant feeling of worry on receipt of abnormal medical test results, along with a clearly expressed wish for additional information. This research suggests that there is room for improvement in existing processes through use of mobile technology with carefully vetted materials which indicate a doctor is interested in the patient's well-being.

Keywords

education, empowerment, mobile technology, Pap test, waiting room

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Introduction

Patient education is important in treatment outcomes. This education may be done formally at doctors' offices by healthcare professionals or through alternative methods which include computer-based learning, video, and media.[1–3] Unfortunately, most alternate methods can be classified as a one way communication. Good information and communication increase patients' capability to contribute to decision-making processes, leading to higher levels of satisfaction and favorable treatment outcomes.[4,5] While it is important to have a patient fully informed and engaged in the decision-making process, it is inevitable that patient comprehension of explanations often is lacking due to the complexity or for other reasons. Evidence suggests that patients often do not understand what is being said when information is given during a medical encounter due to educational gaps between clinicians and patients.[6]

The most important attribute of patient-centered care is the active engagement of patients when fateful healthcare decisions must be made.[7] In other words, the point when an individual patient arrives at a crossroads of medical options and the diverging paths have different and important consequences with lasting implications. Examples include decisions about major surgery, medications that must be taken for the rest of one's life, and screening and diagnostic tests that can trigger cascades of serious and stressful interventions.

For some decisions, one clearly superior path exists, and patient preferences play little or no role. Examples include when a fractured hip needs repair, acute appendicitis necessitates surgery, or bacterial meningitis requires antibiotics. For many medical decisions, however, more than one reasonable path forward exists (including the option of doing nothing, when appropriate). Different paths entail different combinations of possible therapeutic effects and side effects. Decisions about therapy for early-stage breast cancer or prostate cancer, lipid-lowering medication for the primary prevention of coronary heart disease, and genetic and cancer screening tests all are good examples. In such cases, patient involvement in decision-making adds substantial value.

Recently, there has been a shift in the process of receiving medical care. This shift, often referred to as health empowerment, relates to the role patients play when receiving medical care. Health empowerment is frequently defined as a combination of "knowledge, skills, and a heightened self-awareness regarding values and needs" to help patients reach their personal health goals (p. 140).[8] Empowerment within the health context has frequently been operationalized in terms of how much patients participate in the medical decision-making process.[8] Dupuits[9] claims that the Internet and other such information media have had significant influence on patients' empowerment and their participation in the decision-making process. However, other research asks whether high amounts of information are always beneficial to patients. Broom[10] says that for some patients with prostate cancer, Internet health information has served as a source of empowerment, while for others, it has served as a source of confusion.[11] Patients who seek health information in addition to that provided by physicians challenge the physician–patient relationship, and this can lead physicians to further limit collaboration in the treatment decision-making process.[10]

Therefore, further review of the effects of health information on patient empowerment and participation is warranted. This study offers a conceptual framework to examine the benefits of presenting information to women in waiting rooms prior to a genecology professional encounter to discuss initial results regarding positive Pap test indication.

Background

Empowerment

Gibson[12] defines empowerment as the process by which individuals or groups enhance their ability to meet their needs and gain a sense of control over their lives. Research indicates that empowerment can occur at various levels including the individual, organizational, and societal levels.[12–14] At the individual level, empowerment is described as a family of variables that "includes participatory behavior, motivations to exert control, and feelings of efficacy and control."[13] This form of empowerment includes both individual perceptions (psychological aspects) and behavior. In regard to health care, Webb et al.[15] refer to empowerment as the process in which patients and providers equally contribute to the health decision-making process. Webb et al.[15] measure empowerment by asking participants generic questions about their perceived degree of involvement in and satisfaction with their treatment decisions. Thus, Webb et al.[15] allude to the notion that empowerment is a reconceptualization of participatory decision-making. Thus, there appears to be overlap and confusion among the constructs that relate to empowerment. Roberts[16] clarifies that previous research has defined empowerment as the relationship between health and power, an informed and active patient, an equal physician–patient relationship, and a type of health education. According to Roberts,[16] the various conceptualizations suggest psychological aspects of empowerment and empowered behaviors are likely to be intertwined.

Health information, including information provided by a physician as well as information sought by a patient, may have varying effects on patients' senses of empowerment. It appears as though the information provided by a physician may allow patients to feel more empowered and efficacious; however, such information may also confuse patients and ultimately hinder the decision-making process. A great deal of literature suggests that information is a useful tool in increasing a patient's empowerment, while other literature suggests that extreme amounts of information lead patients to information overload and confusion.[17,18]

Information overload

According to Chen and Chang,[19] humans have limited information processing capacity. As amounts of information increase, humans tend to increase their processing efforts accordingly. When individuals are confronted with more information to process than they are able or willing to process, they may perceive themselves as experiencing information overload. Perceptions of overload are the result of the interaction between high amounts of information and limited processing capacity.[19] When processing limits are surpassed, overload occurs and an individual may be left confused and more likely to make poor decisions as a result.[17]

Women's health clinics

A good example to represent the influence of information overload in health sensitive and complex situations can be illustrated by cervical cancer diagnosis cases. Extensive information on this topic currently is available. The effectiveness of this information in reducing anxiety in women receiving abnormal Pap tests is not clear since so much information exists and because information available at home is not always accessible.[20]

Cervical cancer is the second most common cancer in women, affecting nearly 530,000 females worldwide and resulting in 275,000 deaths each year, including 31,000 cases and 13,000 deaths in Europe.[21] Human papillomavirus (HPV) infection can lead to the development of pre-cancerous lesions and cervical cancer.[22] Routine screening and HPV vaccination programs have increased the visibility of cervical cancer in the wider community, and may contribute to increased concerns about developing this cancer, particularly in younger women.[23]

Cervical cancer can be detected using a Pap test. A Pap test uses a sample of cells taken from a woman's cervix or vagina. The test looks for changes in the collected cells that show cancer or conditions that may develop into cancer. The Pap test currently is the best tool to detect pre-cancerous conditions and hidden, small tumors that may lead to cervical cancer. If detected early, cervical cancer can be cured.

A Pap test is not comfortable and its negative perception can be increased by receiving news via phone that one's test result is abnormal. Frequently, women are given little information about what the result means. This leaves them unsure about the next steps to take. In fact, studies report women commonly feel stressed and anxious after being informed of an abnormal Pap smear test result[24–26] irrespective of the severity of the result.[27] These emotions often are long lasting.[28]

Other research confirms that lack of accurate and understandable medical information about the causes, prevention, treatment, and consequences of an abnormal Pap smear result and cervical cancer leads to anxiety.[29] When a doctor reports that a Pap test is abnormal, this means the test has identified abnormal cells on her cervix. But, having an abnormal test result does not mean the woman has cancer. In fact, the chances are very small. However, the patient is requested to schedule a follow-up with a professional genecology clinic and during the intervening time period, anxiety and worry may build. In response, a woman may access information on the web.

When the patient arrives at the medical encounter, she will be experiencing anxiety about the future. In this situation, it is unlikely that she will be involved in any decision-making, and this can add to confusion surrounding the forthcoming medical encounter.

She may have learned there are several options of treatment and all are considered effective to various degrees, but her information may be incomplete. For instance, she may not know the best treatment will depend on the type and extent of her problem. Some doctors will prefer one treatment method over another, and again she may not have access to this information. In this regard, it is important that a patient understand why a doctor recommends one approach or treatment over another. Therefore, it is important to empower, enable, and support women with the ability to ask questions without fear or reservation.[30] This research seeks to examine, *if women's waiting times for gynecological consultations can be leveraged to inform them in a better way, thus empowering her to be an active participant in the medical encounter decision-making, therefore increasing her patient satisfaction*.

Furthermore, we look at the waiting room time as an opportunity to trigger a woman's education regarding such sensitive issues. We hypothesize that the use of mobile technology, which includes carefully controlled health-related information, can help a woman be better informed, empowered, and enable her to communicate better in the forthcoming medical encounter. She ultimately might perceive higher patient satisfaction related to communication with the doctor.

Being well informed is, indeed, critical for lowering anxiety over abnormal results. It may be the case that many women do not understand the meaning of an abnormal Pap result and wish for more information. An Australian study has shown that women wish to participate in decisions about their care but find it hard to ask questions.[31] Physicians should bear in mind that patients may not spontaneously request further information, despite (or perhaps because of) high levels of anxiety.[29] We therefore suggest the use of mobile technologies, such as tablets, in the waiting room to provide easy access to information that was carefully vetted and communicated by the doctor regarding treatment, procedures, and long-term effects,[32] and to help reduce anxiety and improve general situational knowledge.[33]

Mobile use in the waiting room

The widespread adoption and use of mobile technologies is opening new and innovative ways to improve health and healthcare delivery.[34,35] These applications are being assimilated quickly into health care.[36] The use of mobile applications prior to physician encounters regarding birth control information can help foster a better understanding of how a particular method works and the long-term implications of continued use. The mobile application used in the Sridhar et al.[36] study increased patient satisfaction with counseling and showed that mobile applications are best used in addition to physician consulting. A major limitation in the Sridhar et al.[36] study was the lack of a follow-up. The study did not report whether visit times changed when the application was used after the consultation. Due to time constraints that limit a physician's ability to deliver detailed information during a medical encounter, applications for mobile technology can be designed to educate patients and simplify communication between patients and providers.[37] Therefore, there is the potential to examine mobile applications in the waiting room.

Little formal research has been conducted to evaluate time spent in waiting areas. The limited studies conducted have attempted to improve waiting area experiences for patients and their supporters regarding design of the space and reduction in waiting times.[38] This often is specific to a local office, and is focused on patient comfort issues such as temperature, seating, coffee, television programming, or wait times.[39,40] Although many opportunities for redesigning waiting room space for comfort, safety, and even entertainment exist, there also are opportunities to redesign the space to encourage learning. Traditional educational material in waiting areas is often ineffective and unacknowledged. Often, patients are provided with pamphlets and posters to learn about diseases and disorders. General practitioners agreed that patient curiosity regarding health-related information is growing and that the physician should consider the waiting room as a place for patient education.[41]

A previous study assessed the value of various techniques designed to reduce patient anxiety in waiting room.[42] This study and others suggest provision of waiting room information may reduce anxiety when it concerns a care procedure the patient will subsequently experience.[43] Waiting room time can become useful with formal patient education.[44] This is particularly true in light of what is known about creating innovative, empowerment-based, educational materials.[45]

Conceptual framework

Our research used a general model reflecting factors that might influence a better way to improve communication during a medical encounter (Figure 1). We specifically focused on empowerment related to waiting room times and later as an outcome obtained through use of mobile platforms to enable learning through access to physician-controlled education materials.

Patient–physician encounter

Patient–physician interaction is an important aspect of the patient's level of involvement,[46] and is focused on empowering patients.[47] Patient–physician interaction usually seeks to help patients become more active during consultations, and is linked to positive health outcomes such as enhancing self-efficacy, providing better ability to adopt the correct treatment plan, and achieving patient goals. In order for the encounter to empower the patients, a collaborative relation between patient and physician is necessary, as well as development of a patient's ability to engage in self-care, and cooperation.[47]

According to Feldman-Stewart et al.,[48] patient–physician interaction is based on four components: (1) patients' and physicians' communication goals; (2) needs, skills, values, and emotions that affect communication; (3) how messages are verbally and nonverbally conveyed and received; and (4) the communication environment, including external factors such as prior education and experience. All four factors influence the outcomes gained from the encounter.

To return to the sensitive Pap test situation described earlier, a woman and her physician might have different goals during the medical encounter. For instance, the physician may focus on

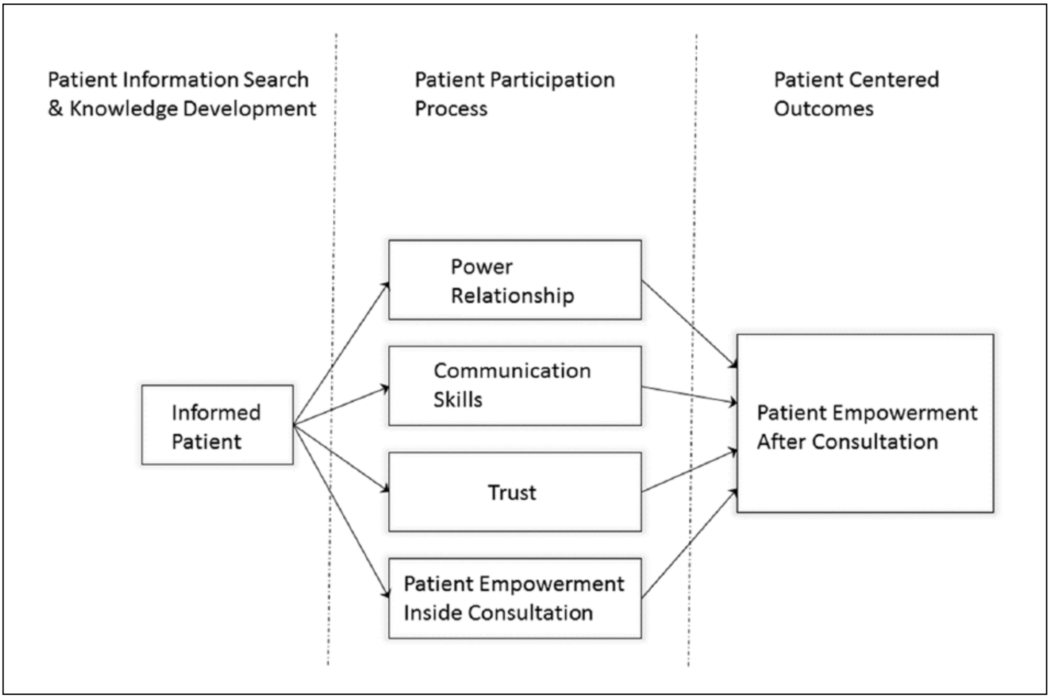

Figure 1. Conceptual framework for mobile use in waiting room.

relevant treatment while the woman seeks to allay confusion, anxiety, and fears. A woman may enter the consultation with very low knowledge, with needs based more on support aspects and less on an interest to be involved in the decision-making process. The way a physician decides to convey the treatment options might influence overall understanding. Furthermore, this might vary from doctor to doctor—for instance, one may decide to explain, while another makes the explanation shorter in order not to inject more stress into the situation. Education and prior experience of the patient regarding the medical situation may also factor into the interaction.

In considering all four characteristics of interaction in the medical encounter, we suggest four constructs that lead to enhancement of empowerment based on self-determination theory (SDT) which proposes how specific needs of individuals drive their self-intended (self-determined) behaviors.[49]

SDT states that human beings have basic psychological needs, such as the need for autonomy, which is the desire to experience satisfaction with exercising and extending one's capabilities and mastering challenging tasks. Individuals strive to satisfy these needs to increase their well-being, and thus engage in certain behaviors they perceive as self-determined[50] such as an information search or participation in decision-making. These self-determined behaviors trigger subsequent actions, during which individuals try to keep consistent with their previous actions and underlying needs.[51] This includes activities such as complying with recommendations.

More specifically, *information search* is the degree to which a patient systematically and actively collects disease and treatment-related information from various information sources (e.g. personal meetings in self-help groups, books, Internet, brochures).[52] Knowledge is developed as a by-product of an information search. *Knowledge developmen*t is the degree to which patients actively organize and understand the information acquired about their disease, with the goal of achieving disease-related expertise to keep up with the physician.[53] *Decision participation* is the degree to which patients actively work with the physician to develop a treatment strategy and make treatment decisions.[54,55]

The information search following knowledge development is represented by the concept of the *informed patient*. Our conceptual research focuses on the intensive efforts of the information search and its contribution to developing an informed patient. Active participation in SDT theory is discussed during our examination of the empowerment process, which emerges as a patient becomes informed. Being informed provides leverage that increases power of the patient in encounters and relationship development with her physician. Additionally, it increases trust and enhances patient communication skills. The results of these processes empower patients more strongly, and yield greater satisfaction.

The informed patient

In order for patients to express their preferences and feel more confident in making decisions about their health care, they must become informed by receiving appropriate information regarding their condition, including potential outcomes and treatments. This information helps patients why a treatment option might be chosen and become more likely to comply with recommended courses of action. Ultimately, the informed patient will accept the prognosis, become an active participant in managing their disease, and feel more satisfied with their treatment.[56,57]

However, there is heterogeneity in the knowledge and information that patients need. Not all patients require the same information and this places considerable demands on healthcare professionals because they must personalize the information to best suit a particular individual.[57]

Research has shown that informed patients make better use of a health professional's time (both quality and quantity), and show improvements in knowledge, self-efficacy, and in self-management behaviors.[58] On the down side, physicians only have limited time for counseling, and often this time is insufficient to develop an informed patient and explain the condition and treatment choices available. Thus, patients may seek information elsewhere.[57]

Power relationship

In order to develop an informed patient, the distribution of power between patient and physician must change. It is important that a patient feels they have more control over their health treatment and are an active part of the decision-making process.[10,16,59]

Using online information challenges previous hierarchical models insofar as it encourages patients to stop being simply passive recipients of information. Instead the Internet's search capability empowers them to actively seek relevant information.[10,59–62]

Henderson,[56] who studied the power imbalance between nurses and patients, found most nurses did not provide patients with information beyond what was necessary. Nurses tended to give information about a procedure, but did not provide the patient with different treatment options and expected outcomes of each. More specifically, nurses often wished to make the decision for patients, instead of assisting them to make their own decisions. We know from empowerment studies, it is important that women feel a sense of control over their situation, and must be involved in decision-making elements during a medical encounter related to a proffered treatment. In these sensitive cases, using online information, which is not controlled, may cause harm to the patient by increasing her anxiety and worry, and by preventing her from taking an active part in the medical encounter. Therefore, we believe having access to controlled information provided through the medium of mobile technology in the waiting room may have the potential to change the power relationship.

Communication skills

When patients meet a physician as part of their clinical care, their wish is to achieve the best medical outcome and get the best possible care. For that to happen, good communication is necessary between the physician and patient.[63] Engel et al.[64] found that patients regard communication with their physician as a key factor in their satisfaction.[65] Good physician–patient communication helps patients work toward their goals.[48] Good communication should be based on information exchange that leads to making treatment-related decisions together, while keeping core conditions such as honesty, empathy, and respect intact. All of these are crucial to the efficacy of the treatment and strongly influence patients' well-being and satisfaction with the healthcare experience.[66–68]

In order to establish good communication, the patient must participate and cooperate during the entire treatment process, while the physician enables her to participate effectively and without worry.[66–71] The information exchange between physician and patient consists of alternating between information provision and seeking. The physician needs information in order to establish the right diagnosis and treatment plan for the patient. At the same time, the patient, who desires to be understood and to understand, needs to provide relevant information including condition symptoms and concerns to the physician. The patient expects to receive all needed information from the physician.[66,67,71] After the physician determines the diagnosis and treatment plan, he or she needs to efficiently impart that information to the patient in a way that enables knowledge acquisition. The informed patient will make decisions together with the physician regarding the next treatment steps.[57,66–70]

In order to occur in a genecology clinic, especially regarding sensitive personal issues, there is a crucial need for earlier, controlled preparation, during which waiting room time can play a role.[38,72] The physician's levels of providing/seeking information and communication skills are directly related to patient satisfaction. Lack of communication skills on either side may cause problems in diagnosis and affect patient involvement in the counseling sessions.[66,70,73] Studies have shown that physicians tend to interrupt patients 50 percent of the time and 45 percent of patient concerns are not disclosed. Half of the time, physicians and patients do not agree on the problem, and patients are dissatisfied with information provided by the physician. Thus, they may try to look for information elsewhere.[68] This may include seeking physician-vetted information provided in the clinic while patients are waiting. Ultimately, this information can change the relationship and enhance active patient participation, as well as their satisfaction with the medical encounter.[38]

Research has shown good communication can influence how much the patient understands provided medical information, their adherence to recommended treatment, and other health outcomes in addition to enhanced satisfaction and empowerment.[16,66,67,69,70]

Trust

Physician communication skills have an effect on a patient's level of trust. When the physician communicates effectively and keeps the patient informed with all desired information, he or she helps the patient develop a higher level of physician trust.[47] A key component of establishing trust relates to development of a physician relationship that meets patient expectations. The patient expects a physician to be supportive and to actively engage them in healthcare decision-making.[47] Patients given information about their disease prior to counseling were more confident and this encouraged them to ask more questions. They also talked more during counseling and were better able to elicit relevant information from their physicians.[10]

Patient empowerment

In a general sense, empowerment may be defined as a "process by which people gain mastery over their lives."[74] Studies of empowerment in different disciplines are based on the proposition that to improve the quality of lives both in the workplace and at home, people should be able and motivated to bring about changes. This applies to personal behavior, social situations, and within organizations that influence someone's life. As such, empowerment is a relational construct (e.g. in the doctor–patient consultation) associated with the concepts of power, equity, and situational control. This implies a capacity to solve problems and get a fair share of resources.[75,76] This concept further refers to both the state of being empowered and the process of becoming so. Empowerment is prominent in the management literature, where it has two meanings, both of which are influential in conceptualizing patient empowerment.[77] One meaning often is denoted as "psychological empowerment" and refers to employees' subjective feeling of empowerment—specifically, feelings of perceived competence to perform tasks well, feeling influential in a work role, feeling their work is important, and feeling free to choose how to execute tasks.[78–80] A second meaning, often called "role empowerment" or "situational empowerment,"[81] refers to objective practice involving delegation of responsibility to employees, in order to give them decision-making authority.

Empowerment discussed in relation to health behavior generally refers to patients.[74,82,83] Patient empowerment is conceived as the patient's participation as an autonomous actor taking increased responsibility for a more active role in decision-making regarding his or her health.[84] The empowered patient emerges as a person who does not passively receive information before trying to comprehend and invariably accept the outcomes. Instead, she is someone who extracts meaning relevant to herself from proffered information and advice, then chooses and enacts behaviors she concludes as appropriate to the present health situation.[85–87] Empirical research on patient empowerment antecedents and consequences is limited.[80]

Patient empowerment, referring to the set of self-determined behaviors based on patients' individual needs for developing autonomy and competence with their disease, increasingly has become a key component of a patient-centered approach to health care (i.e. information search, knowledge development, and decision participation). Patient empowerment assumes a prominent place in visions of optimal health following the Ottawa Charter of 1986, which states that health promotion is the process of enabling people to increase control over, and to improve their health. This vision takes on a relational (e.g. doctor–patient) dimension, emphasizing the need for more egalitarian structures and an equitable distribution of power between practitioners and patients.[88,89]

The sensitive situation of a women dealing with an abnormal Pap result that brings her to a genecology clinic can be refocused within this discussion. The need to develop autonomy associated with a person's self-determination, and the procedural empowerment process of giving and taking power. This is consistent with our working empowerment definition and tends to minimize uncontrollability, which is inherent in living with severe health conditions. In such contexts, the autonomy of a patient may be alternatively regarded as feeling secure in caring relationships, and having "ownership" for one's decisions as a patient. This situation can trigger one's participation in shared decision-making and ultimately contribute to empowerment.

Moreover, patient empowerment needs to be seen as a dynamic and creative process shaped by the patient's own activity in searching information presented on mobile technology during waiting room time. Using mobile technology to present controlled information to the patient can contribute to a sense of choice and control, and supports the need to feel secure and connected, and supports the need to develop a sense of meaning and coherence.[35] Patient needs for competence and control generally are addressed in self-management support interventions where mobile technology is used while waiting for the consultation. This promotes cognitive and enhanced communication during the medical encounter, and results in higher active participation due to greater patient empowerment.

Preserving and enhancing patient empowerment

Within a healthcare organization, empowerment implies providing necessary tools to resolve most problems or questions faced by customers on the spot.[8,10,56,90,91] In most instances, these customers are patients. Empowerment is not a static trait, but rather a dynamic process that changes over time and over different contexts. When a person becomes empowered in a specific moment in a particular environment, this does not make her empowered in other environments and other contexts.[92,93] People can be differentiated in various ways regarding required perceptions as well as skills or actions needed for increasing their empowerment. Different people in the same situation will need to learn different skills in order to become empowered. Likewise, different situations require different skills. While some people have these skills, others may not, and they will have to learn these skills in order to become empowered.[94]

The importance of continuing to preserve and enhance patient empowerment suggests that healthcare decision-makers should consider providing controlled access to information while women wait in the genecology clinic. Furthermore, access to carefully vetted information after the consultation would provide additional benefits leading to deeper learning and understanding as the patient becomes more empowered. This process can also be leveraged by opening a discussion between a patient and her doctor regarding specific aspects of a disease and treatment options that introduce stress and uncertainties. Mobile technology can be used as a tool that the women can use in support of such a sensitive situation.[95]

Another example is participation in an online support group. Patients felt it helped them become more informed as well as to feel more in control, confident, and prepared for their encounter with a physician. An improved physician relationship resulted.[96] Although most of the participants in the Van Uden-Kraan et al.[96] study had positive feelings about online support groups, the possibility of a disempowering process also was mentioned. Some participants were concerned and unsure about the quality of the information provided in these groups, felt that certain questions and topics were constantly repeated, and sometimes had to deal with either information overload or lack of needed information.[96]

Outcomes

The concept of empowerment remains ambiguous. Researchers often assert that empowerment is both a means and an end result.[12–14,97] Gibson[12] adds that empowerment can also be viewed as the result of participatory decision-making, negotiation, collaboration, and/or education. When an employee is empowered, his decision-making authority increases, as well as his responsibility, and he becomes more adaptive and receptive to his environment, and could continue feeling empowered through his work.[16,98,99] An empowered employee feels he has more impact, better self-determination, competence, and meaningfulness.[98] When patients are empowered, they become more experienced and independent in decision-making.[56] Ultimately, this leads to better health care with a team-like partnership between doctor and patient.

Summary

When patients go to a physician, they tend to have little power over their treatment plan. One way to help them gain power is by actively empowering them. People can become empowered in a variety of ways: by being better informed;[100] by having more power and authority in decision-making processes;[98,100] by having a mentor; through participating in support groups; and by achieving one's own goals.[93] However, not everyone can become empowered by the same things. Therefore, using the mobile technology in the waiting room can provide an excellent opportunity to enhance a women's empowerment before they enter physician consultation. This approach to sharing information enables them to become more active in decision-making during the consultation. Additionally, this information will enable the patient to feel supported and, with the continued use of mobile technology to provide controlled access to relevant information, open a communication channel with the physician. Ultimately, this helps resolve anxiety and uncertainty in complex situations. The idea of providing empowering information supports efforts to be more patient-centered.[35]

Limitations

This study provides conceptual information drawn from healthcare, business, and information systems literature. It is not an empirical study and is only meant to provide guidelines for implementing mobile technology–based information in patient waiting rooms. Further empirical research should be conducted to determine if the cited studies provide the benefits described in this article. Likewise, the recommendations provided in this study might be impacted by the emotional state of patients, their prior experience with information systems, and security-related concerns[101] regarding browser history or collection of personal information. Another limitation relates to the population studied. Although this article focuses on women that receive abnormal Pap smear test results, we believe our model of empowerment can be generalized to men and women experiencing other sensitive health issues. However, our emphasis on women is important, particularly in this sensitive situation. In spite of these limitations, we believe this research offers value to healthcare providers, particularly since mobile devices are becoming ubiquitous.

Future research

More research needs to be conducted to mitigate disparities related to heterogeneity in knowledge and the information patients possess and need. Not all patients require the same information, which places considerable demands on healthcare professionals. They must work to individualize information in a way that each patient will receive what is required to enhance their empowerment.[57] We believe mobile technology can be used to provide a customer-based information model customized to each patient based on her needs.

Controlled access to mobile platform–based information prior to patient–physician interaction needs more attention. Research has shown that informed patients make more effective and efficient use of a health professional's time, show improvements in knowledge acquisition, and are more likely to be successful in self-management behaviors.[58] A physician has limited time and often this time is insufficient for helping a patient become informed during a counseling session. Therefore, patients may seek information elsewhere.[57] The use of carefully vetted, specific information provided on mobile technology is important because the Internet is filled with contradictory, confusing, and even incorrect information. Furthermore, information found online often is perceived to contain more reliable information than information found offline and enables a convenient way for accessing a massive volume of information.[10,63,102,103] Printed/written material, however, is considered time-consuming and often requires a higher reading level than possessed by most people, and cannot be updated fast enough to reflect the current best treatment options available.[10,63,103]

Conclusion

Access to carefully controlled information following an urgent request to meet a professional gynecologist can shape the way a doctor provides treatment. This is particularly true when communication is enhanced and a patient feels empowered. The net result is for women to become more active and cooperative in the decision-making process. This patient-centered focus contributes to higher satisfaction of a patient healthcare experience. In this situation, women express their preferences and feel more confident to participate in decisions about their health. Patients become more cooperative and satisfied with their treatment plan, and manage and accept their disease better.[56,57]

Coulter et al.[104] and Lesnovska et al.[57] found that in order for information to help patients make more informed decisions and enhance fluency,[105] it must contain scientifically reliable material about the course of the disease, common symptoms, objective drug-related facts, as well as disease causes and consequences. The information also must contain ways to prevent and control the disease, the full range of treatment possibilities, and an honest assessment of whether recommended treatments are effective.[57,100,103,104]

In conclusion, it is important for health providers to better inform patients and determine what information is needed for their empowerment. Our research suggests carefully deployed mobile technology in a waiting room can mitigate fear and uncertainty. Furthermore, implementing patient empowerment research enabled us to reduce patient stress and enhance patient satisfaction with their health care. These findings highlight the need for more accurate, updated, and easily understood information specifically tailored for use in a clinical setting related to patient visits. This information should be developed in cooperation with healthcare providers, and should be available on mobile devices provided by clinics to help patients become more empowered, thereby more actively involved in their health care.[63,98,103]

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Student-accessible healthcare records: A mixed-methods study of college student and provider

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Abstract

This mixed methods study evaluated student and provider attitudes and expectations about offering students online access to their student health services visit notes (open notes). Six (N=6) health care providers from four public universities in northeastern Massachusetts participated. Qualitative interviews were completed by students (N=14) from one University in fall of 2013 and an online survey was completed at two universities in Spring of 2014. Attitudes and expectations were explored using qualitative data and descriptive statistics were used to analyze survey questions. Students' interviews revealed that they desire control over their health and open notes would give them insight and involvement in their health care. Survey data supported these themes. In contrast, providers worried about how it could impact provider-patient relationships. Open notes has the potential to promote students' understanding and responsibility for their healthcare, which could assist students in their transition from pediatric to adult health care.

Keywords

electronic health records, health communication, health promotion, nurse practitioners, student health services

The Health Information and Technology for Economic and Clinical Health Act of 2009 (HITECH Act) encourages healthcare providers to give patients the copies of their health information.[1] Although patients have long had the right to view their health records, these records are somewhat difficult to access, often involving onerous permissions and copy charges and extensive delays.

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As a result, their usefulness to patients is limited and health records are not typically considered a tool to assist patients in managing their health. However, with the advent of electronic health records (EHRs), some healthcare systems have begun allowing patients to access sections of their health records through patient Internet portals.[1,2] Through these portals, patients are typically given access to their laboratory results, and medication and problem lists. However, few systems provide patients access to providers' office visit notes. Opening the visit notes to patients can have important benefits to patients, including better understanding of their healthcare, tracking health over time, and better planning for healthcare visits.[1,2] This transparency offers the potential to enhance the quality of care by allowing patients to better understand their diagnoses and treatment plans or by detecting errors in their records.[2,3] Recently, Delbanco and colleagues[2–4] were the first to study the impact of providing adult primary care patients with online access to their EHRs, including visit notes, through a patient Internet portal (aka "The OpenNotes Study"). The majority of patients reported that access to their visit notes was beneficial while doctors reported little to no negative effects.[4] Allowing patients to read their healthcare visit notes is an evolving trend, and it may become a standard moving forward.

While more health centers, including mental health, are moving toward the OpenNotes model,[2–5] many college health centers have not yet considered this important step. College is an ideal time to prepare young adults to become effective communicators with their healthcare providers and become effective managers of their own health and health care. Providing opportunities for students to understand how to best access and utilize their medical record, including visit notes, may assist youth in the transition from pediatric to adult care. Gaining this independence will be critically important to learn essential life skills as they become independent, and later, as their parents age and need more assistance and advocacy from them.

To our knowledge, no studies have examined students' and their providers' attitudes and opinions about offering open notes in university health centers. Given the emerging use of open notes in adult ambulatory care, understanding how it could impact college health is warranted. Additionally, college students today have "grown up" with technology and can offer unique insights into how electronic medical records, portal systems as well as other computerized devices, could improve their healthcare experience. The purpose of this study was to evaluate student and provider attitudes and expectations about offering open notes in college health.

Methods

Procedures and study design

A mixed-methods descriptive study was completed to explore attitudes and opinions about student-accessible health records including access to providers' visit notes (i.e. "open notes"). The study was conducted in two phases: the qualitative (Phase I) and quantitative phases (Phase II). Phase I took place in Fall 2013 and used in-depth interviews with providers and students to obtain data about their expectations and attitudes toward open notes. Providers ($n=6$) from four public universities in Eastern Massachusetts completed a semi-structured interview either in-person or over the telephone. Students ($n=14$) from one university were interviewed in-person. All Phase I participants received a gift card, US$20 for providers and US$25 for students. Phase II took place in Spring 2014 and used a survey to explore attitudes about open notes. Prior research on open notes[3] and information from Phase I were used to inform the survey questions. Respondents were entered into a random drawing for a gift card (one valued at US$200, two at US$100, and three at US$50). All study procedures were approved by the institutional review boards of the University of XXa (XXXa) and the University of XXXb (XXXb).

Participants

Phase I: qualitative interviews. Provider participants were recruited from the student health service centers (SHS) at four public universities in Eastern Massachusetts. An e-mail was sent to clinic directors at these institutions to inform them of the study and invite them and their providers to participate in the interviews either in-person or by phone. Snowball recruitment methods were used to recruit additional providers.

Student participants were recruited from only one of the four public universities. Flyers were posted on campus, and a mass e-mail announcement was sent to students with a valid university e-mail address. Students were asked to contact the study office by phone or e-mail if interested in participating. Students were eligible if they were at least 18 years of age, had completed at least one primary care visit to the student health center in the past year, and were currently enrolled full-time at the university.

Phase II: student survey. Student participants were recruited from two of the four public universities. Originally, the study was to take place only at an urban commuter school, XXXa. To gain the perspectives of students at a residential campus, however, an additional public university with campus housing was invited to participate. Students at XXXa were recruited using the same methods as in Phase I, with the addition of an information table set up in the university student center. Students at XXXb were recruited via postings on the university's website and announcements in the daily university e-mails. All interested students were asked to contact the study office (via e-mail or phone) to receive a unique web address to the online survey. Students were eligible if they were at least 18 years of age and currently enrolled in one of the two universities. Surveys were administered using a secure, web-based application, Research Electronic Data Capture (REDCap).[6]

Data collection

In-depth interviews. One of the study investigators (J.W.) conducted interviews with the students, and two trained research assistants interviewed the providers. A semi-structured interview guide was used (see Appendix 1). The interviews were designed to elicit attitudes and expectations about open notes.

Student survey. The online survey was designed to take about 15 min to complete. Questions about age, college enrollment, and healthcare utilization were assessed. Only respondents defined as "users," those who reported at least two healthcare visits to any healthcare provider at any health center or at least one visit to SHS (excluding immunization visits) in the previous 12 months, answered questions to assess attitudes and expectations about open notes (see Appendix 1). All others, defined as "non-users," were not asked about open notes.

The survey included questions from the original OpenNotes survey.[3,7] The questionnaire was used to measure how reading visit notes might affect the respondent. Students were asked whether they disagreed or agreed with each of 16 statements. The stem for each item was, "If I could read my doctor's visit notes on a secure website," for example, "I would understand more about my health and medical conditions"—A 5-point Likert response from disagree to agree plus the option of "I don't know." This scale was originally developed using qualitative methods to generate item content, face validity evaluation, and cognitive testing of the final survey to ensure that patients understood the meaning and intent of each question. The development of the OpenNotes survey is described elsewhere.[3,7] The introduction to the scale was modified slightly to define doctor as either doctor or nurse practitioner (NP).

Data analysis

Qualitative data analysis. Qualitative analyses, including manual data reduction, data display, and data interpretation, were conducted using methods described by Farzanfar.[8] Recordings of five of the six provider interviews were transcribed by a research team member. Recording was unavailable for one interview, and analyses were conducted using interviewer notes. One team member acted as lead coder for the provider interviews and the student interviews. These coders read the transcripts, highlighted and took notes about emerging themes, created a code book, and extracted text that represented themes and categories. Another team member was trained by the lead coders to use the code book to extract text from the transcripts that represented the themes and categories. The codes and text fragments were entered into Excel for review and analysis by an investigator, who conferred with the coders about the results until an agreement was reached.

Quantitative data analysis. Descriptive statistical analysis was used for the survey responses including means, modes, and standard deviations for continuous variables, and frequency percentages for categorical variables. Sample proportions were calculated for students who agreed with statements about potential risks and benefits of open notes.[7] The categories of "agree" and "somewhat agree" were combined, as were the "disagree" and "somewhat disagree" categories; "don't know" responses were retained as a separate category and were included in denominators for that questionnaire.[7] All analyses were performed in SPSS Statistics for Windows (version 22.0; Armonk, NY, 2011).

Results

Qualitative results

Six female providers, who were NPs, participated in the in-depth interviews as the primary providers of college healthcare and represented four public universities. We had no inclusion criteria other than that participants needed to be direct care providers to college students and tend to be of this demographic. In other words, males and physicians were not excluded. In total, 14 full-time students, 4 men and 10 women from one of the public universities, participated in the interviews. Their ages ranged from 20 to 25 years (mean, 22.5 years), and 3 of the 14 were graduate students. The median number of visits to any provider in the last year was 3, with a range of one to five times.

There were three major themes that emerged from the analysis of the provider surveys: (1) communication with students takes time and consideration, (2) a "one woman show" from educator to navigator to provider, and (3) uncertainty about student access to health records. These themes and their subthemes are described below. The overarching theme, however, was that *providers seek to develop and preserve relationships with student patients via good communication*. Most of what providers do and how they currently approach care with their patients (e.g. using phone rather than e-mail, communicating treatment plans verbally, and teaching patients about navigating the healthcare system) are done with the intention of developing or preserving a good patient–provider relationship. Their concerns about open notes (e.g. misunderstandings and offending patients) are things that could negatively impact the patient–provider relationship. Establishing and maintaining a good rapport with patients are important, and the introduction of new technology or procedures that could jeopardize those relationships is not something providers desire.

Theme 1: communication with students takes time and consideration. A subtheme was that providers use verbal instead of written communication. The providers discuss the treatment plan verbally.

While most providers mentioned that there are written patient education materials, it appears that these are not used often:

> I have various teaching sheets in my office that I will hand to the student just to reinforce what we talked about, more from an educational standpoint, but no specific written discharge instructions, unless I write them down myself, which I do on occasion. I can't say 100% of the time.

Additionally, the providers value their interactions with the students and are satisfied with their patient communication. The providers seem to act in ways to protect the patient–provider relationship; for example, most of them take very short notes (e.g. key words) on the EHR or on paper during the visit, then complete the visit notes after the visit, so as to not detract from their time with the patient.

Theme 2: a "one woman show" from educator to navigator to provider. *The first subtheme was that providers see their role as being different from other health centers or practices.* NPs at student health centers take on many roles. Their approach to care might be different, given all the hats that they wear. NPs do everything at the health center and differentiate it from other types of clinic offices:

> … other places have a lot more, um, people doing other things for you. So, you know, like when I go to my primary, … so there is a lot of sort of other stuff that we do. We are sort of like a one man show in a way.

The second subtheme was that providers see themselves as teachers and navigators. The data suggest that providers view themselves as teacher, navigator, and protector of the student. They do things in the visit to help the student navigate the system. They encourage students to obtain their health records upon graduation, teach them about insurance, and they strive to maintain the privacy and security of the student's data.

The providers see it as a part of their job to teach students about the healthcare system:

> So one of the big roles I see fulfilling with this student population is really educating them about the healthcare system, how to use it, how to use it appropriately.

Providers also talked about student patients being a part of the team ("patients really should be partners") and expressed that they would like to see the students become more engaged ("… it would engage students more in their healthcare process … a positive thing to engage them in their own health care"). There was no discussion, however, about how the providers used this approach (i.e. they did not talk about how they used it during the interview).

Theme 3: uncertainty about student access to health records. Providers expressed worry about providing quality care in a limited amount of time. There was uncertainty about open notes. Two subthemes, advantages and disadvantages, illustrate this wavering. For example, a few providers expressed concerns that open notes could generate more questions. Also, a secure messaging function in the portal could allow the student to type questions, which could allow more time to discuss the main reason for the visit but could also generate more follow-up questions later.

The advantage of open notes would be improved patient–provider communication. It was unanimous that the providers thought access to the notes is a "great thing." There was, however, less clarity on what the specific advantages might be. As a whole, the advantages were about better patient–provider communication:

> I think it, you know, if you really look at it from just a fundamental … improvement, I think it, it can't be a bad thing. I think for some of our patients to have access to their records and understand … and take some responsibility and … ownership, I think it is a great thing.

There was a general consensus that English language learner (ELL) students would benefit from being able to read a note or e-mail:

> It is going to make it easier to communicate with them in e-mail because they can read English better than they can hear or understand or speak it.

The disadvantages of open notes might be the misunderstandings and their negative consequences to providers and patients. Although advantages were discussed, providers had a more unified voice about concerns. Providers were concerned that patients may not understand the medical terminology in their notes. They believed that students will not understand the terms, will have questions, or may become overly concerned. They also wanted to know how students will get those questions answered:

> I also would be interested in knowing if they had specific questions about something that was in the note, how would they go about getting those questions answered?

Students' misunderstandings might have a negative impact on the clinician's relationship with the student. All providers voiced concerns about possibly offending the patient because of the medical terminology in the note. They mentioned terms (e.g. obese) that could be offensive to some patients given the cultural meanings or render some patients distraught when seeing terms with emotional connections (e.g. abortion, sexual assault, and risky behaviors). The providers were worried about patients not returning to see them or not opening up:

> I'd have to be extra careful about, I mean the majority of patients, I don't think I document anything that would offend them. But … there are instances where you recommend something and the patient doesn't want to go with that treatment plan, or you spent maybe an extra-long amount of time discussing something you thought should have been quick. You … have got to admit that kind of expense, like 50% of the visit prepping this or patient declined this. I think that is enough that certain people could get offended by and could cause problems between the provider and the patient.

The providers were concerned about how this would impact not only patients but themselves as well. All providers mentioned time as a concern, mostly the time spent answering questions that open notes could generate after a visit. For example,

> Right now, to me, it is accountability that I would have to see if I spent all day trying to reply to people, then I would be concerned.

Results from the student interviews

The overarching theme from the student interviews was *students' desire for control over their health*, which influences how they manage their health and the healthcare system. This desire for control is illustrated in the two major themes: (1) *Gathering information: Web or Family first, provider last* and (2) *Access provides insight and involvement.* Their desire for control is indicated by their positive views on having access to their doctors' notes (e.g. having access to them could help them be more active and informed participants), but that desire for control may also drive, at least in part, their tendency to use the Web and family members first before they see a healthcare provider.

Theme 1: gathering information: web and family first, provider last. Students indicated strongly that they rely on sources other than the provider to manage their own healthcare decisions and information. They use websites as their go-to source of information before and after an appointment. They access the Web for information to help them decide whether they should make an appointment, to help them prepare for the visit, and to improve their understanding of their health:

> When they give you the diagnosis, you can also go online and check. If you don't understand what he is saying, you can say hold on, I need to check this.

Students seek out information from websites or family members, particularly their mothers, to determine what to do about a health issue. They used their sources (Web or family) first, and then go to the provider if necessary:

> First source is definitely mother, then I look online, then I usually talk to a doctor.

The students also talked about self-diagnosis prior to seeking medical help, suggesting a reluctance to make appointments and a tendency to attempt to treat health problems by themselves unless absolutely necessary. This approach suggests that students have a general concern about their health and a desire to do something for it:

> Whenever I have a problem I usually call, um, for, if I don't think it is that serious. Sometimes I will go online and try and self-diagnose, and then if I just don't know …, if I see symptoms that are extreme diseases like cancer, or whatever, I definitely will call and make an appointment.

Theme 2: access provides insight and involvement. The students indicated that being able to view their health records would help them track their health over time and be in control of their health. The students talked about how seeing their medical record could help them analyze and evaluate their health because they would be able to see patterns. These patterns or data could help them make decisions based on what worked in the past:

> Because she [healthcare provider] might not verbalize everything she is writing down, so I can see all the records and feel like I have more control.

The students also indicated that viewing the notes would offer them insight into their provider's recommendation and give them better understanding and would then allow them to be more involved in the treatment plan (e.g. being able to correct communication errors):

> … There have been times when I think they have misheard me and wrote something different than what I said down in the notes that I would see and correct at the moment, um, but I don't know if that is true all of the time. They might be with their back turned and they miss what I say. Um, sometimes I think it helps just to see it, and then I can think, 'Oh, they recommended because they heard this, but I have this instead,' so maybe the recommendation would be different if we could all sit down and look at it to make sure it is accurate.

While students liked the idea of having access to their providers' notes, they were concerned about control over their medical record. The theme that no data are secure arose. Students talked about "hackers and hacking" in general and how that could mean that their medical data are at risk:

> … just because of the risk of that being on the Internet or online access, that kind of thing. Um, it's dangerous … and for certain things to get out that way. Um, so yeah, if you understand the risk of your personal information being put on the Internet that way, then sure; you should be able to have access to it.

Table 1. Descriptive statistics of the students in the survey study.

Characteristics	n	
Age, years	170	
Mean (SD)		25.16 (7.7)
Mode		21
Female, %	175	68
Hispanic, %	173	18.5
Race, %	174	
White	76	43.7
Asian	31	17.8
Black	29	16.7
Other	24	13.7
Mixed	14	8.1
Full-time student	175	83.4%
Undergraduate student	177	81.4%
Employed full or part-time	175	66.9%
Single (not married)	174	87.4%

SD: standard deviation.

Phase II: survey results. There were 194 students who contacted the study office and were subsequently sent a link to the online survey. Of those, 95 percent (n = 184) were at least 18 years old and completed the consent. The final sample consisted of 178 students who completed or partially completed the survey from both universities. Demographics are displayed in Table 1. The percent of students in the survey study was less White (43% vs 56% and 64%) and more female (68% vs 59% and 37%) than the distribution at the two universities.

The majority of the sample, about 80 percent (n = 141), reported having a primary care provider (a PCP, "doctor or nurse practitioner who takes care of your general health"). Of those 141 students who reported having a PCP, 94.3 percent considered their main provider to be outside of SHS. Of the 178 respondents, 92 percent reported a visit to any provider within the last 12 months, and 41 percent (n = 73) reported at least one visit to SHS in the last 12 months. The majority of those who visited SHS reported more than one visit (51%). Of the 178 students, 89 percent reported owning a smart phone, and about 40 percent reported accessing the Internet at least once a week to obtain health information for themselves or someone else.

Student attitudes and beliefs. Table 2 displays the perceived benefits and risks of open notes for those students considered "users" of healthcare. The vast majority of respondents (93%) reported that gaining access to their health records would help them understand more about their health and medical conditions, and they would better remember the plan of their care. Similarly, 89 percent reported that they would feel more in control of their healthcare.

Fewer students agreed with statements about risks of open notes. Less than one quarter of participants reported that open notes would make them worry more (23%), and only 21 percent said open notes would make them go to the doctor more frequently. The biggest concerns were identity theft (47%) and privacy (49%).

Comment

The findings of this mixed-methods study suggest that the attitudes about the concept of open notes in college health are generally positive with some uncertainties. Provider and student interviews

Table 2. Proportion of students defined as users of healthcare who agreed or somewhat agreed with statements about the potential benefits of open visit notes for patients.

If I could read my doctors notes …	N	Agree or somewhat agree (%)	Don't know
It would be a good idea	121	84.5	3.4
I would understand more about my health and medical conditions	121	93	0.8
I would better remember the plan for my care	120	93	0.8
I would take better care of myself	121	83.4	4.1
I would feel more in control of my health care	121	88.4	0.8
I would be more likely to take my medications as prescribed*	112	58.8	10
I would be better prepared for visits	119	79.9	2.5
I would feel more confident talking to my healthcare provider	121	85.2	2.5
I could track my health over time	120	95.0	–
I'd have more trust in my healthcare provider	121	72.7	5.0
I would go to the doctor more often	120	41.7	13.3
I would go to the doctor less often	119	23.5	11.8
I would worry more	118	24.6	3.4
I would be concerned about my privacy	120	48.4	3.3
The notes would be more confusing than helpful	120	21.7	2.5
It could make my provider's job more difficult	120	29.2	10.0
I would be concerned about identity theft	119	45.3	5.9
It would not affect me at all	118	22.9	9.3

SHS: student health service centers; PCP: primary care provider.
The sample includes students who either reported attending one SHS in the past year, not including vaccination visits, or attended at least two visits to a PCP outside of SHS (n = 121).

resulted in contrasting sets of attitudes about access to the visit notes. While provider interviews indicated that open notes would improve communication, stronger themes emerged about the potentially negative impact open notes might have on the patient–provider relationship and the probability that students might not understand the medical terminology used in the notes. In contrast, students had confidence that websites help them understand the medical terminology used by providers. Student interviews and surveys indicated more positive attitudes about open notes. They believed that open notes would allow them to access information that could help them understand and track their health and be more involved in their care. Their main concerns were about privacy and security of their online medical data.

Students in this study overwhelmingly reported that having access to visit notes was a good idea and believed the notes would help them remember their plan of care. These results are consistent with earlier studies in adult primary care.[2–4] Table 3 displays a comparison of this study's findings to the OpenNotes[2] and a more recent study at the Veteran's Administration (VA).[9] All of these studies used the same OpenNotes survey.[2] However, the VA study included nearly 7000 respondents who had already viewed at least one open visit note ("early adopters") through the VA patient portal, MyHealthyVet,[9] which is in contrast to the OpenNotes and the present study where the respondents did not have access to open notes. Three out of four early adopters reported they were very satisfied with open notes (rating 8 out of 10 on a 10-point satisfaction scale). Although the VA patients had actually viewed open notes, their attitudes were similar to those reported by patients in the *initial* OpenNotes Survey, that is, patients' attitudes prior to having access to open notes[7] and

Table 3. Comparison of the student sample with an adult primary care sample from the OpenNotes[2] and the Veteran's Administration (VA) study.[9]

Percent who agreed that …	OpenNotes (%)	VA (%)	Student (%)
Making visit notes available to patients is a good idea	94		84.5
Patients who read notes will better understand their health and medical conditions	93	92	93
Patients who read notes will be more likely to take medications as prescribed	73	80	59
The notes will be more confusing than helpful to patients	11	6	21

the students. The largest difference appears to be with whether open notes would be more confusing than helpful to patients. Although the percentages were low, 21 percent of students thought the notes would be more confusing than helpful compared to 11 and 6 percent of the OpenNotes and VA patients, respectively.[7,9] Another difference was the lower percent of students who agreed (59%) that they would be more likely to take medications as prescribed if they read the notes compared to the other open notes studies, 73 and 80 percent, respectively. This question may not be as relevant to students who most likely to take fewer medications than VA and primary care patients. Overall, these comparisons suggest that although demographically different, students perceive open notes in similar ways. It will be important to examine whether students report fewer worries or less confusion once they have access to their visit notes.

Similar to our study, others have reported patient concerns about privacy and security related to having access to their medical records online.[4,7,11] In the original OpenNotes survey, 34–38 percent of patients responded that they had privacy concerns in anticipation about open notes.[7] In a later report, once patients had seen at least one note, 26–36 percent of patients reported privacy concerns, reflecting no material change in this area of concern.[4] In this study, about half of the students reported concerns about privacy in regard to the possibility of accessible medical records. Students have grown up in the age of great transparency through the Internet; in some ways, their attitudes may be more relevant given the frequent media reports of massive security breaches. Such concerns, however, may not have any effect on whether students decide to view their notes through the patient Internet portals. Indeed, a study of privacy concerns among OpenNotes patients came to a similar conclusion,[9] reporting that patients felt that the benefits outweighed the risks of having accessible visit notes.

Although students' attitudes toward open notes were generally positive, a small percentage of students agreed that it might lead to worry or confusion, or that it would create more work for their providers. This concern was echoed in the themes that emerged from the provider interviews. Providers were more specific in voicing their concerns about open notes and were more ambivalent about the benefits. They used general statements about the benefits like "transparency is a good thing," or said that patients taking "responsibility" and "ownership" was a "great thing." In contrast, they described more specific situations where they could foresee open notes either causing more work for them or affecting the patient–provider relationship in a negative way. Providers expressed greater concerns regarding patient access to notes than did patients.

Providers viewed their student populations as fairly healthy, in general, with issues mostly related to risky behaviors or sexually transmitted infections (STIs). Statistics from the American College Health Association (ACHA) suggest that the greatest health concerns are alcohol, tobacco and other drugs, sexual health and mental health, along with weight, nutrition and exercise, and personal safety and violence.[10] Providers in this study echoed these health issues as priority among their patients. At this time, it is unknown how open notes will influence the quality of care or patient engagement among the college population. Furthermore, given that college students may have fewer chronic care needs than the general population, their encounters with the healthcare system tend to be more acute or episodic in nature. These acute healthcare issues can provide opportunities for students to learn about the healthcare system and how to utilize resources, including how to go about filling prescriptions and completing insurance procedures. The findings from our provider interviews suggest that student health providers differentiate their role from the typical primary care clinician in the community. They see themselves as teachers and navigators, primarily educating students about various aspects of their health and healthcare.

An open notes system could include an option to allow family members or other healthcare providers to view a note. As students transition from childhood dependency to independency, they may be more likely to consult other people about their health issues. Students could benefit from such an option in the electronic record system by having the ability to share their records while conferring with trusted adults about their healthcare. Of the students in this study who thought they might share their records with others, many chose a parent or healthcare provider as the person with whom they would share the information. An area of great interest in adolescent and young adult healthcare research is the transition from pediatric care to adult care. The students' opinions seemed to express that access to open notes would help them be in control of their health. The strong themes that emerged from the interviews suggest that providers value teaching and guiding the students and they strive to help them learn to be independent adults who are able to manage their own health. The providers also value communication with their student patients to the extent that they do not want to jeopardize the patient–provider relationship.

Another potential benefit of open notes for the student population is that it may help in managing students' back and forth lifestyle in regard to their healthcare. Students tend to rely on student health services during the academic year and then return to their PCPs at home during school breaks and in the summer. An open notes system would help improve communication and facilitate care from provider to provider if students could print notes from the portal website and bring them to their healthcare provider at home. This benefit, however, was not identified by the providers we interviewed. Their current approach with students appears to be more education-focused, guiding students through acute episodes rather than encouraging students to take more active roles in managing their own care. This incremental approach described by providers is understandable because students need knowledge and experience first before being able to take control over their healthcare. In addition, development-wise, they may need to *gradually* transition into assuming responsibility for their own healthcare; thus, their years in higher education is an optimal time to do so. The question remains, however, how to best accomplish this with busy student and provider schedules. Open notes may be a viable facilitator to assist students in assuming more responsibility with their healthcare and may increase engagement in the future; however, the true impact of open notes in student health is yet to be determined.

Limitations

This study was conducted in a very diverse student population at four public universities in the Eastern Massachusetts and, because of the variety of recruitment methods used, we cannot conclude that the participants were representative of the broader student populations on these campuses. Nonetheless, the diversity of the student respondents reflects the diversity of the participating campuses. Similarly, only a small group of providers were interviewed for this study and they were relatively homogeneous which may be secondary to a high number of female NPs practicing in college health. It may be that their views do not represent the majority of student health service providers limiting transferability. Although our findings cannot be generalized to the campus populations or other college populations, this is the first study to explore student and provider attitudes toward open visit notes. It is important to begin to understand expectations and the potential impact of open visit notes, which are likely to become available through most university health services in coming years with the expansion of secure patient Internet portals.

Conclusion

This study was one of the first conducted to determine the attitudes and expectations of college students and college health providers regarding patient access to medical records, provider visit notes, in particular. The findings suggest that the attitudes and beliefs of the college population are not different than other general adult patient populations with vastly different demographic characteristics, including veterans and adults in primary care who already have accessible records. Students want to be able to view their records, and they indicate that it would help them take control of their own healthcare and help them understand it better. While the actual benefits and risks of open notes in the college health population remain unclear, the potential risks appear to be modest and do not outweigh the potential benefits. Implementing open notes may potentially help young adults effectively manage their own healthcare, an important step in the transition from pediatric to young adult care.

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Appendix I

ON shore: OpenNotes Student Health Open Records Evaluation

OpenNotes at University of Massachusetts Boston: in-depth interview discussion guide (phone interview). I would like to get your opinion about student healthcare. The main focus will be on offering students access to their electronic health records (EHRs) online through a secure patient portal, BUT before we get to those questions …

Topic 1. Provider's current practice experience and communication strategies (10 min).

1. I would like you to paint a picture for me of what happens during a typical student healthcare visit. How do you communicate the treatment plan with your patients, that is, what strategies do you use to communicate the plan of care?

Follow-up questions only if necessary:

Do you provide written summaries?
Do you ever write a clinical note together?
Do you encourage patients to use e-mail?
Do you typically follow up with phone, letter, or e-mail?

2. The next big question is about how satisfied you are with your current methods of communication with your patients?
3. How might communication during the visit be improved? How about after the visit?
4. Can you tell me about the communications you have about health behaviors. What kinds of conversations do you have about health behaviors? How do you approach it?

Topic 2. Student's current knowledge of healthcare management and use of medical records (5 min).

1. I'd like to take the remainder of the interview to talk about the main focus of today's call, which is providing students with online access to their University Health Services (UHS) EHRs. But, first, (*pause, if no answer than rephrase*, Or, what do they know about navigating the healthcare system? In general? Their own healthcare? How do you help your student health system?).
2. How frequently do students ask you for a copy of their medical records from UHS? Not all, rarely, sometimes, frequently, and always.
3. Do students ever bring in their medical records from their previous clinic, pediatrician, or other health center? Not all, rarely, sometimes, frequently, and always.

Topic 3. Future impact of open notes in UHS (15 min).

4. I am wondering if you have ever heard about the OpenNotes Study that was done at Beth Israel Deaconess. Yes, No, or Maybe (provide a handout on the project at the end).

Describe the study briefly to them

1. What if you opened up the EHR so that the students could easily access the clinical notes along with the usual labs, medications, immunizations, and other information? Open notes

> … secure system … such as going through the open communicator … the student would have secure access using the portal and open communicator—access the EHR after the visit or at any time but during the visit … What would happen?

Follow-up if not addressed:

> So, if students could see everything, what would happen?
> How would it affect the way you practice?
> How would it affect the way you document?
> What about risky behaviors, and how would an open-note affect documentation?
> How concerned are you about students being offended about what is in the note?
> How concerned are you about students being confused or worried about what is in the note?

2. What do you see as the biggest pro to opening up the notes? Biggest cons? (Do you think everyone should have access to their notes? or, what components might you be ok with and what was might remain hidden. Administrative notes, which are not part of the medical record? At Beth Israel, they call it monitored notes which are not viewable to the patient).
3. *If it hasn't been addressed*, how will it affect how the student manages his or her own health?
4. One of the principal investigators (PIs) of this study interviewed doctors at Beth Israel Deaconess, where they were most worried about their time. How do you think opening the notes to students would influence your time?
5. So, the study that we are thinking about doing is to open up the clinical notes to the students using a secure Internet portal. They would be able to see what you wrote plus labs, immunizations, and appointments. We will be doing focus groups with students. I am wondering if you have any ideas about questions we should ask the students in these groups?
6. Ok, two more questions. On a scale from 1 to 10, how willing you would be to participate in an open notes study at a UHS____? What if you had the option of having administrative notes that aren't viewable or restricting access (which means that the student can still get their notes but not easy access)?
7. Ok, finally tell me why you said ______? (What are your reasons?)

Appendix 2

ON shore: OpenNotes Student Health Open Records Evaluation

OpenNotes at University of Massachusetts Boston: student interview guide. Today I will ask you specific questions about medical records and electronic medical records. Medical records are the notes and information that your doctor, nurse, or other provider keeps about you so they know how to care for you and can track your healthcare needs over time. Medical records traditionally are on paper. Electronic medical or health records are the same as medical records but they are stored in a computer. These days, many hospitals and health clinics are starting to use electronic medical records instead of paper medical records. In the United States, there are plans for every health center to change from paper to electronic records in the coming years.

Warm-up

1. Have ever noticed your healthcare provider using paper or electronic medical records when you visit with him or her. Or, tell us if you are not sure what they use.

Communication with your provider

1. Would like to start off by finding out more about how you interact or communicate with your doctors or nurse practitioners (NPs) when you visit the UMass clinic. How do you let the nurse or doctor know why you came in for a visit? Did you fill out a form or talk to someone?
2. When the UHS provider gives you instructions to do something or take some medication, how does that happen? Describe what they do?

Follow-up: Do they give you instructions verbally, on paper, or by e-mail?

3. How do you usually know what to do after you leave the health center?

Follow-up: Do you have any personal strategies or things that you do to help you?

4. Have you ever forgotten what they recommended? What do you do if you forget?
5. Do you ever find the instructions confusing? If so, how do you handle it?
6. In general, how do you get in touch with the NP or doctor at the health center?

Follow-up: Did you call, e-mail, or go to the center? Do you contact him or her between appointments?

7. Do you have any ideas about ways that might make it easier to communicate/talk to the NP or doctor at the UMass clinic?
8. Now I would like to know how you get information about your health or a health condition. You don't need to say what your condition is. I am interested in how you seek out information? What is your most trusted source of health information?

Follow-up: Do you talk to someone or look up information?

Medical records

9. Have you ever, at any time, asked to see a copy of your medical records? Have you ever seen your visit notes before?

Follow-up: For those of you who have read your medical records, what was it like to read the notes yourself? Did you find it helpful? Did reading your record cause you to worry?

Open notes—electronic medical records

Now I would like to discuss what it might be like to see your doctor's notes or medical record. Pretend that you have easy access to your notes. In fact, you are given the ability to use the Internet to go on a secure health site to see what your NP or doctor or other healthcare providers wrote in your electronic medical record.

10. Does this sound like something you would want?
11. How might this be useful or helpful for you?
12. Would you show it to someone else? Who would you share it with?

13. Would it change how you talk with your NP or doctor?
14. How might *it not* be useful to you? Or, what do you NOT like about this ability?

Follow-up: What would you do if you read words or sentences you didn't understand?

15. What would you do if you found an error in your record?

Follow-up: Do you think you might ever ask the healthcare provider to change something in their notes, or add to it, take things out?

16. Ok, what do you think? Do you think clinic notes should be available for patients who want them? Why or why not?

Follow-up: Other concerns might you have?

Grand tour questions

17. What types of healthcare services do you think students want or would be useful?
18. What do you envision as the future of healthcare on our college campus?
19. In what ways do you use electronic programs such as mobile apps or the Internet to help you with your health?
20. What would you like to see happen?
21. What do you think University of Massachusetts Boston (UMB) college students need the most help with when it comes to managing their health?

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Selecting antithrombotic therapy for stroke prevention in atrial fibrillation: Health professionals' feedback on a decision support tool

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Abstract

A Computerised Antithrombotic Risk Assessment Tool was developed for assisting the selection of antithrombotic therapy based on the risk versus benefit assessment. In view of the recent availability of the novel oral anticoagulants, this tool has been updated to CARATV2.0. To explore health professionals' perspectives on the tool, semi-structured interviews were conducted in seven pharmacists, seven specialists, six general practitioners and six nurses, who were involved in management of antithrombotic therapy for atrial fibrillation. Three overarching themes emerged: (1) CARATV2.0 provides comprehensive structured assessment of patients and could assist with the prescription and review of antithrombotic therapy, (2) subjective issues such as health professionals' and patients' preferences for a particular antithrombotic therapy may affect the usefulness of CARATV2.0 and (3) CARATV2.0 requires integration into existing systems and processes. The majority of health professionals surveyed would like to use CARATV2.0 in practice, believing it would improve antithrombotic use and might reduce stroke incidence.

Keywords

anticoagulant agents, atrial fibrillation, computer-assisted, decision-making, decision support

Introduction

The decision-making around antithrombotic therapy (e.g. anticoagulant and antiplatelet therapy) in atrial fibrillation (AF) is complex because it involves assessment of risks versus benefits.[1] For many years, warfarin was the only available OACs, but its unpredictable therapeutic effects, various food and drug interactions and the need for regular monitoring have been associated with

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great difficulties in its use. Such difficulties have led to a potential increase in adverse events and reluctance by clinicians to prescribe the medication.[2–4] The recently marketed novel oral anticoagulants (NOACs) – dabigatran, rivaroxaban and apixaban – have substantially expanded the treatment armamentarium and are intended to overcome the limitations of warfarin. However, these new anticoagulants are not without risk because some of their so-called advantages can be regarded as potential disadvantages in specific situations.[5]

To optimise the use of antithrombotic therapy in patients with AF, and specifically assist health professionals in selecting appropriate agents, an electronic decision support tool – the original Computerised Antithrombotic Risk Assessment Tool (CARAT) – was developed.[6] Its decision-making algorithm was computerised by first preparing a prototype in Microsoft Excel™ and then formatting it as a web-based interface for online access.[6] The tool generated treatment recommendations (e.g. warfarin vs aspirin therapy) for individual patients based on their risk (bleeding) versus benefit (stroke prevention) estimation, as well as the relevant medication safety considerations (e.g. drug–drug interactions, renal function and medication adherence). The original CARAT has been trialed in real-world hospital patients[7] and general practice patients[8] and evaluated by specialist clinicians for its potential clinical application in a vignette-based study.[6] CARAT has demonstrated its potential utility in practice.[6,7] Although other risk assessment tools have been developed to synthesise the assessment of stroke and bleeding risks – for example, the clinical decision aid developed by LaHaye et al.[9] and the decision model developed by Casciano et al.[10] – none consider the broader medication safety issues that particularly affect the selection of therapy in the target at-risk patient population.[9,10] Thus, the CARAT provides a novel, more holistic and pragmatic approach to the decision-making around antithrombotic therapy.

Our previous (i.e. original) version of CARAT was designed to address the complexity in decision-making by integrating the relevant assessments around stroke risk, bleeding risk and medication safety for individual patients;[6] at that time, the tool was able to assist in selecting among two main treatment options – warfarin and aspirin. Now that we have moved forward in time, there are additional issues to consider in the decision-making process which need to be factored into the CARAT. First, the expanded range of treatment options incorporating the NOACs (dabigatran, rivaroxaban and apixaban) has increased the number of parameters (e.g. drug–drug interactions, side effects, doses and frequency of administration) that need to be considered, further complicating decision-making.[11] Second, the range of risk assessment tools for stroke risk (e.g. $CHADS_2$ and CHA_2DS_2VASc[12]) and bleeding risk (HAS-BLED[13] and $HEMORR_2HAGES$[14]) has evolved. Third, the evidence-base around the effectiveness and safety of available treatment options has grown, for example, aspirin is no longer recommended for stroke prevention in AF.[15] Fourth, a broader range of health professionals is now involved in therapeutic recommendations and decision-making around antithrombotics therapy, whereby hospital specialists and general practitioners (GPs) are able to draw upon the services of nurse practitioners (NPs)[16] and consultant pharmacists (e.g. as part of medicines review process[17]). Collectively, these issues have warranted a revision of the original CARAT, into its second version CARATV2.0, which considers the latest clinical evidence (e.g. guidelines[15,18,19] and practice reviews[5,20,21]) and available treatments (warfarin and NOACs).

As an initial evaluation of this revised (prototype) CARATV2.0 tool, the aim of this study was to obtain feedback from a wide range of health professionals who are involved in the decision-making around antithrombotics in AF (specialist clinicians, GPs, nurses and pharmacists), to help inform the future implementation of this tool in practice. Specific topics explored were the (1) strengths and weaknesses of this tool; (2) appropriateness and relevance of the content of this tool; (3) usefulness of this tool for selecting appropriate antithrombotics, especially between warfarin and NOACs; (4) feasibility of using this tool in clinical practice; and (5) suggestions for further improvement.

Method

Design and setting

This qualitative study was based on face-to-face interviews. From August to October 2014, health professionals (subgroups: specialist clinicians, GPs, nurses and pharmacists) practising in the Sydney metropolitan area were involved in this study (Figure 1).

Participant recruitment

Purposive sampling was used to identify and recruit health professionals with experience in prescribing antithrombotics and managing antithrombotic therapy for patients with AF.[11] Specialist clinicians, hospital-based pharmacists and nurses were recruited via an invitational flyer emailed or faxed to the network of hospitals affiliated with the university. Community-based pharmacists accredited for Home Medicines Review were recruited through an emailed flyer (using contact details from the Australian Association of Consultant Pharmacy). Flyers were also emailed to community-based nurses in community health services affiliated with the university network of hospitals. By visiting family practices and medical centres in the Sydney metropolitan area, the researcher also distributed invitational flyers to GPs. Emails and faxes were also sent to GPs listed on the Internet. Eligible health professionals who agreed to participate provided written consent.

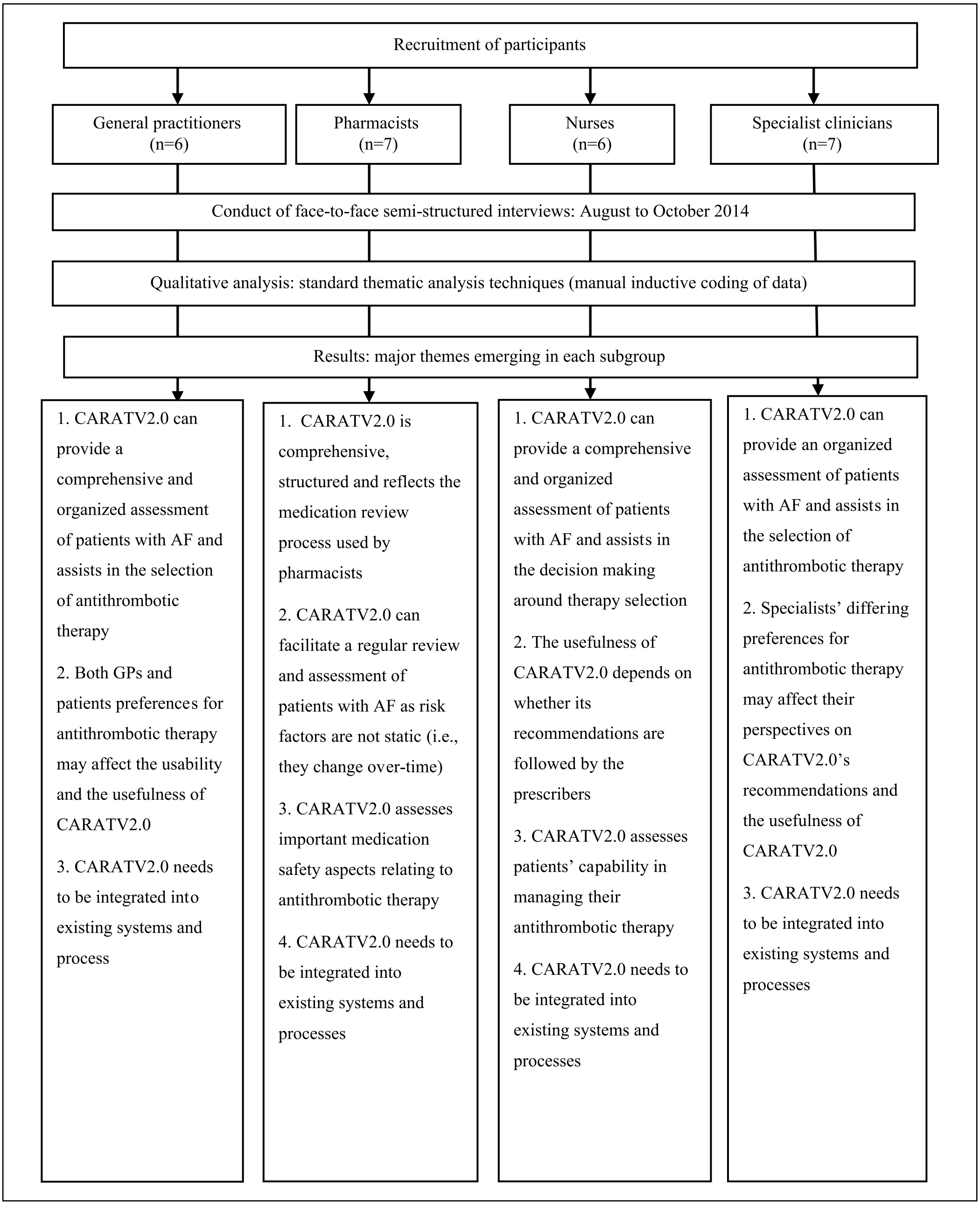
An estimated 24–40 participants (6–10 participants per group) were needed to achieve theme saturation within each subgroup of health professionals (specialist clinicians, GPs, nurses and pharmacists).[22] As this tool was developed to support a broad range of health professionals who are involved in the day-to-day management of older persons taking antithrombotics, in particular those who had previously expressed a need for assistance in decision-making,[3,11] the study largely focused on canvassing feedback from GPs, nurses and pharmacists, in preference to experienced cardiologists. For this reason, relatively few cardiologists were recruited to this study.

Data collection

Semi-structured interviews (20–30 min each) were conducted by the researcher at a location convenient to each participant. At the beginning of each interview, demographic data for each participant were collected using a predesigned questionnaire. Then, the researcher presented CARATV2.0 (on the researcher's laptop) to the participant. After this familiarisation with the tool, the participant was given the opportunity to explore CARATV2.0. Finally, the researcher used a set of open-ended questions to explore the participant's feedback on the content of the tool and the feasibility of using CARATV2.0 in clinical practice. All questions were pretested in mock individual interviews with nonparticipants.

Prototype of CARATV2.0

The underpinning algorithm of this revised tool has been developed as a Microsoft Excel-based prototype for pretesting, with the intention of subsequently formatting the tool into an online (web-based) platform or mobile application that will enable the integration of this tool into prescribing software and/or electronic health data management systems. The prototype comprises four distinct sections: (1) stroke risk assessment, that is, $CHADS_2$[23] and CHA_2DS_2VASc;[12] (2) bleeding risk assessment, that is, HAS-BLED[13] and $HEMORR_2HAGES$;[14] (3) medication safety issues, for example, mini–mental state examination[24] for cognition, estimated glomerular



1. CARATV2.0 can provide a comprehensive and organized assessment of patients with AF and assists in the selection of antithrombotic therapy
2. Both GPs and patients preferences for antithrombotic therapy may affect the usability and the usefulness of CARATV2.0
3. CARATV2.0 needs to be integrated into existing systems and process

1. CARATV2.0 is comprehensive, structured and reflects the medication review process used by pharmacists
2. CARATV2.0 can facilitate a regular review and assessment of patients with AF as risk factors are not static (i.e., they change over-time)
3. CARATV2.0 assesses important medication safety aspects relating to antithrombotic therapy
4. CARATV2.0 needs to be integrated into existing systems and processes

1. CARATV2.0 can provide a comprehensive and organized assessment of patients with AF and assists in the decision making around therapy selection
2. The usefulness of CARATV2.0 depends on whether its recommendations are followed by the prescribers
3. CARATV2.0 assesses patients' capability in managing their antithrombotic therapy
4. CARATV2.0 needs to be integrated into existing systems and processes

1. CARATV2.0 can provide an organized assessment of patients with AF and assists in the selection of antithrombotic therapy
2. Specialists' differing preferences for antithrombotic therapy may affect their perspectives on CARATV2.0's recommendations and the usefulness of CARATV2.0
3. CARATV2.0 needs to be integrated into existing systems and processes

Figure 1. Key stages in eliciting feedback from health professionals about the decision support tool.

filtration rate (eGFR) (MDRD and Cockcroft and Gault equation[25]) for renal function and Child-Pugh score[26] for liver function; and (4) therapy recommendations and advice. The application of the tool requires the user to input relevant data into the cells, which auto-populates the formulae underpinning the decision-making algorithm, and which, in turn, generates a treatment recommendation. A patient is considered to be eligible for OACs whenever the risk of stroke is equal to or more than the risk of bleeding, otherwise the patient is deemed to be unsuitable for OACs. CARATV2.0 also provides initial advice around any identified medication safety issues which need to be addressed by the clinician. This study explores feedback on the data inputs and usability of CARATV2.0.

Data analysis

The interviews were digitally recorded (audio) and transcribed verbatim by the researcher. The accuracy of the transcripts was confirmed by listening to the digital records and reviewing the transcripts. The transcripts were analysed for themes, using standard thematic analysis techniques (manual inductive coding).[27] The two authors independently reviewed the transcripts and identified themes before reaching a consensus through discussion. The accuracy and reliability of the analysis was confirmed by inter-researcher validation (with three other independent researchers).

Results

Overall, 26 participants comprising 7 specialist clinicians, 6 GPs, 7 pharmacists and 6 nurses were interviewed (Table 1). Similar themes were identified among the four subgroups, with three overarching themes emerging (Tables 2 to 4 and Figure 1).

Theme 1: need for comprehensive structured assessment of patients to assist with the prescription and review of antithrombotic therapy

The most highly appreciated feature of CARATV2.0 was that it provides comprehensive assessment of a patient's risk versus benefit of using antithrombotics. Perhaps more importantly, the ability of CARATV2.0 to provide guidance and assistance in selecting among OACs, especially between warfarin and the NOACs, was highlighted by health professionals. Overall, health professionals considered this tool helpful in the decision-making for antithrombotic therapy and hoped that it could help reduce the incidence of strokes.

Specifically, many GPs and specialists felt that CARATV2.0 validated or organised their own decision-making process. Interested in using this tool for the prescription of antithrombotics, GPs and specialists tended to see the tool as most useful in those cases in which there are clinical dilemmas (i.e. where the risk versus benefit of using OACs is not clear-cut). With regard to selection among OACs, both GPs and specialists appreciated that the tool offered a specific recommendation among the OACs (especially either warfarin or an NOAC). The doctors considered this useful because they perceived that the differences in the benefits and risks of individual anticoagulant agents were not clear to many doctors. One GP mentioned that this tool could be useful for the initiation of therapy.

Similarly, the senior accredited and hospital-based pharmacists (with ⩾40 years of experience) also stated that CARATV2.0 validated or organised their own decision-making process. In contrast, nurses and the junior accredited pharmacists felt that they could use this tool as a reference for their medication reviews and patient assessments, especially when choosing among OACs. Pharmacists and nurses also emphasised that patients' risk factors associated with antithrombotic therapy were not static; therefore, they tended to see this tool as most useful for regular reviews of patients. This aspect of tool use seemed to be overlooked by the GPs and specialists.

Table 1. Participant characteristics.

Participant characteristics	Mean years of experience in managing patients with AF ± SD (range)	Mean number of patients with AF managed annually ± SD (range) (self-reported)
Specialist clinicians (n = 7) • 3 geriatricians • 2 haematologists • 1 cardiologist • 1 neurologist	23.4 ± 13.1 (5–40)	117.5 ± 109.3 (5–300)
General practitioners (n = 6)	22.3 ± 10.1 (12–40)	21.5 ± 12.4 (4–35)
Pharmacists (n = 7)[a] • 6 accredited pharmacists • 1 hospital pharmacist	20.4 ± 17.7 (5–50)	46.9 ± 39.4 (5–100)
Nurses (n = 6)[b] • 3 nurse practitioners (NPs) (2 cardiology, 1 neurology) • 3 clinical nurse consultants (neurology)	20.2 ± 9.5 (8–30)	145 ± 77.8 (100–300)

AF: atrial fibrillation; SD: standard deviation.

[a] All six accredited pharmacists (home medication review and/or residential medication management review) were community-based pharmacists.

[b] Among them, the two cardiology nurses were community-based, while the others were hospital-based.

Theme 2: health professionals' and patients' preferences for a particular antithrombotic therapy

Health professionals' opinions on CARATV2.0's recommendations were underpinned by whether they perceived the tool as preferring any particular antithrombotic therapy and whether this therapy was the one they preferred to use. While warfarin was preferred by the majority of health professionals, one neurologist, two haematologists, one GP and one nurse stated that they preferred using NOACs. Some pro-NOAC health professionals perceived that CARATV2.0 was biased towards warfarin and thus distrusted CARATV2.0's recommendation when it did not recommend their preferred therapy. Similarly, several pro-warfarin health professionals questioned and disliked CARATV2.0's recommendations because it did not allow negotiation with their preference. Because patients were routinely referred to either GPs (in remote and regional areas) or specialists (in metropolitan areas) for the prescription of antithrombotic therapy, many health professionals believed that the usefulness of CARATV2.0 in improving antithrombotic selection would depend on whether the tool's recommendations are followed by the GPs and hospital doctors.

Some GPs believed that CARATV2.0 might be able to assist in negotiations with patients by providing evidence (e.g. stroke risk score) for explanations. However, one GP argued that CARATV2.0 could not help in persuading patients to take certain OACs because the negotiation to persuade or convince patients to take antithrombotic therapy involves managing individualised health expectations rather than only presenting scientific evidence about this form of therapy.

Pharmacists' and nurses' perspectives on the usefulness of CARATV2.0 was largely determined by whether they thought this tool considered important issues in medication management when selecting antithrombotic therapy for individual patients. While pharmacists focused more on the medication safety issues (e.g. drug–drug interactions, adherence and international normalised ratio (INR)) when using this tool, nurses paid more attention to the tool's assessment of patients' capability to manage

Table 2. Theme 1: need for comprehensive structured assessment of patients to assist with the prescription and review of antithrombotic therapy.

General practitioners	Pharmacists	Nurses	Specialist clinicians
It (CARATV2.0) is very thorough. It has everything there that we should definitely take into account. When I see a patient … there may be aspects that I wouldn't have thought about that I should have thought about that wasn't there. So it is a very good tool that has everything on it. (G03) *You (CARATV2.0) have all renal liver function, gastrointestinal problem and other illnesses. You seem to cover everything that a good clinician would have to take into consideration anyway … As a doctor you think along these lines anyway, so all you (CARATV2.0) are doing is to put them into a chart or table or tool that gives you a visual and a check list, I suppose.* (G05) *The strength is that it is very important that as clinicians whether we still use the warfarin or the newer agents. I think if the prescribers have got a tool that would help them … Having it as a rigid module, I think it is a good idea.* (G06) *I can see it (CARATV2.0) would be useful for GPs that don't have access to a cardiologist … It is good for doctors who are not certain or don't have access to cardiologist … The new doctors love to have something like that, because it gives them the confidence to manage the patient and to be able to assess the patient to know what they should be doing.* (G02)	*I will definitely use it (CARATV2.0) … if I have a patient that I wasn't sure whether or not they should be on say warfarin … All of these criteria that you have got listed here, taken into account with the choices basically they will go. Ok this person had an event and he need to be on kind of anticoagulant. Ok then let's put him on warfarin. Maybe there are CHADS$_2$ score and HES-BLAD score … but they (CHADS2 score and HES-BLAD) are not looking at such comprehensive criteria, so this (CARATV2.0) is much more specific.* (P02) *The strength would be that it (CARATV2.0) considers all the factors of a patient which I usually consider when I am recommending an anticoagulant or checking what they are already taking, so I will look at the safety issues I look at the drugs that they are taking. I look at their actual medical condition as well so it has got all those things covered. And having that universal tool would be a big strength because as I said I can refer to a doctor what I am referring to.* (P06) *I think it (CARATV2.0) is good for pharmacist. It looks good to show this to doctor to say this is my recommendation. You have got something to back it up. So decision-making tool to back it up.* (P04) *Comprehensive. All the factors that I would consider starting someone on anticoagulant is in this tool.* (P07)	*I think that (CARATV2.0) offers a global assessment around anticoagulation not just simply risk stratification tool but a global assessment tool. It takes into consideration other factors that are above and beyond stroke and bleeding risk, such as adherence.* (N01) *… we might be in a situation especially with patients in nursing homes things like that. I would not feel confident without a pharmacist's recommendation, but with that tool (CARATV2.0) I can possibly.* (N02) *I think it (CARATV2.0) is good because one again it makes you look at the patient as a whole … It (CARATV2.0) brings in all those other factors like their cognition their function and those sorts of things. I think that gets forgotten when people are prescribing. They forget the whole patient … I think that is what is good about being able to select or being able to choose between warfarin and other OACs.* (N05) *I think it (CARATV2.0) is good because it would make you also think about things that you might not think about when prescribing these medications that you might forget about the drug interactions and things like that.* (N06)	*For me it (CARATV2.0) might be useful but I imagine that I would most likely be using it in patients where it is not certain either way. Like I probably wouldn't use it if it clear in my mind that there is high risk of stroke and low risk of bleeding … Whereas for patients who a bit equivocal then I may use this tool to help me choose one or the other.* (S01) *The benefit is that you (CARATV2.0) are assessing both the risk of stroke and the risk of haemorrhage, and you have also got some aged care risk factors in there, which a lot of other tools don't have.* (S03) *One of the first thing that is good is that if a doctor who has not treated many patients with AF is that by going through this (CARATV2.0) they see a lot to consider and it also makes them to think the patient a little bit more thoroughly. I think that is good … It is good that these scores (CHADS$_2$ and CHA$_2$DS$_2$-VASc, and HAS-BLED and HEMORR$_2$HAGE) are included and the scores are also given at the end.* (S05) *All the components (in CARATV2.0) are the same as the experienced clinicians would use and make a judgement about whether to use or not to use anticoagulant therapy. So the use of CHA$_2$DS$_2$-VASc and HAS-BLED scores, the differentiation between warfarin and NOACs are all quite appropriate.* (S04)

CHADS$_2$: congestive heart failure, hypertension, age = 75 years, diabetes mellitus, stroke; CHA$_2$DS$_2$-VASc: congestive heart failure, hypertension, age $\geqslant$ 75, diabetes, prior stroke or transient ischaemic attack, vascular disease, age 65–74 and sex; HAS-BLED: hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalised ratio, elderly, drugs/alcohol; HEMORR$_2$HAGE: hepatic or renal disease, ethanol abuse, malignancy, older age, reduced platelet count or function, re-bleeding, hypertension, anaemia, genetic factors, excessive fall risk and stroke; OACs: oral anticoagulants; NOACs: novel oral anticoagulants.

Table 3. Theme 2: health professionals' and patients' preferences for a particular antithrombotic therapy.

General practitioners	Pharmacists	Nurses	Specialist clinicians
I think traditionally that people with high risk score of CHADS$_2$ should be a candidate to warfarin. That is the decision that I always made, so I would need be shown why I should be changing my decision. Why somebody might not be given warfarin but given NOACs instead. (G01) *My only concern is that I am always very aware of warfarin, so if it (CARATV2.0) does recommend warfarin I may not take the recommendation, I would have to looking closely to see why it recommends warfarin instead of NOACs.* (G03) *The difficulty is to negotiate with the patients about their degree of risk. The meaning behind not being on an anticoagulant. What it would mean in terms of follow-up for it to be safe, if they are on anticoagulant. And the management around that … A lot of patient, where warfarin is appropriate have bad stories. Maybe the parents have been on it or the relatives, then they had a bleeding and regular blood test. So for lots of GPs, to address these issues is in fact the main task … So to manage the people's expectation of health is the most important part of the consultation about anticoagulants. So I suppose with this tool it is really more about the technical decision.* (G04) *One of the difficulties in general practice is the cardiologist does something different from what you do. That becomes quite complicated, because I have been quite surprised that some of my patients are under cardiology care who are not on medication.* (G02)	*Well, you (CARATV2.0) have got all these you have listed all possible risk factors. As much as you can, of course sometimes these risk factors might vary or might be severe than in other situations. Like anaemia for instance, that might not be present might later be present. So it is just you would have to constantly measure these from time to time.* (P03) *Because some people do not like to go to their doctor to get the blood check, I don't think it (CARATV2.0) addresses this problem, but otherwise it is pretty good.* (P04) *It is good tool. A lot depends on the patient … the doctor may evaluate the patient according to this tool. But the outcome does not depend on that they recommend warfarin or NOACs, it really depends on the patient's cognitive function. Because sometimes, they (patients) don't understand this situation very well and they don't know how to ask questions. And even Webster pack is not always suitable.* (P05) *If there is an option to include all the drugs that the patient is on or if they want to do a little drug interactions … put the drug that they (patients) are on you might come up with some extra interactions. But that is probably going take away the simpleness of this tool, which is a big plus to it. So obviously it (CARATV2.0) is very very good but there still be a few little drugs that might interact that might be missed.* (P06)	*I think the nurses have limited input into choices and decision makings. I think the decision of anticoagulant actually come from the cardiologist in the end. Nurses may fill it (CARATV2.0) in and the pharmacist can fill it in. Is cardiologist going to look at it and follow? … I think still a lot of clinicians are hesitant to use NOACs … if you have cardiologist who have been using warfarin for the last 40 yrs and why they are going to change to NOACs? No. If they have someone who is on warfarin and adherent why change it … So it (CARATV2.0) doesn't really consider the clinicians preference … Well it is nice to give a recommendation based on international guidelines validated risk assessment tools, I think it doesn't consider the clinicians previous experience of the agents and that is going to influence their decision making. But I think this is still useful tool.* (N01) *I think it is good that it (CARATV2.0) makes you think about other things from a nursing point of view. I think it makes you think very much the cognition the falls risk visual deficit … that is good. Because all these things can be difficult for patients to actually overcome. So by taking that into consideration I think that is good … I like that.* (N04) *I think that is what is good about being able to select or being able to choose between warfarin and the NOACs. Because warfarin is a really hard medication to manage whether we can actually say this patient would definitely benefit from one the NOACs, because of their cognition bla bla then I think this tool is helpful in that respect.* (N05)	*I do not believe you should use warfarin as first line. It is a choice and some patients who we would prefer them to be on warfarin typically with renal impairment and maybe noncompliance. And certainly people who are well established on warfarin, they do not need to switch them. But for anyone who is new, I do not see there is any justification for saying warfarin first and then the new drugs.* (S06) *The other thing that I am not totally convinced by it yet, is whether there is enough data in older patients for the NOACs. That is the other thing that I am not sure about given that they have been safety signals for things like gastrointestinal bleeding. You know I probably want more data in older patients.* (S01) *One of the clinical concerns that we all face now with the NOACs is what happen to people who are elderly and who are around NOACs because of AF and happened to get gastrointestinal disturbance get diarrheal, vomiting, dehydration, renal impairment. And suddenly get an eGFR that drops down to 30 and they are on a NOACs. Unless they are aware of the risk. They are going to have increased risk of bleeding. So I think as an educational tool it is useful and that is going to be one of the main clinical concerns that I have in the use of NOACs.* (S04)

CHADS$_2$: congestive heart failure, hypertension, age = 75 years, diabetes mellitus, stroke; GPs: general practitioners; AF: atrial fibrillation; NOACs: novel oral anticoagulants; eGFR: estimated glomerular filtration rate.

Table 4. Theme 3: integration into existing systems and processes.

General practitioners	Pharmacists	Nurses	Specialist clinicians
I think if you can incorporate it (CARATV2.0) into the (practice) software and the software would populate as much as the data from our file as much as possible that would be very good. (G03) *The weakness will be if this tool is not in cooperated in the practice software, so it must be integrated. Because it would be very difficult for a doctor to go somewhere else or another website. It is going be there as you are prescribing and also in a hospital situation it has to be accessible. So you know in the patient's file it is going to be part of that medical record and accessible to people.* (G06) *I think if you can incorporate it (CARATV2.0) into the software and the software would populate as much as the data from our file as much as possible that would be very good. Also, we have got a chronic disease nurse, and she could administer it and fill the answer then that could also make it quite easier for us.* (G02)	*If you are doing a medication review, you look at the pathology first before you went out … It will be better your renal function and liver function altogether, because that will be the pathology that the patients wouldn't know those answers. So it will be better if they are together at the beginning or at the end (of CARATV2.0) …* *I think it (CARATV2.0) will work really well within HMR or RMMR … mean a lot of questions you going to ask anyway.* (P01) *I usually not initiating treatment, so in my practice it would be basically just check what the patient is taking is best for them. And particularly if they are recently being changed or initiated a drug, I will be checking that it is the right drug that they should be on. So for me it (CARATV2.0) is a good checking mechanism.* (P06) *I think it is good as well. In a community would be useful. For annual review or something, they (patients) can not reach therapeutic level they have a labile INR … using this tool to determine whether warfarin still the therapeutic choice for this patient or not.* (P07)	*I think the mobility thing is important to have. Like to have it (CARATV2.0) with the patient. Like explaining to the patient about the things. And have it portable not on a desk top. I guess there is access issues around if it is something like internet based.* (N01) *Maybe you can get an app. If you can get it (CARATV2.0) into an app, maybe everyone would use it because it would be easy to carry around and ask patients questions.* (N06) *I think that (integration into electronic health system) will be useful. Because there is a lot of things there that you don't need to do it again … A lot of that stuff whether the patient has AF or not could then go into that system.* (N05)	*I think easy to use is the main thing. If you do turn it (CARATV2.0) into an app make it simple to enter things so you don't have to enter a lot of text more than that you have tick box to make it bit easier. Might be useful to have section of patient information, so you know based on this tool your doctor has recommended XYZ, these are precaution whenever using this agent is. So if you use a website or something that it can generate patient information sheet.* (S01) *I think we probably need it (CARATV2.0) as an app and need it to be electronic and need to be touch screen if we can have that. And then we just need to practice.* (S03) *It (CARATV2.0) will be much more acceptable on an app … Because you can just have it in your phone and download the things and much quicker than finding a computer and calling it up in computer and excel file to type it in for me.* (S02)

HMR: Home Medicines Review; RMMR: Residential Medication Management Review; INR: international normalised ratio.

their medications (e.g. mobility, cognitive function and lifestyle). Although pharmacists and nurses believed that CARATV2.0 comprehensively assessed the major medication management issues, they also pointed out that CARATV2.0 did not consider every issue, for example, use of fish oil supplements or binge drinking. But they also admitted that the selective inclusion of the most important medication management issues ensured the simplicity and ease of use of this tool.

Theme 3: integration into existing systems and processes

Hospital-based health professionals (including specialists, nurses and pharmacists) and GPs suggested integration of CARATV2.0 into existing systems and processes due to the limited time available for making clinical decisions. Most hospital-based health professionals and GPs recommended that the tool's usefulness could be improved if it was integrated into or linked with electronic medical records or the electronic prescribing software used in hospitals and general practices. They recommended it be accessible through mobile phones, computers and tablets in order to self-populate the medical records and databases and to make the tool easily accessible and portable. However, both GPs and hospital-based health professionals were worried that some of the practice computer software might not interact well with CARATV2.0. They were also concerned that some of the information required by CARATV2.0 might not be available in the electronic health system, which would mean that such information would require manual entering. To solve this problem, some suggested that pharmacists, junior medical residents, medical students or practice staff (e.g. nurses) could populate CARATV2.0 manually, allowing senior clinicians more time to review CARATV2.0's recommendations.

In contrast to hospital-based health professionals, the time needed for populating CARATV2.0 was not raised as a major issue by community-based pharmacists and community-based nurses. Some of these practitioners actually thought that CARATV2.0 would save them time because it considers all the antithrombotics indicated for AF and integrates many relevant risk assessment tools into one tool. They paid more attention to how the tool's usability could be improved by incorporation into their medication review and patient assessment processes within an electronic format (e.g. 'apps', websites or software).

Discussion

The results from this study show that CARATV2.0 is generally welcomed by health professionals and that they consider it can potentially improve prescription of OACs and clinical outcomes of patients. This is consistent with the evidence that computerised decision support tools can significantly improve prescription among clinicians and can improve the quality and safety of care provided.[28,29] Although decision support tools that focus on the assessment of stroke and bleeding risk are widely available,[30] so far CARATV2.0 is the only tool that integrates stroke risk assessment, bleeding risk assessment and medication safety assessment and that considers both the traditional antithrombotic agents, warfarin and the NOACs.

Since decision-making is an emotive process, comprehensive risk versus benefit assessment, systematic documentation and communication of decisions can assist in the selection of optimal therapy for individual patients.[3] However, due to limited experience with the use of newly available NOACs, especially NOAC use in elderly patients, the risk versus benefit assessment of using OACs in these, and other, patients is a complex task for many health professionals. CARATV2.0's comprehensive risk versus benefit assessment of individual patients provides guidance and a reference for, and confidence in, not only the decision on whether a patient should be treated with antithrombotics but also choosing the appropriate therapy among various OACs. Furthermore, because CARATV2.0 is based on the latest clinical guidelines, the tool can also reinforce the use of clinical guidelines by health professionals.

The study found that subjective issues, including clinician and patient preferences for particular antithrombotic therapies, can have a substantial impact on the clinical decision-making process.[31] Studies have shown that clinicians tend to override recommendations made by a decision support tool if they have a strong preference for a particular medication.[32] Also, patients' preference of therapy has been reported to substantially affect the clinical decision-making for therapy.[33] Although it is widely recognised that computerised decision support tools have the potential to improve the behaviour of clinicians in terms of prescription and consistency of decision-making, evidence supporting the long-term impact of decision support tools on clinicians' prescribing behaviour is lacking.[34] Given these subjective issues, the impact of CARATV2.0 on decision-making for antithrombotic therapy in AF needs to be further explored.

The suggestion of integrating CARATV2.0 into existing systems and processes shows that the health professionals valued the tool as an effective support for clinical decision-making.[32] According to a systematic review by Kawamoto et al.,[35] a successful decision support tool needs to be computer-based, to have automatic provision of decision support as part of clinician workflow, to provide recommendations rather than just assessments and to provide decision support at the time and location of decision-making. However, this suggestion also reflects that clinicians are reluctant to prioritise and allocate time for the initial decision-making around antithrombotics, which contrasts with the time spent in managing the adverse outcomes of poor or suboptimal prescription. Also, 'pharmacotherapy' as an intervention follows a less structured decision-making process than other interventions such as surgery.

Some limitations of the study need to be acknowledged. The participating specialist clinicians, GPs, pharmacists and nurses in this study were volunteers who showed interest in the study. This could have biased their feedback on CARATV2.0. Also, the sampling strategy affects to some extent the generalisability of the study findings beyond these participants. Furthermore, CARATV2.0 inputs are based on available evidence from guidelines and reviews, which may not be relevant to all patient populations and may change over time as new evidence emerges. Since the findings from this research are restricted to the content and feasibility of this tool, the potential clinical and economic impact of the tool and the feasibility of using the tool in real-world clinical practice require further evaluation.

Overall, the feedback from health professionals identifies that the only drawback of this tool is the time needed to complete the assessment (i.e. input the relevant data). To address this issue for future application in practice, CARATV2.0 may be integrated into other systems (e.g. electronic medical records) to enable the auto-population of patient data into the tool. Furthermore, the tool may be used by other health professionals (e.g. NPs and consultant pharmacists) where comprehensive patient assessment and medication review are part of their targeted services.[17,36]

Conclusion

CARATV2.0 was regarded by a variety of health professionals as a potentially useful tool that provided a systematic assessment around the decision-making for antithrombotic therapy in patients with AF. The tool also shows potential for rationalising the use of antithrombotics and for improving the clinical outcomes of patients with AF. Future research should evaluate the impact of this tool on the prescription of antithrombotics in clinical practice. The main drawback of this prototype tool is that it requires the manual input of data, which may not be time-efficient for busy health professionals. Therefore, processes for the auto-population of the tool with relevant patient data need to be explored, for example, the integration of CARATV2.0 into electronic databases or prescribing software or/and re-formatting it into a mobile online application.

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Authors' contribution

All authors have made substantial contributions to all of the following: (1) the conception and design of the study, acquisition of data, analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be submitted.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Ethical approval

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An empirical study of opinion leader effects on mobile technology implementation by physicians in an American community health system

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Abstract

This study empirically examines the opinion leader effects on a mobile clinical information technology implementation by physicians in an American community health system using a fixed effect regression model. The model result suggests that the opinion leader effects are statistically significant during this information technology implementation process. Quantitatively, if opinion leaders increase their technology usage by 10 percent, the physicians who work closely with those opinion leaders would increase their technology usage by 3.5 percent, after controlling for physician individual-level fixed effects, time effects, working environment, and workload. This empirical result of opinion leader effects provides policy implications such as, if a healthcare system wants to promote a new information technology or a new mobile information technology implementation within their organization, they should leverage this opinion leader effects.

Keywords

collaborative work practices and information technology, e-health, healthcare policy, healthcare service innovation and information technology, mobile health, organizational change and information technology

Introduction

Research shows that e-health can have positive impacts on reducing medical errors, saving costs, improving usability, and convenience.[1] However, the healthcare information technology (IT) adoption rate in the United States is low at both the physician office and hospital levels. Less than

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30 percent of US physicians adopt e-health in their work and less than 10 percent of US hospitals use a robust healthcare information system.[2,3] Even up to 2014, the physician office e-health adoption rate in the United States is 74 percent on average at national level, which is much lower than that of other developed countries, such as New Zealand, the Netherlands, and the United Kingdom, which is 89 percent or more.[3,4] The US healthcare industry has already realized its inadequacy in this area.[5] However, the healthcare industry in the United States has many special characteristics, including the fact that many physicians or physician offices are independent or practice in facilities independent from the major healthcare systems or hospitals, even when they are associated with them. This means that the health organizations have no power or very weak influence to mandate the implementation of new IT over physicians. This issue makes the promotion of IT implementation and utilization among healthcare providers more challenging in the healthcare industry in the United States.

At the same time, interest in mobile technology applications has been rising in healthcare.[6–9] One study found 62 percent of surveyed clinicians expressing interest in using apps to view electronic health records (EHR).[8] Another survey shows that 68 percent of surveyed junior physicians said that using smartphones' clinical apps saved their time in clinical activities.[10] However, a 2013 survey of physicians indicates that nearly 60 percent are non-users of e-health.[11] Although there are some studies on mobile technology usage or acceptance at work,[12,13] there are limited empirical studies about physicians' mobile technology usage or implementation behavior and the factors that impact them.[14,15]

Also, the authors noticed that since 1980s, there are a large number of technology acceptance model (TAM) studies in information systems as well as in healthcare.[16–21] But, this study takes a different angle from the TAM research on the technology adoption and implementation. We are interested in using a secondary data set, from an objective perspective, to examine physicians' technology usage behavior in a clinical setting, not survey questions to investigate the technology acceptance by physicians.

In the United Kingdom, a study found that the most important factors that impact IT implementation in healthcare are human factors, not technology factors.[22] Therefore, this study is interested in examining how the social influence, or opinion leader effects, impacts a new mobile IT implementation in healthcare, using a secondary panel usage data from a community health system in the United States.

Social influence and opinion leader effects have been examined by scholars in information systems for a long time, and its importance has been noted in medical research as well.[23,24] Particularly, the classical innovation diffusion study by Rogers[23] emphasized that innovation diffusion is a process; when a new technology is introduced, initially people perceive using the new technology as uncertain and risky, so many may not adopt the new technology in the beginning, but instead, may seek out others around them who have already adopted the innovation, such as early adopters or opinion leaders, which may help to reduce their uncertainty, resulting in subsequent adoption. Thus, the innovation will diffuse from the early adopters or opinion leaders to their circle of acquaintances over time. Conceptually, opinion leaders are respected people who possess sufficient interpersonal skills to exert influence on others' decision-making.[23,24] Empirically, there are many ways to identify opinion leaders among a population. We will discuss more specifically later in section "Data."

This study is interested in investigating opinion leader effects on a mobile technology implementation because if social influence is established as a strong factor, then as a policy adjustable factor, it can be leveraged to promote the implementation and utilization of the new technology, rather than the technology design users, gender, or age, which we cannot change once the technology has been deployed by an organization. Thus, our hypothesis is that opinion leaders have a strong impact on technology usage by physicians around them. The more opinion leaders use the new technology, the more the physicians around the opinion leaders would use the technology. If so, policy makers or health organization's administrative can utilize the opinion leader effects to promote technology adoption or implementation within their organization, thus improve the quality of care using the new technology.

Data

Study context

The study site is a community-based health system located in Southwestern Pennsylvania, USA. In partnership with about 300 physicians and nearly 4000 employees, the community healthcare system offers a broad range of medical, diagnostic, and surgical services at two hospital campuses with over 500 beds, and many small clinical practices distributed across the community. In June 2006, the health system deployed a Mobile Clinical Access Portal (MCAP), which is a wireless personal digital assistants (PDA)-based, client-server solution providing physicians with online access to clinical data and about 24 clinical functions such as searching patient information, reviewing patient medical histories, using electronic prescribing, placing lab orders, and checking lab results. Physicians of this health system were provided PDAs free of charge, and the physicians were able to use the PDA to access the MCAP anywhere, anytime, at their convenience, such as in the office, at home, or while traveling. All the MCAP use was optional, not required, because the system wide electronic medical record (EMR) is on a desktop computer system which is the entry for all the major clinical data.

Data

The Chief Information Officer of this healthcare system and his technical team provided four data sets for this study. The first data set included de-identified demographic information about 250 full-time physicians, comprising a unique coded physician ID and demographic data. The second data set included the clinical group practice information, which indicates which physicians practice together and which physicians are solo practitioners. The third data set contained MCAP usage data from their system computer server's log files, and each record represents a certain application that was being used at a given time by a given physician. The fourth data set included physician ID, patient visit date, and four types of patient visit volume for each physician: inpatient visit, outpatient visit, physician office visit, and emergency room visit. This data set is from their system's servers as well.

It was necessary to exclude 58 out of the 250 physicians with either missing demographic information or missing patient visit information after merging the four data sets, leaving 192 physicians in the merged file for this study. Since almost 23 percent (58 out of 250) of the physician records were dropped due to incomplete data, we performed four two-sample t-tests between the dropped out group and the remaining group for age variable, gender variable, specialty area, and patient visit, respectively, to see whether those variables' mean values are equal or not between the two groups. Since none of the t-tests are statistically significant, which means those mean values from dropped group are not statistically different from the mean values from the remaining group, we concluded that the dropped data should not impact our analysis or bias our model result.

Ideally, we would like to examine the technology usage behavior for every specialty area separately. But as a community health system with limited size, many specialty areas only had one specialist or one practice (such as Oral and Maxillofacial Surgery, Nephrology, and Psychology).

Also, the MCAP features are not very medical specialty dependent just as the online Blackboard system is not designed for every subject in a university. Therefore, after discussing with the health system decision makers, we divided the 30 medical specialty areas into two general categories, General Practitioners and Specialists, in order to control for how specialty areas may affect physicians' implementation of MCAP. The General Practitioner category includes internal medicine, family practice, and pediatrics, and Specialist category includes the remaining specialty areas. Furthermore, since age is not believed to have a linear impact on technology usage behavior, we divided the physicians into three nominal age groups as prior literature has done: ages 45 years and below (with the youngest physician being 30 years old), ages between 46 and 55 years, and ages 56 years and above.[25]

As scholarly studies have discussed, there are many ways to identify opinion leaders in an empirical study and different identifications may have different impact on the study results.[23,26–28] In this study, opinion leaders for MCAP (for simplicity, from now on we only call them opinion leaders but it does not mean they are opinion leaders for everything) were identified by the health system administration based on their dynamic observations, referred to as the informants' rating method.[23] In our case, the health system's administrators identified some physicians who were opinion leaders of this MCAP technology. Those physicians were enthusiastic drivers to encourage the community health system to adopt and deploy the MCAP, and they were also early (received the new technology in the first 2 months) and frequent users of the MCAP. The rest of the physicians of the health system received the PDA gradually over time after the third month. Such exogenous identification of opinion leaders avoids the problems that arise when users are asked to nominate their opinion leaders using a survey as in prior studies, which provides a unique opportunity for our study.[26–28]

We also need to clarify the social structure of this community system, to understand who are influenced by the opinion leaders. This is a typical American community health system, which means many clinics are spread throughout the community, miles away from each other. Those clinics are also financially autonomous and independent entities. Physicians in the clinics are loosely associated with the hospital, and they only go to hospital for performing surgeries or visiting their patients for post-surgery. Physicians rarely see other physicians from other clinics because of the physical distance and irregular visit to hospital campus. The most interactions that physicians have are with physicians from their own clinics. Thus, we assume the medical practices (clinics) as the basic social influence groups, and opinion leader effects occur within the group, not across groups. This implies that physicians are only influenced by the opinion leaders from their own group practice, not by the opinion leaders from other practices.

Finally, there is no indication of group formation endogeneity problem because these group practices are based on the medical specialties, not the interests of IT or mobile technology. Furthermore, the group practices were formed long before the MCAP was deployed. Thus, this definition of social influence groups provides an unambiguous, theoretical foundation for identifying any peer effect (opinion leader effects are one type of peer effects) as discussed in the seminal paper by Manski.[29]

In summary, the MCAP data sets provide several advantages for our study of opinion leader effects on physicians' mobile technology implementation. First, the PDAs and MCAP system were provided to the physicians free of charge by the community health system, with no incentives for using it; therefore, there was no user acquisition cost which might confound technology usage decision due to users' heterogeneous socioeconomic situations. Second, MCAP system was designed with a straightforward menu-click interface, so the learning curve was very low and the non-usage behavior should not be due to "difficult to use" reasons. Third, the use of MCAP was not mandated, and it was only an optional choice for physicians to use as part of the EMR features

Table 1. Descriptive statistics for 171 physician users, no opinion leaders.

Variable	Statistics
Total number of users	171
Total number of solo users	51
Total number of users in non-opinion leader group	88
Total number of users in opinion leader group	32

Variable	Mean	Standard deviation	Minimum	Maximum
Male	78%	NA	0	1
Age	50	9.8	30	78
Age 45 years and below	34.5%	NA	0	1
Age between 46 and 55 years	35.7%	NA	0	1
Age 56 years and above	29.8%	NA	0	1
General practitioner	45%	NA	0	1
Group size	3.4	3	1	12
Total months used	15	5.2	1	20
Total MCAP use	796	1857	1	13,438
Average monthly MCAP use	36	84	0.05	611
Average monthly inpatient visit	42	40	0	177
Average monthly outpatient visit	444	514	0	2153
Average monthly physician office visit	355	435	0	2170
Average monthly emergency visit	45	95	0	601

MCAP: Mobile Clinical Access Portal; NA: not applicable.

in a mobile version. This indicates that whether the physicians use this mobile technology or not would not affect the formal EMR system or the physicians' daily work. Additionally, since it is a mobile technology, physicians or opinion leaders probably may use it when they move around within their clinics, such as switching between different exam rooms, lunching in the kitchen, and chatting in the lounge. Therefore, it is reasonable to assume that physicians would probably see their colleagues or opinion leaders using this new mobile technology more than a desktop computer application, and they may chat about it too and learn about each others' use of MCAP.

Descriptive statistics

As a real-world project for an optional use technology, there was no clear timeline or deployment plan regarding when to give out the PDA to which physician. Generally, this deployment process was a little random according to physicians' personal interest or technical staff's schedule. Thus, the panel data that we received are an unbalanced data set.

Descriptive statistics of 171 physicians (not including the 18 physicians who are opinion leaders of MCAP) and their usage are presented in Table 1. We do realize that our data set is a little small but this is an average size of a typical community health system in the United States. The descriptive statistics shows that the majority of physicians are males (78%). The age range is from 30 to 78 years old, and the average age is 50 years. The three nominal age groups have approximately similar membership. There are fewer general practitioners (45%) than specialists (55%).

Although we have usage data at the individual instance level, we study the technology use behavior at monthly level due to data sparsity at the daily and weekly levels. One month is

Table 2. Descriptive statistics for opinion leaders.

Variable	Mean	Standard deviation	Minimum	Maximum
Male	89% (16)	NA	0	1
Age	49.5	6.69	39	60
Age 45 years and below	33% (6)	NA	0	1
Age between 46 and 55 years	50% (9)	NA	0	1
Age 56 years and above	16% (3)	NA	0	1
Group size	4.1	2.25	2	12
General practitioner	78% (14)	NA	0	1
Total MCAP use	1018	2119	2	13,438
Total months used	15	5	1	20
Average monthly MCAP use	61	117	0.11	707
Average monthly inpatient visit	91	46	25	170
Average monthly outpatient visit	1149	736	36	2584
Average monthly physician office visit	706	589	1	1998
Average monthly emergency visit	69	49	0	184

MCAP: Mobile Clinical Access Portal; NA: not applicable.

one time period in this study. Therefore, we aggregate the physicians' MCAP usage data and patient visit data at the monthly level for descriptive statistics. We also can see the average monthly usage of MCAP by general physicians is 36 times per month and 61 times by opinion leaders.

The descriptive statistics about opinion leaders are presented in Table 2. There are 21 opinion leaders and 3 of them are solo practitioners who are not discussed in this study because solo opinion leaders do not influence anybody in the health system. We also performed three two-sample t-tests between opinion leader groups and non-opinion leader groups for age variable, gender variable, and specialty area variable to examine whether the variables' means from those two groups are statistically different or not. None of the t-test results were statistically significant. That means that the mean values of those three variables from opinion leader groups and non-opinion leader groups are not statistically different, which indicates no bias for the demographic composition of opinion leader groups or non-opinion leader groups.

Figure 1 shows the average monthly usage by three types of users: solo physician users, group physician users with opinion leaders, and group physician users without opinion leaders over 22 months. We can see that solo practice physician's average monthly usage of the MCAP is the lowest one among those three groups, and the group practice physicians with opinion leaders are higher most of time, and the group physicians without opinion leaders is in between. It indicates that besides opinion leader effects, a general peer effect may also exist.

Empirical model and results

Empirical model

Based on Figure 1 and our observation of this community healthcare system, it is likely that peer effects, effects from general colleague physicians or general peer physicians, not from opinion leader physicians, may exist too. Hence, besides opinion leader effects (having opinion leader

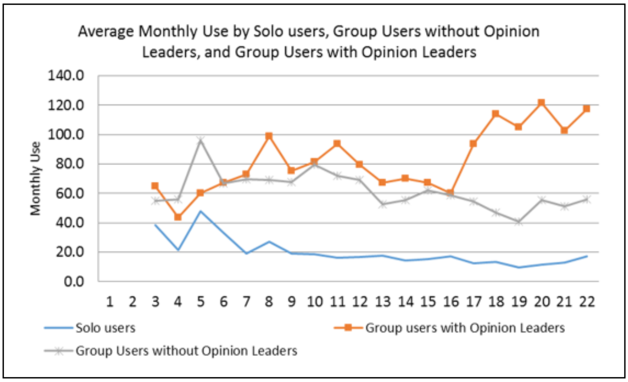

Figure 1. Average monthly technology usage by three types of physician users.

physicians in the same practice), some physicians may be exposed to peer effects (having general colleague physicians in the same practice), relative to solo practice physicians. We do not want to assume that those peer physicians do not have an impact on the focus physician's technology usage Or do that physicians who practice with general colleagues (non-opinion leaders) would be the same as physicians who practice solo. Thus, in order to estimate the opinion leader effects more accurately, we should control the peer effects in our model.

Furthermore, the physicians in this health system rotated among different clinical settings, such as inpatient, outpatient, emergency rooms, and office visit. The number of patient visits each physician had at each time period is also different, thus the number of patient visits at different clinical environment should be controlled in our model to examine opinion leader effects on new technology usage.

We construct the following fixed effect regression model to examine the correlation between the technology usage by physicians and their opinion leaders over time, controlling for general peer effects, the number of patient visits a physician had in different clinical settings, and the individual-level fixed effects including all the time-invariant variables such as observable characteristics: gender, age, and education, and unobservable characteristics: personal interests or technology preference[30]

$$\begin{aligned} Y_{it} = {} & \beta_0 + \alpha_i + T_t + \gamma_1 \text{Opinion\_Leader}_{k,t} + \gamma_2 \text{General\_Peers}_{k,t-1} + \beta 1\ \text{InPt\_Visit}_{it} + \\ & \beta_2 \text{OutPt\_Visit}_{it} + \beta_3 \text{PhyOff\_Visit}_{it} + \beta_4 \text{Emg\_Visit}_{it} + \varepsilon_{it} \end{aligned} \tag{1}$$

where Y_{it} is the monthly usage of physician i at time period t, β_0 is the model intercept, and α_i is the fixed effect of the physician i, including both visible and invisible individual-level time-invariant characteristics. We also include the time trend dummies, T_t, to control time effects. ε_{it} is the model error term. $\text{Opinion\_Leader}_{k,t}$ is opinion leader effects, and we use the total technology usage by the opinion leaders within group k at time period t as the proxy of the opinion leader effects on physician i in group k. $\text{General\_Peers}_{k,t}$ is peer effects, and we use the total technology usage by the peers within group k at time period t as the proxy of the peer effects on physician i in group k. InPt_Visit_{it}, OutPt_Visit_{it}, PhyOff_Visit_{it}, and Emg_Visit_{it} are the number of patient visits physician i had at time period t in the inpatient setting, outpatient setting, physician office setting, and emergency room setting. Note, some groups have both opinion leaders and peers. Some groups

Table 3. Model results.

Parameters	Model (1)	Model (2)
	Opinion leader effects and peer effects	Opinion leader effects and lagged peer effects
Intercept	1.370	1.445
Log of opinion leaders' usage	0.315**	0.318**
Log of peers' usage	0.171**	–
Log of lagged peers' usage	–	0.097*
Log of inpatient visit	0.101	0.100
Log of outpatient visit	0.141	0.134
Log of physician office visit	0.065	0.071
Log of emergency visit	0.015	0.018
Model statistics		
R-squared: overall	0.218	0.199
No. of observations	2583	
No. of groups	171	
No. of time periods	20	

The dependent variable is log of physician i's technology usage at time period t.
*Indicates statistically significant at 5 percent level; **indicates statistically significant at 1 percent level.

have one of them. Some of physicians practice solo which means they have neither opinion leader effects nor peer effects.

To address concerns that peer effects may have potential simultaneity problem here because physicians are peers to each other, in Model (2), we use the lagged usage by peers as the proxy to avoid this issue.[31] The only difference between Model (1) and Model (2) is that in Model (2), we use peer physicians' previous time period's MCAP usage, not the current time period's MCAP usage

$$\begin{aligned} Y_{it} = {} & \beta_0 + \alpha_i + T_t + \gamma_t \text{Opinion\_Leader}_{k,t} + \gamma_2 \text{Lag\_Genera\_Peers}_{k,t-1} + \\ & \beta 1 \text{ InPt\_Visit}_{it} + \beta_2 \text{OutPt\_Visit}_{it} + \beta_3 \text{PhyOff\_Visit}_{it} + \beta_4 \text{Emg\_Visit}_{it} + \varepsilon_{it} \end{aligned} \tag{2}$$

Model result

We present two fixed effect model results in Table 3, including both lagged peer effects and non-lagged peer effects models. We can see that opinion leader effects are statistically significant and similar in both models, which are 0.315 and 0.318, respectively. Because we have taken logs on both sides of the model when running this fixed effect regression (easier interpretation of the model estimates), the result suggests that when opinion leader/s increase their technology usage by 10 percent, the physician in the same group would increase their technology usage by 3.2 percent.[30] This result is consistent with our expectation that opinion leader effects exist during physicians' technology implementation process, and the more the opinion leaders use the technology, the more the physicians under opinion leader effects use the new technology.

In both models, the general peer effects are statistically significant too. But, when general peers increase their technology usage by 10 percent, the physician in the same group would only increase their technology usage by about 0.1 percent, which is quite small. Also, none of the patient visit volumes affect physicians' technology usage, which may indicate that this technology is quite simple, straightforward, and independent from clinical setting.

Conclusion and limitations

In this study, we examine opinion leader effects on a new mobile technology implementation by physicians in an American community health system using a fixed effect regression model. According to authors' knowledge, this is one of the first empirical studies to examine opinion leader effects on mobile technology implementation in healthcare using a quantitative approach. The empirical results show that opinion leaders' usage have statistically significant effects on their colleague physicians' technology usage, controlling for general peer effects, the number of patient visits, and the individual-level fixed effects. Hence, without any special stimulants or financial incentives, as long as opinion leaders continue using or increasingly using the new technology, the physicians under the influence of the opinion leaders will likely use the new technology. This may suggest a few policy implications. First, when a healthcare organization implements a new IT or a new mobile technology, the administration should train a few opinion leaders in different clinics to encourage them to implement the new technology first. Once those opinion leaders accept and implement the new technology into their work, their influence will be naturally and gradually spread out to the people around them. This is a practical and easier solution for an organization to leverage than to launch an organizational wide campaign to work with every physician or every employee to promote a new technology implementation because opinion leaders are a small fraction of the entire organization. Second, peer effects are statistically significant too, although it is not as large as opinion leader effects. Peer effects indicate that a physician working with general peer colleagues, even if there are no opinion leaders, is relatively more likely to adopt a new technology than physicians practicing solo, or alone. Third, physicians' clinical setting or the number of patient visits does not have a statistically significant impact on physicians' technology usage behavior.

This research has some limitations. First, we do not know if physicians learned about this new mobile technology from friends, families, or other physicians outside of their own clinics. They might but our model only catches the opinion leader effects and peer effects from the same clinic because of data limitation. However, since this technology is very clinical and work specific, we would not worry too much that physicians would discuss a work technology with family or friends which may disclose their patients' information. Second, we do not know whether the number of patient visits would be an accurate measure for each physician's work because some patient visit may take longer time and some patient visit may take shorter time per service. This may bring some bias to our model estimates. Third, the exact social structure of the health system, such as within and crossing groups' professional network, is not known. We simplified this community health system's social structure based on its characteristics. Future research can investigate these limitations by collecting more data on physicians' social networks and the real workload to improve the research on social influence on technology implementation.

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