Patient Preference and Adherence

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ORIGINAL RESEARCH

Factors determining patients' intentions to use point-of-care testing medical devices for self-monitoring: the case of international normalized ratio self-testing

This article was published in the following Dove Press journal:
Patient Preference and Adherence
27 December 2012

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Purpose: To identify factors that determine patients' intentions to use point-of-care medical devices, ie, portable coagulometer devices for self-testing of the international normalized ratio (INR) required for ongoing monitoring of blood-coagulation intensity among patients on long-term oral anticoagulation therapy with vitamin K antagonists, eg, warfarin.

Methods: A cross-sectional study that applied the technology-acceptance model through a self-completed questionnaire, which was administered to a convenience sample of 125 outpatients attending outpatient anticoagulation services at a district general hospital in London, UK. Data were analyzed using descriptive statistics, factor analyses, and structural equation modeling.

Results: The participants were mainly male (64%) and aged $\geq$ 71 years (60%). All these patients were attending the hospital outpatient anticoagulation clinic for INR testing; only two patients were currently using INR self-testing, 84% of patients had no knowledge about INR self-testing using a portable coagulometer device, and 96% of patients were never offered the option of the INR self-testing. A significant structural equation model explaining 79% of the variance in patients' intentions to use INR self-testing was observed. The significant predictors that directly affected patients' intention to use INR self-testing were the perception of technology ($\beta = 0.92$, $P < 0.001$), trust in doctor ($\beta = -0.24$, $P = 0.028$), and affordability ($\beta = 0.15$, $P = 0.016$). In addition, the perception of technology was significantly affected by trust in doctor ($\beta = 0.43$, $P = 0.002$), age ($\beta = -0.32$, $P < 0.001$), and affordability ($\beta = 0.23$, $P = 0.013$); thereby, the intention to use INR self-testing was indirectly affected by trust in doctor ($\beta = 0.40$), age ($\beta = -0.29$), and affordability ($\beta = 0.21$) via the perception of technology.

Conclusion: Patients' intentions to use portable coagulometers for INR self-testing are affected by patients' perceptions about the INR testing device, the cost of device, trust in doctors/clinicians, and the age of the patient, which need to be considered prior to any intervention involving INR self-testing by patients. Manufacturers should focus on increasing the affordability of INR testing devices for patients' self-testing and on the potential role of medical practitioners in supporting use of these medical devices as patients move from hospital to home testing.

Keywords: oral anticoagulation, INR self-testing, technology-acceptance model, trust in doctor, home testing, affordability, structural equation modeling

Introduction

Technology developments present increasing opportunities for health care monitoring to occur outside hospitals and clinics. However, in order to be successful, such initiatives have to be accepted by the potential patient population. Many conditions that could be self-monitored and managed remotely occur more frequently within the older population, who are typically less willing to adopt new technology.[1] This paper focuses on the example of self-testing of blood-coagulation intensity by patients taking oral anticoagulation therapy (OAT) with vitamin K antagonists (VKAs) such as warfarin (Coumadin). VKA therapy is indicated on a long-term basis in a number of medical conditions, such as stroke, deep vein thrombosis, pulmonary embolism, heart valve surgery, and atrial fibrillation.[2,3] The limited therapeutic index of warfarin requires regular measuring of the international normalized ratio (INR)[4] to avoid complications associated with either higher or lower blood-coagulation level.

Traditionally, the blood-coagulation level is tested at a hospital or clinic such as an anticoagulation clinic. However, it can now be tested outside of a traditional health care facility – when at home or on holiday, for example – using a portable and handheld medical device known as a "coagulometer." In the UK, regulatory bodies have approved different makes and models of coagulometer devices, which are now commercially available.[2,4] In some countries, such as the US, INR self-testing devices are covered by medical/health insurance for some medical conditions, such as heart-valve replacement, when recommended by the general physician/practitioner (GP).[5] In the UK, patients have to buy these devices themselves; however, the associated test strips can be obtained on prescription from a GP in the National Health Service (NHS).[6]

However, despite the widespread availability of portable coagulometer devices to facilitate INR self-testing,[4] positive health outcomes (such as reduction in bleeding episodes and risk of thrombosis due to INR self-testing[7]), and other advantages, eg, freedom from visiting hospital clinics on a regular basis, reduction in travel and associated costs, as well as time savings,[3] use of INR testing devices by patients at home remains relatively low,[4,5] with most patients continuing to attend traditional health care settings for regular monitoring of their INR levels.

In the UK, there are about 1 million patients taking OAT.[4] The exact number of self-testing patients is not known; however, there are anecdotal reports that the uptake of INR self-testing devices is not more than 1%. Patients' low uptake of these devices may be due to a number of factors. For example, the patient's clinical condition may render him/her not suitable for INR self-testing; hence, the GP will not recommend self-testing on clinical grounds. Alternatively, if patients do fit the criteria for home-based testing, it may be that high levels of trust in, and satisfaction with, INR testing through a clinic/hospital and the voluntary nature of adopting INR self-testing leads to the opportunity being declined.[8] Other barriers to acceptance of home INR testing may include the cost of coagulometer devices and associated test strips, a lack of awareness about INR self-testing, and a lack of confidence in the self-testing device.[3,9]

In addition, patients' limited physical and cognitive abilities, low manual dexterity, older age, literacy, and income, as well as negative attitudes towards the technology, which might include inconvenience, usability, design, and safety issues, can also prove to be barriers in the acceptance of the technology.[1,10,11] Moving the focus away from the individual patient, there is evidence of reluctance on the part of some clinicians/GPs for incorporating INR self-testing as part of the service they deliver due to a lack of resources.[12,13] There may also be limited ability to manage the increased initial workload involved in educating and preparing suitable patients for self-testing.[12,13] Despite all these limitations, health care providers are expected, and compelled by the present regulatory and financial situation, to encourage INR self-testing by suitable patients.[14] In this context, patients' attitudes towards the process of INR self-testing and the INR testing devices are also important factors in shaping the adoption of INR self-testing.[15]

The aim of this research was to study patients' intentions to use INR self-testing using portable coagulometer devices for determining blood-coagulation level. The objective was to identify factors determining patients' intentions to use portable coagulometer devices for INR self-testing. The analytical framework and the model tested in our study are described below.

Analytical framework

In studying patients' intentions to use point-of-care (POC) medical devices for INR self-testing, we applied the framework provided by the technology-acceptance model (TAM).[15–17] The TAM provides the opportunity to explore the factors affecting the individual's (user's) intention to use (IU) a technology/device.[15,16] These include the user's behavioral beliefs, ie, perceived usefulness (PU),[15,16,18] and perceived ease of use (PEOU);[15,16,18] user's characteristics, eg, age,[19] technological self-efficacy (TSE),[19] and ability to afford a device;[20] characteristics of technology, eg, device output quality (DOQ),[21,22] cost,[23] and perceived risk;[24] and external factors, eg, subjective norm/social influence (SN/SI),[23,25,26] and training and support.[24] In addition, "trust" is an important independent construct in the TAM,[25] and more broadly is an important factor in accepting/using health care technologies. In the field of medical care, trust can have different facets.

For example, patients' trust in doctors (TID)[27] could be interpersonal trust in doctors[28] or collective trust in health care provider institutions,[29] and either of these dimensions could affect a patient's willingness to accept medical advice and care.[30] In relation to medical devices, it is perhaps most relevant to frame the trust issue in terms of patients' confidence that the device output/results are accurate and reliable.[20,31]

The TAM has been widely used in different disciplines including health care,[31,32] where it has been mainly applied in relation to IT-related systems.[32] In addition, some constructs of the TAM have also been used in studying self-monitoring intentions of patients with diabetes mellitus, asthma, and chronic obstructive pulmonary disease.[33] However, thus far, TAM has had a limited application in studying patient acceptance or IU, particular POC testing (POCT) medical devices, such as portable coagulometers for INR self-testing. We chose to use the TAM due to its coverage of various dimensions that are relevant to the use of portable coagulometer devices for INR self-testing.

Our model

In line with the TAM, we used the IU for a technology, ie, INR self-testing device, as the outcome (dependent) variable.[15,16] Our hypothesized direct predictors of the IU were the PU and PEOU,[15–17] the "affordability" (cost of the device) and TID, and hypothesized indirect predictors of the IU were the SN/SI, DOQ, TSE,[19,23,25] age,[19] affordability, and TID.

Methods

Study design

This was a cross-sectional questionnaire survey of patients who attended outpatient anticoagulation services at a district hospital in the NHS for testing of their INR levels.

Settings

This survey was conducted at an outpatient anticoagulation clinic at an NHS district general hospital in Greater London. Patients' blood-coagulation levels are tested by drawing blood samples by venipuncture at the clinic, and the blood samples are analyzed at the central laboratory located at the same hospital. Patients get the test results by letter from the clinic, generally within 1 week of testing.

Patients' recruitment

Patients were accessed and recruited through the anticoagulation clinic during May–June 2010. Posters advertising the study were displayed in the clinic, and the clinic nurses invited all patients attending the clinic to this survey. The focus of the study was on patients who were unfamiliar with INR self-testing but were having their INR tested in the setting of a hospital clinic. Information was presented in the questionnaire about the procedure of INR self-testing using a handheld INR testing meter, the approximate cost of an INR meter to be purchased by the patient, and the availability of INR test strips on the NHS prescription.

In total, 350 patients were given a copy of the information sheet and survey questionnaire for self-completion. At the end of the study, 125 completed surveys were returned. No reminders were issued to the nonrespondents because the researchers had no access to their contact details for ethical reasons.

Ethics approval

Ethics approval for this study was obtained from the NHS London Research Ethics Committee (reference no 10/H0718/7, dated February 2, 2010), Research and Development Office, Hillingdon Hospital NHS Trust (dated March 13, 2010), and the Research Ethics Committee, Brunel University (dated March 12, 2010).

Survey questionnaire

A self-administered survey questionnaire was used to gather participants' demographic information, time since INR testing started, knowledge about INR self-testing by a portable INR testing device, suggestion of INR self-testing by the GP/doctor, and the use of an INR self-testing device at home (Table 1). In addition, the survey asked patients for ranking of 30 items representing seven constructs of TAM, ie, IU, PU, PEOU, SI/SN, DOQ, TSE, and TID, taken from the literature (Table 2). The cost of an INR testing monitor was measured with affordability as a single item (Table 2). Finally, one open-ended question asking participants for their comments was also included.

Response options of the attitudinal items were ranked on a 7-point Likert scale:[34] "strongly disagree" = 1, "moderately disagree" = 2, "slightly disagree" = 3, "neutral" = 4, "slightly agree" = 5, "moderately agree" = 6, and "strongly agree" = 7. The questionnaire was pilot-tested on seven patients who were similar with respect to the age, sex, and ethnic composition of patients taking OAT in the same locale. Following the pilot work, a few minor changes in wording and formatting were made prior to the main study.

Data analysis techniques

The data were manually entered on to the SPSS Predictive Analytics Software Statistics v 18 package (IBM Corporation, Armonk, NY). First, we determined the frequency statistics

Table 1 Participants' demographic characteristics and international normalized ratio (INR) testing

	Percent	Frequency
Sex		
Male	64	80
Female	33.6	42
Information not provided	2.4	3
Age		
18–25 years	0.8	1
26–40 years	1.6	2
41–55 years	9.6	12
56–70 years	27.2	34
71–80 years	40.8	51
Over 80 years	19.2	24
Information not provided	0.8	1
Highest education level		
Primary	6.4	8
Secondary	67.2	84
University degree	7.2	9
Postgraduate degree	4.8	6
Other†	12	15
Information not provided	2.4	3
Ethnic origin		
White British	84	105
Asian or Asian British	8	10
Black or Black British	2.4	3
Other‡	3.2	4
Information not provided	2.4	3
Time since INR tests started		
Less than 6 months	22.4	28
6–12 months	7.2	9
1–2 years	11.2	14
3–5 years	22.4	28
6–10 years	19.2	24
More than 10 years	16.8	21
Information not provided	0.8	1
Knowledge about INR self-testing using a handheld device		
Yes	14.4	18
No	84.0	105
Not sure	1.6	2
Suggestion of INR self-testing by GP/doctor as something beneficial		
Yes	3.2	4
No	96.0	120
Not sure	0.8	1
Use of INR self-testing device at home		
Yes, using it currently	1.6	2
Yes, but given up	0.8	1
Never used	89.6	112
Information not provided	8	10

Notes: †Technical, professional, and moderate school education; ‡Irish, Anglo-Indian, and Jewish.

of demographics and INR testing-related variables (Table 1) and the descriptive statistics of all items measuring different constructs of the TAM (Table 2). Then, scale reliabilities of TAM constructs, ie, IU, PU, PEOU, DOQ, SN/SI, TSE, and TID constructs were checked by determining Cronbach's alpha levels (Table 2), which were higher than the minimum required level of $\alpha = 0.70$, thus confirming an acceptable reliability of the constructs.[35] Thereafter, assumptions for multivariate data analyses such as the absence of multivariate outliers and the homogeneity of variance were checked and met before running inferential analyses.[36]

To identify latent dimensions, we performed an exploratory factor analysis (EFA) of measured TAM items (n = 26), excluding five items, ie, TID1 item, affordability item, and three items representing the IU construct. In the EFA, the number of extracted factors was based on Kaiser's Eigen values $>$ 1 (EVG1) criterion and breaks in the scree plot.[36] For EFA, we used the principal component analysis (PCA) as a factor-extraction method and the Varimax with Kaiser normalization as a rotation method.[21] Given our sample size of 125, we chose a higher level of minimum factor loading, ie, 0.50.[37] In addition, assumptions necessary for EFA such as the minimum participant-to-variable ratio (ie, 4:1) and minimum communalities $\geq$ 0.50 were applied.[36]

Given the limitation of the EVG1 and Scree plot criteria,[38] we conducted a parallel analysis (PA)[39] using the Monte Carlo PCA for Parallel Analysis software[40] (Ed and Psych Associates, State College, PA) for determining and retaining the number of factors in EFA.[41] Thus, all components with initial eigenvalues (EVG1 criteria) higher than the random eigenvalues obtained in PA are retained.[41] Comparing the eigenvalue results (Table 3) generated in the EFA on our data and the random eigenvalues generated under the PA (with data input: variables = 26, subjects = 125, and replications = 1000) revealed that we could only retain the first two factors in the EFA model for our data on the basis of eigenvalues being higher than those generated under the PA.[42]

Finally, using the SPSS Analysis of Moment Structures software for structural equation modeling (IBM Corporation), we performed confirmatory factor analysis (CFA)/structural equation modeling (SEM) to confirm/test our model (Figure 1). For the CFA/SEM, we employed the "maximum likelihood" estimation method for estimating the model fit. The measured items loaded on each factor served as indicator variables for the relevant latent factors. No bootstraps were used.

Results

Response rate, demographics, and INR testing

In this survey, the response rate was 36% (125 surveys were returned out of 350 distributed). Participants' demographic details (Table 1) revealed that the majority of participants was male (64%, n = 80), aged $>$ 70 years (60%, n = 75),

Table 2 Technology-acceptance model constructs and measured items with descriptive statistics

Construct (item code)	Item content	Mean values	Standard deviation	Construct reliability (Cronbach's α)	References
Intention to use (IU)				0.71	19,21,43,44
(IU1)*	Assuming that I have the chance, it is likely that I will use an INR handheld device at home	3.5	2.3		
(IU2)	Assuming that I have the chance, I intend to use an INR handheld device at home	4.5	2.2		
(IU3)	If I have the chance, I predict that I would use an INR handheld device at home	4.9	2.2		
Perceived usefulness (PU)				0.88	15,16,19,21
(PU1)	Using an INR device would enhance my effectiveness in managing my health care	4.5	1.9		
(PU2)	Using an INR device would help me to manage (control) my blood-coagulation levels	4.9	2.0		
(PU3)	Using an INR device would support critical aspects of my health care	4.7	1.8		
(PU4)	Overall, an INR device would be useful in managing my health care	5.0	1.8		
Perceived ease of use (PEOU)				0.94	15,16,19,21,44
(PEOU1)	Learning to use an INR device would be easy for me	5.0	2.0		
(PEOU2)	It would be clear and understandable to use an INR device	4.7	1.8		
(PEOU3)	I would find it easy to measure my blood coagulation using an INR device	4.8	1.9		
(PEOU4)	It would be easy for me to become skillful at using an INR device	5.1	1.9		
(PEOU5)	An INR device would be clear and easy to use	4.8	1.8		
Subjective norm (SN)/social influence (SI)				0.91	19,21
(SN/SI1)	The people who are important to me would think it was good to use an INR device at home	4.7	1.9		
(SN/SI2)	My family would be supportive of me using an INR device at home	5.0	1.8		
(SN/SI3)	My friends would think it was a good thing to do INR testing/use an INR device at home	4.7	1.8		
Output quality of device (DOQ)				0.84	21,22
(DOQ1)	Handheld INR devices give reliable results	4.4	1.4		
(DOQ2)	I believe that an INR device used at home would give accurate results	4.8	1.7		
(DOQ3)	Handheld INR devices give equivalent results to the tests conducted at hospital	4.5	1.4		
Technological self-efficacy (TSE)				0.91	17,21,45
(TSE1)	I would be able to check in the manual if something in the INR-testing procedure was unclear	5.2	1.9		
(TSE2)	I am confident that I could learn to do INR self-testing at home	5.4	2.0		
(TSE3)	I would be able to manage to test my blood coagulation myself with the INR device	4.9	2.0		
(TSE4)	Among my peers I am usually one of the first to try out new technologies	4.0	1.8		
(TSE5)	In general, I am not hesitant to try out new technology	4.2	2.0		
(TSE6)	I like to keep abreast of new technology	5.0	1.6		
(TSE7)	I like to experiment with new technologies	4.5	1.8		
Trust in doctor (TID)				0.75	23,25,46–48
(TID1)*	I know that my doctors act in my best interests	6.0	1.6		
(TID2)	My doctor is knowledgeable about INR testing at home	4.1	1.4		
(TID3)	My doctor is the best person to give me advice about the best way of testing my INR	5.2	1.8		
(TID4)	I would follow my doctor's recommendation if s/he suggested that I should use a self-testing INR device at home	5.3	1.9		
(TID5)	My doctor is committed to my well-being	6.1	1.4		
Cost of device					
(Affordability)	Self-testing INR devices are affordable	3.3	1.8		

Notes: Rating scale: 1 = strongly disagree, 2 = moderately disagree, 3 = slightly disagree, 4 = neutral, 5 = slightly agree, 6 = moderately agree, 7 = strongly agree. *Excluded from inferential statistical analysis (scale reliability statistics suggested exclusion of IU1 item will increase Cronbach's α of IU construct from 0.71 to 0.95, and TID1 item failed to meet requirements of homogeneity of variance).
Abbreviation: INR, international normalized ratio.

Table 3 Initial (actual) eigenvalues generated in EFA and random eigenvalues generated in PA

Component/ factor no	Initial eigenvalues (EFA)	Random eigenvalue (PA)	Decision
1	14.691	1.9566	Accepted/retained
2	2.252	1.7980	Accepted/retained
3	1.347	1.6775	Rejected
4	1.167	1.5784	Rejected
5	0.934	1.4869	
6	0.797	1.4077	

Abbreviations: EFA, exploratory factor analysis; PA, parallel analysis.

and white British (84%, n = 105). Eighty-four patients (67.2%) reported secondary school as the highest education level. Eighty-four percent (n = 105) patients had not heard about INR self-testing by a handheld device before this survey, 96% (n = 120) had not been recommended for INR self-testing by their GP/family doctor, and 89.6% (n = 112) reported that they had never used an INR testing device at home (Table 1).

Descriptive statistics of TAM items/constructs

Results of descriptive statistics of measured TAM items along with their respective constructs are shown in Table 2. The mean rankings of all measured items were ≥4 except the IU1 item (assuming that I have the chance, it is likely that I will use an INR handheld device at home) and affordability item (self-testing INR devices are affordable), which had mean rankings of 3.5 (±2.3) and 3.3 (±1.8), respectively (Table 2).

Analysis of initial scale reliabilities revealed that Cronbach's alpha reliabilities of PU, PEOU, SN/SI, and DOQ constructs were 0.88, 0.94, 0.91, and 0.84, respectively (Table 2).

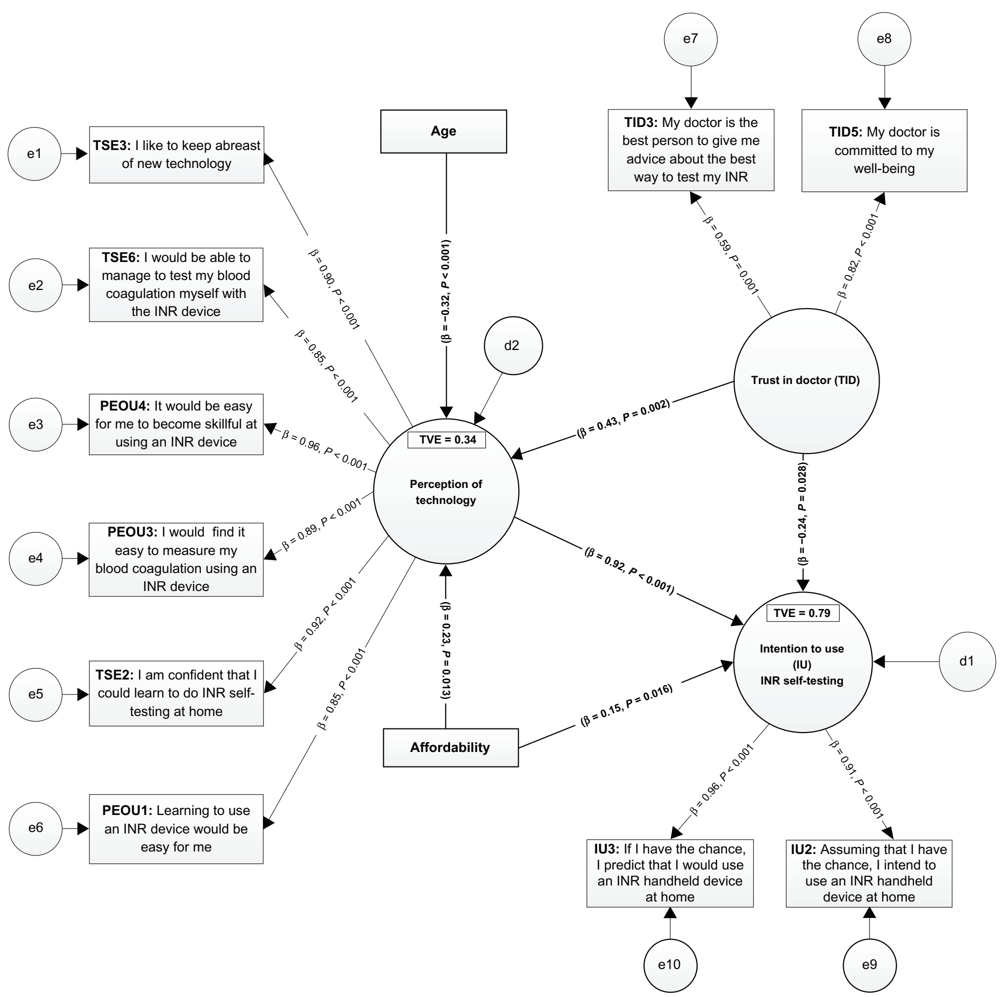

Figure 1 Confirmatory factor analysis (measurement model) and structural equation model of patients' intentions to use international normalized ratio (INR) self-testing.
Notes: Rectangles represent measured items (endogenous variables); circles represent latent (unmeasured/exogenous) variables.
Abbreviations: d, disturbance; e, error; PEOU, perceived ease of use; TSE, technological self-efficacy; TVE, total variance extracted.

The item-total statistics showed that α reliability of these constructs would not improve with deletion/exclusion of any of the measured items included in each of these constructs. However, item-total statistics revealed that deletion of the IU1 item would improve α reliability of the IU construct from 0.71 to 0.95, deletion of TID4 would increase α reliability of the TID construct from 0.75 to 0.77, and deletion of TSE5 would enhance α reliability of the TSE construct from 0.91 to 0.94. In addition, TID1 failed to meet the requirements of test of homogeneity of variance (Levene's statistics based on mean = 7.559, $P = 0.007$). Therefore, two items – IU1 and TID1 – were excluded from further inferential statistical analyses.

Exploratory factor analysis of TAM items

Results of the EFA revealed Kaiser–Meyer–Olkin measure of sampling adequacy of 0.914 and Bartlett's test of sphericity with approximate Chi-square = 747.468 (degrees of freedom = 28, $P < 0.001$), which confirmed that the data were suitable for EFA.[36] The first run of the EFA showed a four-factor model; this was compared to the PA results for determining the number of latent factors to be retained. The comparison of results of Eigen values observed in EFA and PA suggested that we could retain only two factors (Table 3). Items that had cross-loadings with coefficient values > 0.35 on more than one factor were also excluded. In the final EFA model, communalities extracted were between 0.70 (for TID5) and 0.92 (for PEOU4). Based on Kaiser's criterion of EVG1, three rotations led to identification of a statistically significant model with two latent factors, which extracted 82.2% of total variance in the model. The rotated component matrix (Table 4) showed that six measured items were loaded on factor 1. These included three items – PEOU1, PEOU3, and PEOU4 – representing the PEOU construct and three items – TSE2, TSE3, and TSE6 – representing the TSE construct. Based on the nature of the loaded items, we named factor 1 the "perception of technology." Factor 1 explained 62.7% of the extracted variance in the model (Table 4). The rotated component matrix also revealed that factor 2 was loaded with two items, TID3 and TID5, which was deemed to represent the construct of TID. Factor 2 contributed in extraction of 19.4% of the variance in the model (Table 4).

Results of EFA also revealed that all measured items retained in the final model had communalities ≥ 0.70 and their loadings on the main factor were ≥0.77, while their-cross loadings on the other factor were ≤0.30. Cronbach's alpha coefficients for both latent factors were determined (Table 4).

Confirmatory factor analysis/structural equation modeling of TAM items

Results of the CFA, also known as the measurement model, and the SEM confirmed a statistically significant model (Figure 1). The goodness-of-fit measures obtained for the model were within the recommended limits, which revealed a good fit of the model with the given data (Table 5).

Results of standardized regression weights/loadings (β) of measured variables and latent constructs are shown in Figure 1. The results of standardized loadings revealed that the major determinant of patients' IU for INR self-testing was perception of technology ($\beta = 0.92$, $P < 0.001$). In addition, TID had a significant but negative effect ($\beta = -0.24$, $P = 0.028$), and affordability had a significant and positive effect ($\beta = 0.15$, $P = 0.016$) on patients' IU for INR

Table 4 Exploratory factor analysis showing factors with loadings, communalities (h^2), variance extracted, and scale reliability of latent factors of patients' acceptance of international normalized ratio (INR) self-testing device

Item code – content	Loadings		Communalities
	Factor 1	Factor 2	h^2
PEOU1 – Learning to use an INR device would be easy for me	0.936	0.214	0.811
PEOU4 – It would be easy for me to become skillful at using an INR device	0.933	0.057	0.874
TSE2 – I am confident that I could learn to do INR self-testing at home	0.920	0.187	0.922
PEOU3 – I would find it easy to measure my blood coagulation using an INR device	0.914	0.146	0.881
TSE3 – I would be able to manage to test my blood coagulation myself with the INR device	0.898	0.075	0.857
TSE6 – I like to keep abreast of new technology	0.830	0.243	0.747
TID3 – My doctor is the best person to give me advice about the best way of testing my INR	0.002	0.882	0.779
TID5 – My doctor is committed to my well-being	0.308	0.779	0.702
Eigenvalues	5.322	1.251	
Average variance explained (%)	62.72	19.44	
Cronbach's α reliability	0.96	0.59	

Notes: Extraction method, principal component analysis; rotation method, varimax with Kaiser normalization; rotation converged in three iterations.
Abbreviations: PEOU, perceived ease of use; TID, trust in doctor; TSE, technological self-efficacy.

Table 5 Goodness-of-fit indices observed in the confirmatory factor analysis and structural equation model

	χ^2	Df	Sig (*P*)	χ^2/df	GFI	RMSEA	NFI	CFI	AGFI	Reference
Recommended values			>0.05	≤ 3.00	≥ 0.9	≤ 0.08	≥ 0.9	≥ 0.9	≥ 0.9	48
Observed values in this model	58.453	50	0.193	1.169	0.903	0.043	0.941	0.991	0.849	

Abbreviations: AGFI, adjusted goodness-of-fit index; CFI, comparative fit index; Df, degrees of freedom; GFI, goodness-of-fit index; NFI, normated fit index; RMSEA, root mean square error of approximation; Sig, significance level (*P*).

self-testing (Figure 1). Moreover, results showed an indirect effect of TID ($\beta = 0.40$), age ($\beta = -0.29$) and affordability ($\beta = 0.21$) on IU for INR self-testing through the perception of technology. Overall, the model showed that all the aforementioned predictors explained 79% of the variance in the IU for INR self-testing (Figure 1).

Results also showed that perception of technology was significantly and positively affected by TID ($\beta = 0.43$, $P = 0.002$) and affordability ($\beta = 0.23$, $P = 0.013$), as well as significantly but negatively affected by age of the patient ($\beta = -0.32$, $P < 0.001$). All these three variables explained 34% of the variance in the perception of technology construct (Figure 1).

Construct (composite) reliabilities (CR) and average variance extracted (AVE) for latent factors used in the CFA/SEM model were also calculated.[37] Results revealed that the perception of technology had CR = 0.96 and AVE = 80.43%, TID had CR = 0.67 and AVE = 70.55%, and IU for INR self-testing had CR = 0.93 and AVE = 93.4%. These values of CR and AVE revealed adequate internal reliabilities and convergent reliabilities of these factors/constructs.

Patients' free comments on INR self-testing and related issues (qualitative data)

Forty-one (32.8%) patients provided open-ended comments in relation to INR self-testing. The main issues highlighted in these comments (Table S1) were regarding INR self-testing in general, eg, "Home testing INR is a good idea" and "I never knew you could do this [INR testing] at home. I think information should be available at the clinic" (Table S1, section A); INR testing device cost, eg, "Will patients have to buy their own device? Sensible idea, pity about the costs" and "I would not mind buying a machine if they were less expensive" (Table S1, section B); access and use, eg, "Have no experience of home devices […] tell us more" (Table S1, section C); hospital outpatient anticoagulation services, eg, "Hospital provides good service" and "Although sometimes awkward to attend clinic, but does keep you in touch with health matters, general gossip and a reason to get out and exercise" (Table S1, section D); outpatient anticoagulation clinic staff, eg, "Visiting the clinic is a very interesting experience with all staff making you welcome … reassuring at all times … answering any questions … all staff have time to explain even small requests … something handheld device cannot do" (Table S1, section E); patients' comorbidities, eg, "I have diabetes, a DVT [deep vein thrombosis], a bad back, and wobbly left hand and had triple bypass … so not pleasant to spend a morning and walk down to the clinic" (Table S1, section F); and limitations and illnesses, eg, "INR device … unsuitable for me as I am 90 years, and visually impaired" (Table S1, section F).

Discussion

Self-testing of INR is suggested only to those patients who fulfill self-testing criteria recommended by professional bodies.[49,50] Results of our study have revealed that only a small minority, ie, three patients in this sample, were suggested INR self-testing by their GPs, and two of those patients were currently self-testing their INR. This finding is in line with previous literature that suggested that the number of INR self-testers is very low, although of course the strong representation of older people in the sample may go some way to explain this.

Our findings regarding the demographic characteristics (Table 1) and comorbidities (Table S1, section F) among outpatients attending hospital outpatient anticoagulation services have revealed these patients are mostly older people with multiple illnesses, such as DVT and pulmonary emboli, requiring VKAs on a long-term basis, which is in agreement with other studies.[2,3] The majority of participants were not familiar with INR self-testing devices, and they had been visiting hospital anticoagulation services for their INR testing for at least several months (Table 1). These patients' responses vis-à-vis performing INR self-testing must therefore be considered in the context of their experience of INR testing in hospital outpatient settings.

The comments that participants provided suggest that some patients may not have been considered suitable for INR self-testing due to multiple illnesses and severe physical limitations and impairments (Table S1, sections F and G). Nevertheless, some participants were interested in INR self-testing (Table S1, section A). Apart from the nature of comorbidities and impairments (Table S1, sections F and G), the main barriers for INR self-testing by these patients included the cost of an INR testing meter that was adjudged unaffordable (Table S1, section B). It seemed that satisfaction with the hospital anticoagulation services and clinic staff (Table S1, sections D and E) who provided reassurance (Table S1, section E) and a human touch (Table S1, section C) also rendered INR self-testing at home as a less attractive option.

Turning to the analysis of the quantitative data, our findings of a statistically significant structural equation model of patients' IU for INR self-testing revealed that apart from patients' perception of technology (ie, INR self-testing device), patients' TID, affordability, and age significantly affected (determined 79% variance) participants' intentions to use INR self-testing. The main findings vis-à-vis our model and the main factors affecting INR self-testing are discussed below.

INR self-testing and the TAM

In the present study, we have identified factors that significantly contribute to predictions of patients' IU for INR self-testing. This has been done within the frame provided by the TAM, previously applied for studying acceptance of a range of technologies.[31] The present study is the first, to our knowledge, that has sought to study the TAM with respect to patients' acceptance of portable INR-testing devices.

It is notable that our survey did not obtain the generally expected structure of the TAM. We can surmise that there are at least two possible reasons for this. First, although some of the survey participants knew about coagulometer devices in principle, the fact that, by definition, the majority had no day-to-day experience in practice of them, we would argue, is less likely to enable a clear differentiation and result in significant relationships between TAM constructs.[51] Secondly, it is quite possible that the applicability of the TAM is limited in relation to acceptance of medical devices, especially for self-testing by patients, and especially the older people with chronic diseases. Previous work in the area of the TAM, even within health care, has, as outlined earlier, focused on information technologies. Further work to clarify this and thus to explore further the potential of the TAM around acceptance of self-testing medical devices is required.

However, our study identified two constructs, ie, perception of technology and TID, that significantly contributed to our model of acceptance of portable INR testing devices, which was operationalized as IU for INR self-testing. In addition, we have identified that affordability has a significant relationship with IU for INR self-testing. We discuss these findings below by focusing on the constructs and variables that comprised our model (Figure 1).

Perception of technology

In our survey, perception of technology emerged as an important factor, which included six items that measured two things: (1) PEOU and (2) TSE of the respondent (user). PEOU is one of the core constructs in the TAM and it measures participants' attitudinal beliefs about the technology, while the TSE of the respondent (user) contributes in the PEOU construct.[17,18] However, in our data, it was not possible to separate PEOU and TSE, and they loaded on one factor. In addition, there was no role for the PU factor, which is usually an important construct in the TAM.[15–17] The reason for this is unclear. It may be the case that patients could not envisage the usefulness of INR self-testing possibly due to a general satisfaction with hospital-based testing, or they may have been reluctant to report a PU in case this was seen as an indication of their interest in self-testing.

We found that perception of technology is the main determinant of these patients' IU for INR self-testing. Unsurprisingly, our results show that IU for a self-testing device is higher when there is a higher and positive perception about the device. In addition, our results also revealed that the effect of perception of technology on the IU for INR self-testing had indirect contributions from TID, affordability, and age. Contributions of these factors both indirectly via the perception of technology and directly on the IU for INR self-testing are discussed below.

Trust in doctor

Our results show that TID has both a direct and an indirect effect on patients' IU for INR self-testing. The direct effect of TID on IU for INR self-testing was significantly negative, that is, that those with high levels of trust in their doctor had less intention to conduct self-testing. One reason for the negative effect of TID on these patients' IU for INR self-testing could be a reflection of their satisfaction with the current practice of their INR testing by a health care professional at outpatient anticoagulation clinics, and the nature of some of the comments made by patients (Table S1, sections D and E) gives credence to this possibility. In hospital outpatient clinic-based INR testing, there are opportunities for the patients to meet and discuss issues related to their illness and INR levels with the clinic staff (Table S1, point E.2), as well as exchange experiences and socialize with other patients (Table S1, point D.5) with similar health concerns.[52] Thus, high TID may be strongly anchored in the experience of hospital testing and the benefits this is perceived to bring. TID may thus not be transferred into the imagined experience of home testing, plus of course we know that home testing had not been recommended by the GP for these patients. The other influencing factor in this regard is respondents' age, as the majority of patients in our study were aged 71 years or more, which has a negative effect on the acceptance of technology in general.[10] It would be interesting to investigate acceptance of the scenario of home-based INR testing carried out by a health care professional, eg, a nurse, using a portable INR-testing device, representing as it does the continued involvement of health care professionals but within the context of the home.

We also found that TID has a significant and positive effect on perception of technology, which was positively related to IU for INR self-testing. This could be indicative of two alternative "routes" with which patients are faced, which may be more or less salient at any single point in time. On the one hand, where patients are largely satisfied with their doctor and trust the provision of outpatient anticoagulation services that the doctor has commended, this trust will thus be linked to a rejection of the suggestion of alternative INR-testing provision (eg, via self-testing). On the other hand, it may be the case that where the trusted doctor's communication focuses on or perhaps triggers a positive perception of the self-testing device (eg, positive perception of technology), under these circumstances there is greater IU for the device.

These findings therefore might suggest that doctors can play a pivotal role in the adoption of POCT medical devices for INR self-testing and that there is value in particularly encouraging a positive perception of self-testing medical devices for certain types of patients, such as the older patients with chronic and multiple illnesses. Doctors have an integral role in recommending use of POCT medical devices for INR self-testing, and this finding is important for medical device manufacturers that might see little or no role for clinicians in their push for home-use medical devices and therefore focus their marketing efforts on patients or their caregivers.

Affordability

When we explored the relationship between affordability and IU for INR self-testing, our results showed that affordability had a direct and significantly positive effect: the more affordable it was seen to be, the greater the intention to conduct self-testing. There was also an indirect effect on intention ($\beta = 0.21$) via perception of technology. The findings suggest that affordability is an important factor for patients with regard to INR meters for self-testing.

The open-ended comments of patients showed that these patients saw the cost of an INR-testing device as a barrier in their INR self-testing, and the device cost was seen as too high and beyond their means (Table S1, section B). This was also reflected in the low mean rating for the affordability item (Table 2). The cost of coagulometer devices and test strips, unless covered by the insurance or health care provider, is likely to be a decisive factor in INR self-testing by some types of patients, such as those who are unemployed, on low incomes, and retired people. Consequently, adoption of INR self-testing is low in health care systems such as the NHS, where the cost of the device is not reimbursed and the patients have to bear the cost. In such situations, about half of the eligible patients might decline to perform INR self-testing due to cost.[53] In contrast, acceptance of INR self-testing is higher in health care systems in countries such as Germany, where the cost of the device and test strips is fully reimbursed.[53] In addition, INR self-testing is reported to be more expensive than conventional hospital/clinic-based INR testing,[54] which is mainly due to high costs of portable INR-testing devices and test strips.[3,4,49] Therefore, the cost of testing equipment could be one of the major barriers in the wider adoption of INR self-testing.[9] Arguably, while technologies are not considered as affordable, there is little engagement with their potential benefits, and this in turn affects IU. The manufacturers of portable coagulometer devices, and health care providers recommending the use of these devices, should take note of the affordability/high cost of the devices and related materials such as test strips.

Age

Our findings show that the age of the patient has a significant but negative effect on the perception of technology and through that age has an indirect and negative effect ($\beta = -0.29$) on IU for INR self-testing: younger patients have more positive perceptions about self-testing medical technology. This finding is in agreement with previous literature, which suggests that technology acceptance is lower in older people compared to younger people.[1,10] Therefore, our findings suggest that younger patients are more likely to accept self-testing medical devices such as portable coagulometer devices for INR self-testing.

Overall, our results have shown that perception of technology, TID, affordability, and age are important factors that have a significant effect on patients' IU for INR self-testing using portable coagulometer devices. Our results have also shown limitations of the TAM in its present format to predict patient's IU for POCT medical devices for INR self-testing.

Study limitations

We recognize the limitations of the study. First, the sample size is relatively small, although as noted earlier it was large enough to allow the legitimate use of multivariate analysis techniques. Second, the response rate achieved (about 36%) was relatively low; however, this is in line with other studies involving older patients with chronic illnesses.[55] Third, participants were from only one NHS primary care trust, and they used anticoagulation services at the same district general hospital. Fourth, only three participants in our sample had any experience of INR self-testing, and the findings of this study must be interpreted recognizing that participants were responding in the light of the information they were provided about INR self-testing and against the backdrop of their own experiences of INR testing within the context of the hospital where the test was administered by health professionals. Care should be taken in generalizing the results of this study to other types of home-use medical devices. The results are most applicable when considering the use of self-testing for those patients who already have their INR monitored within the hospital context.

Despite the aforementioned limitations, this is the first study that has applied the TAM in studying patients' IU for portable coagulometer devices for INR self-testing. However, our findings should be interpreted with caution, as stated earlier, and we suggest further research to confirm or reject the model that has emerged in our study.

Conclusion

Factors affecting patients' IU for portable medical devices for INR self-testing (home testing) are different from the factors that affect acceptance of other technologies. Important determinants of patients' IU for INR self-testing include patients' perceptions about the INR-testing devices, the cost of these devices, TID, and the age of the patient. Health care service providers and medical device manufacturers need to consider the importance and contributions of these factors in patients' adoption of INR self-testing, especially by patients previously tested in the hospital context.

Author contributions

All authors were involved in planning and conducting this study. SGSS compiled and analyzed the data and drafted the manuscript. JB, JK, KH, and RK reviewed the manuscript for important intellectual content and input. All authors approved the final version of the manuscript submitted for publication.

Acknowledgments

The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) program (EPSRC grant EP/GO12393/1) funded this work, although the views expressed are entirely those of the authors. The authors wish to thank patients for taking part in this survey, as well as the outpatient anticoagulation services staff, especially Ms Carly McMullen for help and cooperation in conducting this study.

Disclosure

The authors report no conflicts of interest in this work.

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Supplementary material

Table S1 Qualitative data: patients' comments on international normalized ratio (INR) testing

A. INR self-testing
A.1 "Home-testing INR is a good idea."
A.2 "I would love […] to test my own blood."
A.3 "I have been attending appointments for 6 months taking blood tests […] I would like to […] do my own blood tests at home […] I feel I have been left by the hospital services to just get on with it and have had no advice or help."
A.4 "I would like home-testing as driving and parking is getting more and more difficult and expensive!!"
A.5 "I never knew you could do this [INR testing] at home. I think information should be available at the clinic."
A.6 "Performed INR self-testing but given up." [No reasons reported.]
A.7 "I would really like to try this. I am a nurse […] I will be on warfarin for the rest of my life due to recurrent PEs [pulmonary emboli] and DVTs [deep vein thromboses]."

B. INR-testing device cost
B.1 "Will patients have to buy their own device? Sensible idea, pity about the costs."
B.2 "I would not mind buying a machine if they were less expensive."
B.3 "The price is a deterrent."
B.4 "I know nothing about the INR device […] certainly could not afford £ […] for one."
B.5 "As a diabetic, I test [blood sugar level] regularly […] these tests are about 10% of the cost quoted for an INR meter."
B.6 "INR testing device is not affordable at the current price."
B.7 "[The device] price would deter me."

C. INR-testing device access/use
C.1 "Have no experience of home devices […] tell us more."
C.2 "I spoke to the nurse about this but received no encouragement."
C.3 "How would you obtain advice regarding warfarin dosage if the INR was [slightly] different from last test?"
C.4 "I prefer the human touch to some inanimate object that I may not even know is accurate!"
C.5 "Not having INR testing machine on [NHS] prescription."
C.6 "I have never seen the [INR] device."
C.7 "I would not be happy carrying out my own INR."
C.8 "I would panic if bleeding occurred while I did INR testing."
C.9 "I purchased my own [INR testing] monitor. Good but not always true to hospital results. Both work well but confidence not wholly in the machine results."

D. Hospital anticoagulation services
D.1 "Visiting hospital every month was not a problem."
D.2 "Hospital provides good service."
D.3 "Occasionally have to phone [clinic] for results."
D.4 "Trips to […] hospital are very taxing."
D.5 "Although sometimes awkward to attend clinic but does keep you in touch with health matters, general gossip and a reason to get out and exercise."

E. Anticoagulation clinic staff
E.1 "The staff there were excellent."
E.2 "Visiting the clinic is a very interesting experience with all staff making you welcome […] reassuring at all times […] answering any questions […] all staff have time to explain even small requests […] something handheld device cannot do."
E.3 "I cannot see that a home tester would relieve my concern and I would have to check with doctor or hospital every month."
E.4 "The team at […] hospital are great. I look forward to my visits about once a month. They are very efficient and treat you like people."

F. Patient illness and comorbidities
F.1 "I have diabetes, a DVT, a bad back, and wobbly left hand and had triple bypass […] so not pleasant to spend a morning and walk down to the clinic."
F.2 "I have muscular degeneration […] I have stopped taking my blood samples with the diabetic device."
F.3 "I will be on warfarin for the rest of my life due to recurrent PEs and DVTs."

G. Patient limitations
G.1 "INR device […] unsuitable for me as I am 90 years, and visually impaired."
G.2 "I have had stroke and have use of one hand only […] I have home visits."
G.3 "I have serious heart disease."
G.4 "INR testing for rest of life. I am blind, hence GP has not suggested me for INR self-testing."