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A Wireless Health Outcomes Monitoring System (WHOMS): development and field testing with cancer patients using mobile phones

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Abstract

Background: Health-Related Quality of Life assessment is widely used in clinical research, but rarely in clinical practice. Barriers including practical difficulties administering printed questionnaires have limited their use. Telehealth technology could reduce these barriers and encourage better doctor-patient interaction regarding patient symptoms and quality-of-life monitoring. The aim of this study was to develop a new system for transmitting patients' self-reported outcomes using mobile phones or the internet, and to test whether patients can and will use the system via a mobile phone.

Methods: We have developed a prototype of a Wireless Health Outcomes Monitoring System, which allows structured questionnaires to be sent to the patient by their medical management team. The patients' answers are directly sent to an authorised website immediately accessible by the medical team, and are displayed in a graphic format that highlights the patient's state of health. In the present study, 97 cancer inpatients were asked to complete a ten-item questionnaire. The questionnaire was delivered by display on a mobile phone, and was answered by the patients using the mobile phone keypad.

Results: Of the 97 patients, 56 (58%) attempted the questionnaire, and all of these 56 completed it. Only 6% of the total number of questions were left unanswered by patients. Forty-one (42%) patients refused to participate, mostly due to their lack of familiarity with mobile phone use. Compared with those who completed the questionnaire, patients who refused to participate were older, had fewer years of education and were less familiar with new communications technology (mobile phone calls, mobile phone SMS, internet, email).

Conclusion: More than half of the patients self-completed the questionnaire using the mobile phone. This proportion may increase with the use of multichannel communications which can be incorporated into the system. The proportion may also increase if the patient's partner and/or family were able to assist the patient with using the technology. These preliminary results encourage further studies to identify specific diseases or circumstances where this system could be useful in patients' distance monitoring. Such a system is likely to detect patient suffering earlier, and to activate a well-timed intervention.

Background

Health-Related Quality of Life (HRQOL) measures simultaneously capture both past and current concepts of health. In 1948 the World Health Organisation identified health as "a state of complete physical, mental, and social well-being – not merely the absence of disease or infirmity" [1].

HRQOL measures can potentially aid routine clinical practice in the following eight ways: 1. prioritising problems; 2. facilitating communication; 3. screening for potential problems; 4. identifying preferences; 5. monitoring change or response to treatment; 6. training new staff; 7. clinical auditing; and 8. clinical governance [2].

HRQOL assessment is widely used in clinical research, yet rarely in clinical practice [3]. It appears barriers include lack of knowledge surrounding questionnaires, methods and terminology, and too little attention to subjective information [4,5]. Evaluation is generally carried out by giving patients printed questionnaires, which have proven difficult to administer in daily clinical practice.

Quality of life instruments

Over a thousand generic or specific questionnaires are used world-wide for HRQOL assessment of people with chronic diseases [6]. Other questionnaires have been developed to evaluate needs, satisfaction or treatment compliance. In the majority of cases the questionnaires are 'self-reported' and contain a list of questions (from 10 to over 100) requiring structured responses chosen by the patient between 4/7 possible options using a Likert scale (e.g. from "not at all" to "very much so").

Questionnaires are developed using a procedure that must demonstrate their psychometric properties, which include validity, reliability, responsiveness and interpretability. Questions usually refer to the physical, psychological, and social domains of health, and ask patients to recall their experiences during a fixed time frame, generally a week. A new generation of succinct instruments has proven to be potentially useful in clinical practice. Some of these have been developed for patients suffering from ageing [7], chronic respiratory diseases such as asthma [8], chronic obstructive pulmonary disease (COPD) [9], neurological diseases such as stroke [10] or headache [11], rheumatological diseases such as osteoporosis [12], nutritional and metabolic diseases such as obesity and weight loss [13], cardiovascular diseases such as arterial hypertension [14] and neoplastic diseases such as prostate cancer [15] or cancer in advanced or terminal phases [16,17], to cite but a few.

Quality of life monitoring

It has been observed that health care providers tend to underestimate the functional status and intensity of some physical symptoms like pain, and overestimate patients' feelings of anxiety, depression and distress [18-22]. The consequence of such errors in evaluation is inadequate treatment [23,24].

It is usually difficult for medical staff to obtain up-to-date information when patients return home. HRQOL monitoring by means of a questionnaire completed by the patient may assist in determining the problems of the patient to the same degree as standard biological assessments. This may provide an easy way to monitor a patient and prevent major problems developing. The function of a questionnaire could be considered similar to that of a thermometer, which detects fever without revealing its cause, leaving it to the physician to determine the nature of the problem. Such monitoring should not be considered as a bureaucratic tool or a way to reduce communication with the patient, but as a way to detect patient suffering earlier, and to activate a well-timed intervention.

New communication technologies can be used to reduce certain barriers, thereby encouraging better doctor-patient interactions through periodical monitoring of health status and physical symptoms in particular. The wide and growing use of mobile phones and the internet by the general population provides important new methods for communication between doctor and patient. The aim of the present study was to develop a new system for transmission of patients' reported outcomes using mobile phones or internet and to test the acceptability and the ability of patients using this system through mobile phones.

Methods

Development of the system

A Wireless Health Outcomes Monitoring System (WHOMS) prototype was designed and developed in order to satisfy two main objectives:

1. To allow patients to receive and self-report structured questionnaires via either WAP [25,26] or the Web [27];

2. To allow the physician to examine data reported on questionnaires through a graphical and chromatic interface.

These objectives can be met in the following ways (Figure 1):

• (Scenario 1) Periodical sending of questionnaires to patients with mobile handsets. The questionnaire shipment uses a WAP/GPRS connection to send a "WAP Push

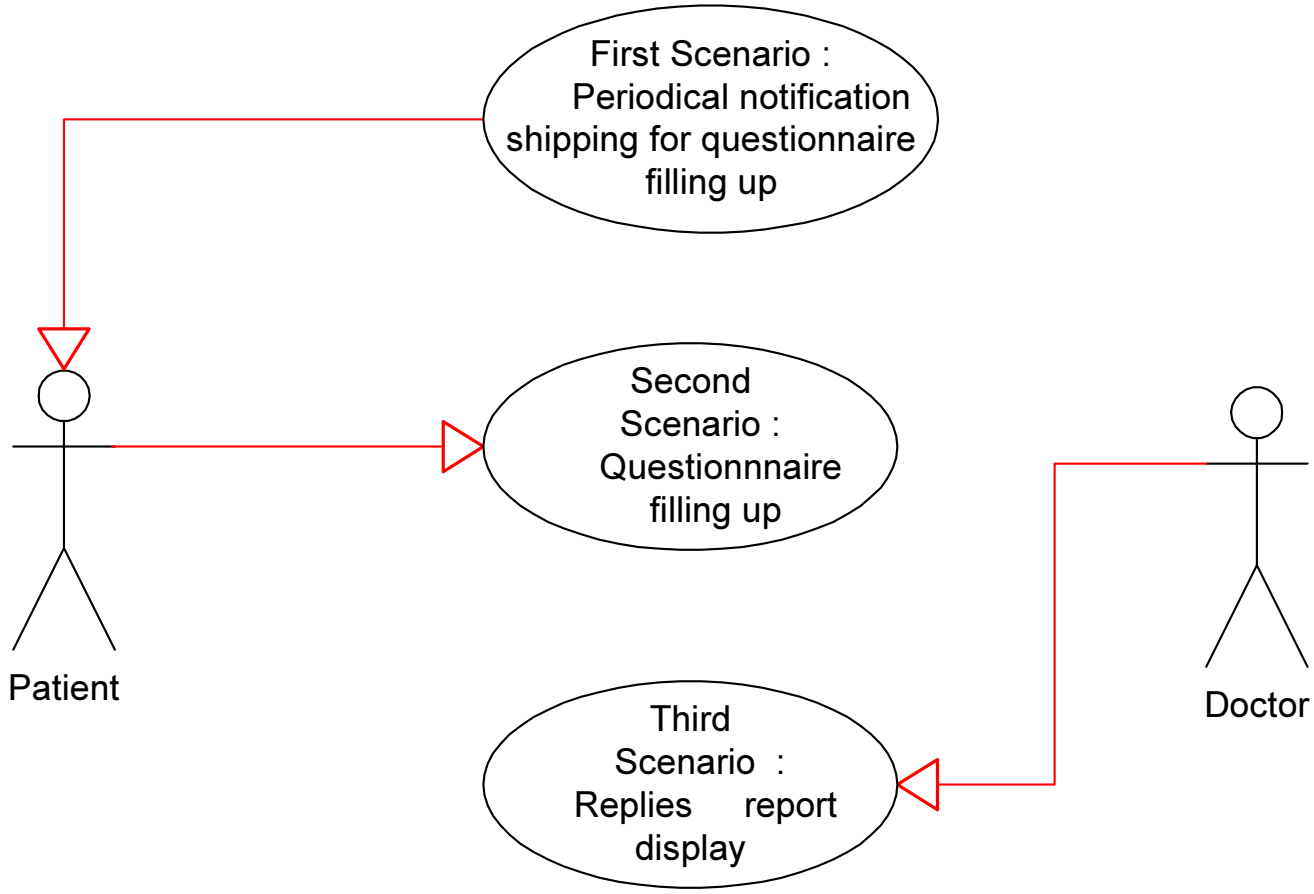

Figure 1
Scenarios representation.

Service Indication" message to the patient's mobile phone. The patient can see the questionnaire on the phone display via the GPRS connection.

• (Scenario 2) Questionnaire (10 symptoms questions in the prototype) completed by the patient. Using their mobile phone, the patient completes the questionnaire following the directions presented on the display. Questions are displayed one at a time and a set of answers is presented in a menu (Figure 2). The patient chooses the most appropriate answer according to their symptoms. Alternatively, for patients who prefer to use personal computers, a reserved online area can be accessed, where questionnaires can be compiled or overall reports containing previous answers can be displayed (note this internet option for patients was not trialled in the present study).

• (Scenario 3) Answer management. Using a reserved online area, the physician can examine patient's symptoms according to their questionnaire answers. The graphical and chromatic representation allows the doctor a quick and clear vision of how the patient's symptoms are evolving. A light flashes by the names of those patients that present seriously modified symptoms, so that the physician can identify the most significant changes at once and immediately take the necessary action. The parameters that determine the type of change that will cause a flashing signal can be customised by the physician and are specific for each questionnaire (Figures 3 and 4).

Functional architecture

The functional requirements have been translated into a system architecture made up of the following modules (Figure 5):

Identification system: this component manages accounts, profiles assigned to system users and related identification. Once identified, the user is authenticated

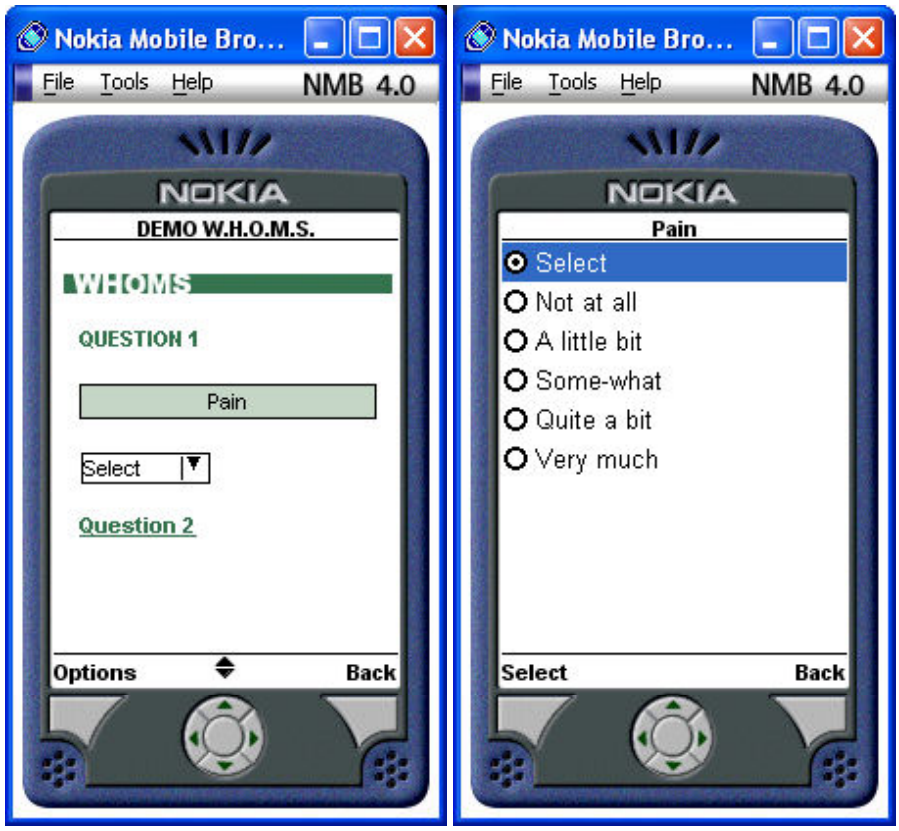

Figure 2
Questionnaire compilation. Questionnaire compilation using a mobile phone. The question is displayed on the left, and the answer set associated with each question is displayed on the right.

and authorised to use certain functions based on their profile and role recognised by the system. The authentication process is based on the user's MSISDN (mobile number) if connected through WAP, or on the user's account (login and password) if connected through the internet. The users' authentication guarantees both transmitted and accessed data privacy.

Questionnaire management system: this represents the heart of the system, and allows us to manage questionnaires (i.e. create, modify and delete). Through this module, it is possible to assign a questionnaire to one or more patients by specifying the examination elapse and the delivery recurrence. Questionnaire results are processed using the analysis function of this module.

Messaging system: this supplies the interface for sending SMS and MMS messages in order to solicit patients for recurrent compilation of questionnaires.

Rendering system: this module controls the questionnaire display based on user's type of handset. As far as possible, it aims to make the display not dependent on the type of device used.

Technological infrastructure

The prototype has been developed through use of open source software. The data structure was implemented through the MySql database [28], while the application logic was based on PHP language [29] and the Apache Web Server [30]. A Nokia emulator [31] was employed to develop and run preliminary tests on the WAP component of the system. The WHOMS was designed to offer a tool that can comprehensively enter each user's home. The channels used at present are WAP and WEB (Figure 6).

For most patients, mobile phones are easily available at reasonable prices, which is why we have recruited GPRS technology for questionnaires. In contrast, the use of ad

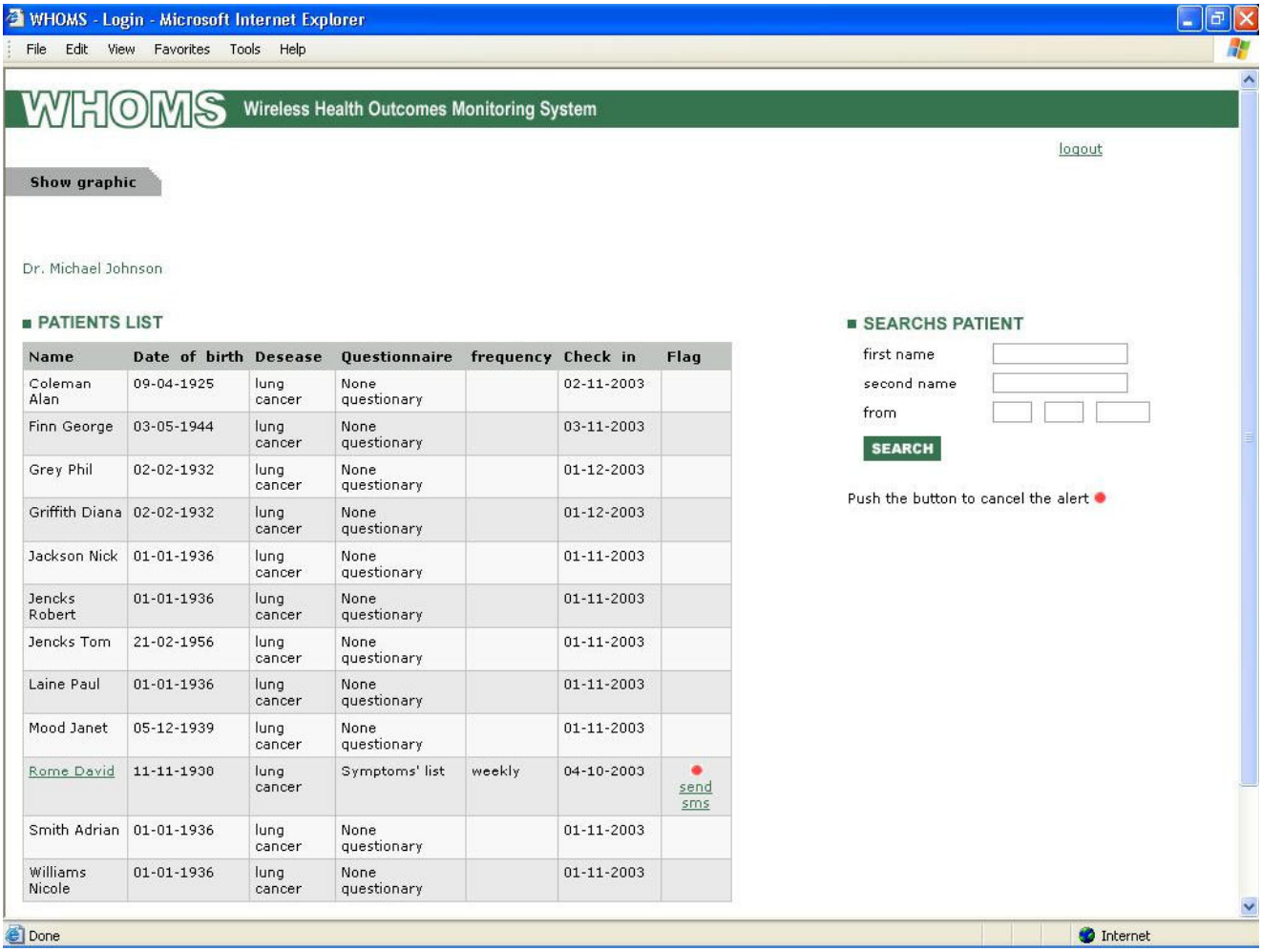

Figure 3
Patients' list. Patients' list display example. The physician can monitor all patients in a schematic way. A flashing light allows the physician to identify patients in which there has been significant change.

hoc media requires a bigger investment in terms of time and cost, and would have brought about many organisational issues linked to its propagation and maintenance, in addition to user training.

In order to limit problems linked to the display of questionnaires on handsets, only one mobile phone model was used in the present study. This allowed prompt implementation of a prototype and rapid feedback from pilot users. The mobile phone selected can display questionnaires with a very simple, immediate and appealing graphical interface.

A demonstration has been developed on the internet that allows us to test some of the functions offered by the system. It is possible to simulate a questionnaire completed by a patient, and then see the monitoring report for the physician updated with this new information transmitted by the patient http://www.qlmed.org/whoms/.

While the ultimate aim is for patients to also use this system via the internet, the current study focussed on patients accessing the system by mobile phone.

Patients

In the present study, the WHOMS was tested using a sample of 97 cancer inpatients. The patients were asked to complete a ten-item questionnaire using a mobile phone.

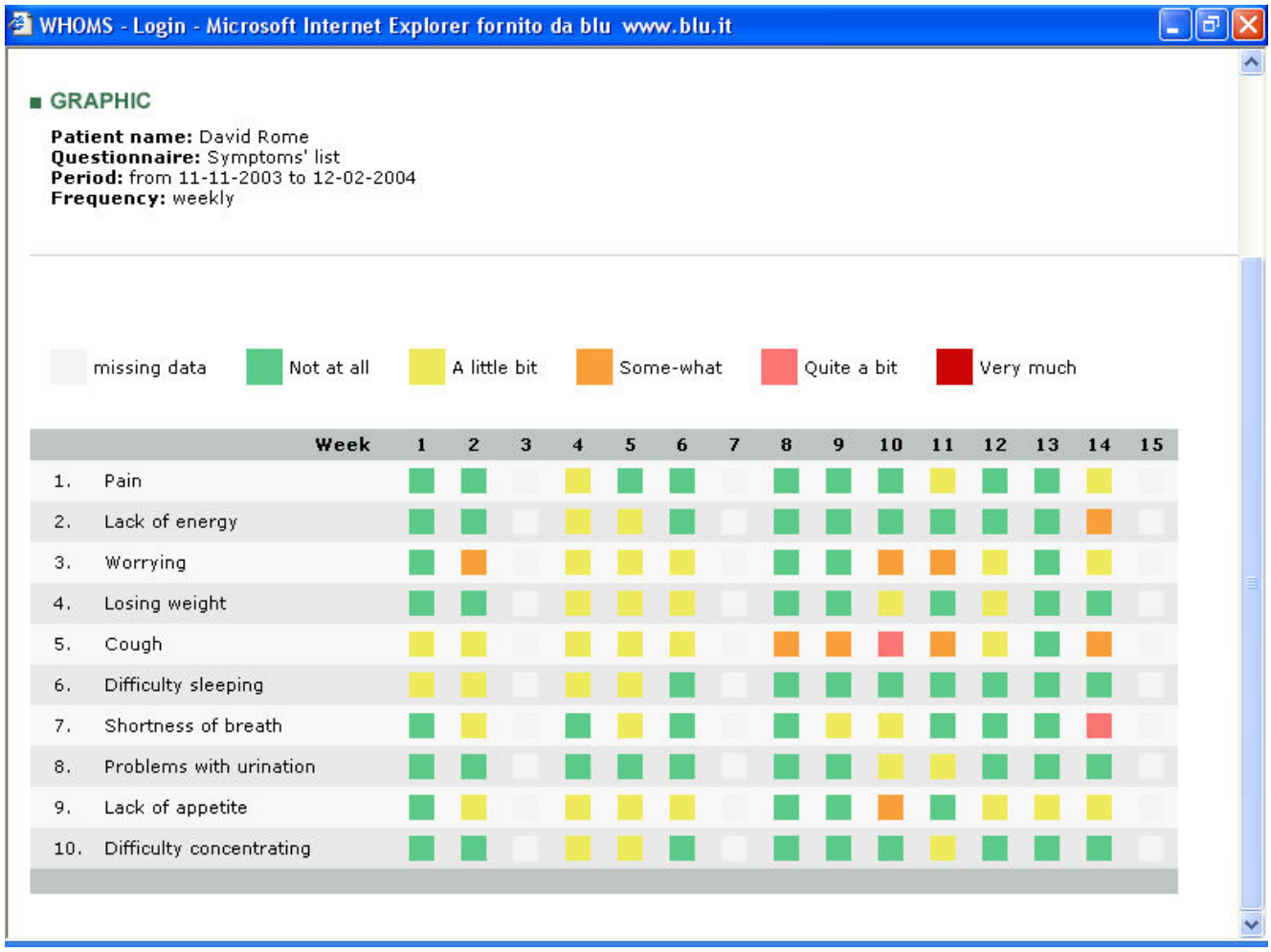

Figure 4
Patients' graph simulation. Example display of a patient's answers to the questionnaire.

The survey was conducted in 12 sample days during two months (January–February 2004) in 5 Hospital's Units at the Istituto Nazionale Tumori of Milan. All inpatients (with the exception of those in the immediate post-surgery period or with visible physical impairments or slipping) were invited to use the system after receiving a ten minute explanation and demonstration of how the questionnaire was to be completed. The aim of this pilot study was to determine whether this mobile phone-based WHOMS questionnaire method would be successfully used by patients. Thus, patients would not directly benefit medically from this particular questionnaire compilation as their doctors would not be invited to see the answers or make clinical decisions based upon them. For this reason patients were volunteers rather than compulsory recruits. All patients used the same model of mobile phone – a Nokia 6600 – and the GPRS connection was via Vodafone.

Data regarding gender, age, years of education, primary tumor site, surgical unit, use of communication technologies (calls or SMS from mobile phone, internet or email use by personal computer), time to compile the questionnaire and the number of items missing were also collected. Patient's free observations after compilation were also documented.

The questionnaire

For this pilot study we used an easy questionnaire regarding 10 symptoms (pain, lack of energy, worry, weight loss, cough, difficulty sleeping, shortness of breath, problems urinating, lack of appetite, difficulty concentrating)

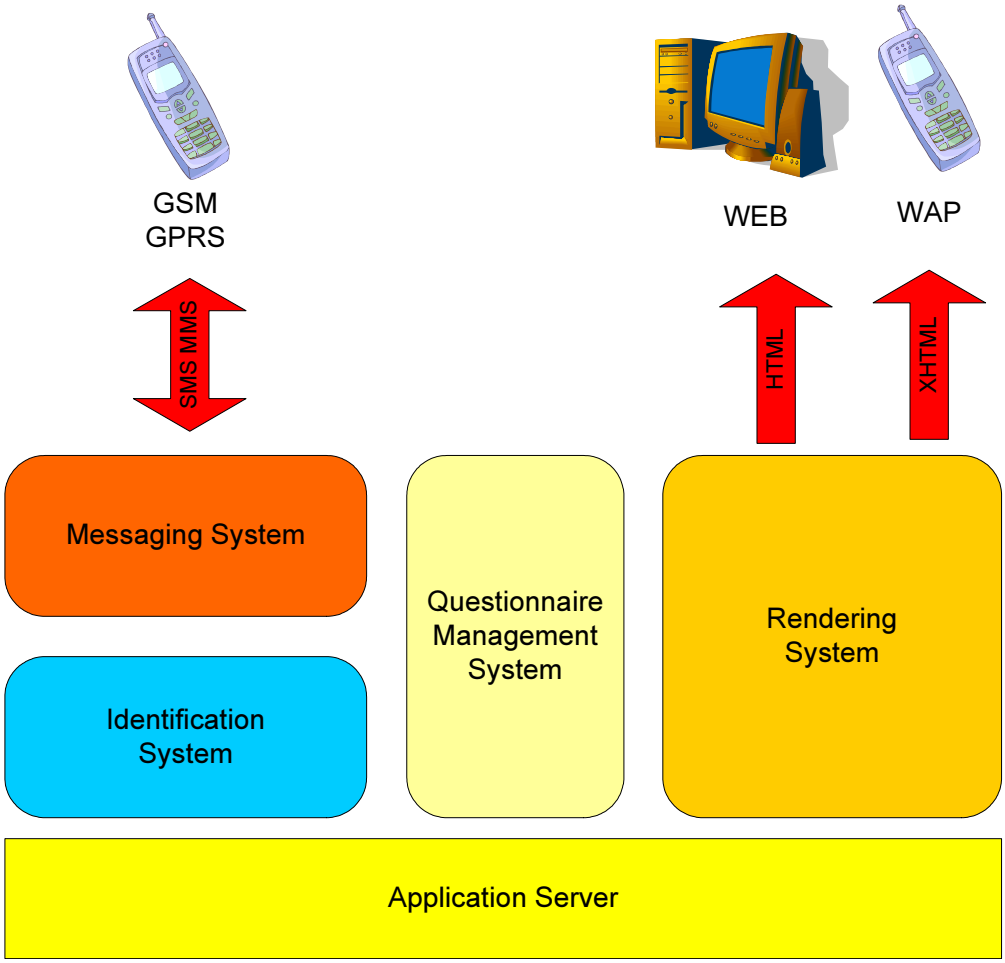

Figure 5
Functional architecture.

extracted from the MSAS-SF [17]. Patients were requested to select the response that best described the extent to which the symptoms distressed or bothered them during the past week. They were asked to select from one of the following responses: Not at all / A little bit / Somewhat / Quite a bit / Very much.

Statistical analysis

The association between the outcome variables (ability to compile and acceptability of WHOMS) and patients' characteristics was examined firstly at univariate and then multivariate level using logistic regression models. Regression diagnostics and indices of model fit were applied to evaluate how well the models fitted to the data. Results are presented in terms of odds ratios and their 95% confidence intervals (CIs).

In order to reduce the dimensionality in the set of predictors, and to avoid sparseness of data, the four variables dealing with use of communication technology (mobile phone calls, mobile phone SMS, internet, email) were collapsed into a single score representing the number of communication tools they declared to have used in the week prior to hospital admission. Using this approach, the Familiarity with Communication Technology (FCT) score obtained ranged from 0 (no familiarity – no tool used in the week before) to 4 (high familiarity – all the tools used in the week before).

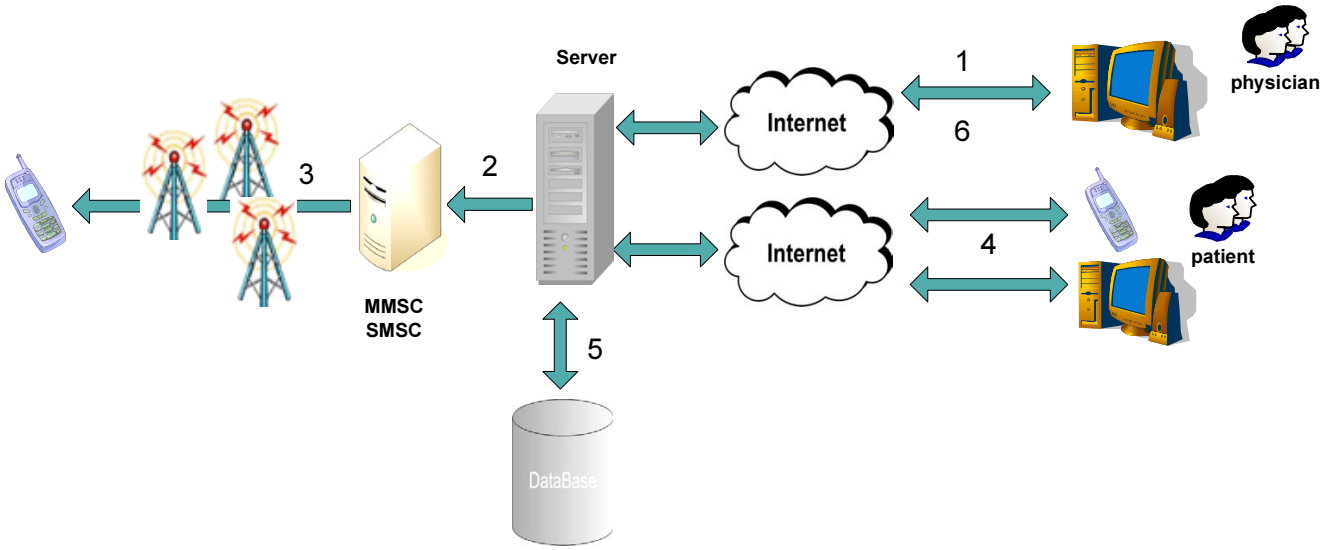

Figure 6
Operational workflow. The physician accesses the system through the internet and assigns a questionnaire to one or more patients by specifying the examination elapse as well as the delivery recurrence. The web server, through the use of a scheduler and interfacing the MMSC and SMSC modules, forwards a message to patients, inviting them to compile the questionnaire. Once compiled, the patient forwards their answers to the server which then stores the data using another module. A physician can then monitor the patient's health by connecting to the internet and viewing a graphical representation of the patient's answers.

Results

The data in Table 1 shows patient profiles and indicates the number that either accepted or rejected the offer to complete the questionnaire. Patients had a mean age of 52 years, a mean of 10 years education, and the majority were women. In terms of use of communication tools, twice as many used mobile phones compared to the internet, and in the week prior to hospital admission, the most used communication type was mobile phone calls, and the least was email (Table 1).

Of the 97 patients approached, 56 (58%) agreed to attempt the mobile phone-based questionnaire, and all of these completed the questionnaire. Forty-one (42%) patients refused to use the mobile phone. Of the 560 expected answers, only 6% were missing. The last item of the questionnaire had the highest number of missing answers (27%; Table 2). Patient profiling showed that compared those who attempted the questionnaire, those who refused were older, had fewer years of education and were less familiar with communication technology (mobile phones, internet, email). No differences emerged with respect to other factors such as gender, type of tumor or the hospital department to which patients were admitted.

One study aim was to determine the main reasons for inability to complete the questionnaire (i.e. visual or manual problems). However, this aim became redundant since all patients who attempted the questionnaire completed it satisfactorily.

Multivariate analysis for the "WHOMS acceptability" outcome confirmed the pattern of association that emerged in univariate analysis. Variables most strongly associated with acceptability were: FCT score, age and number of education years (Table 3). The model showed a good fit with the data (Hosmer-Lemeshow chisquare = 3.55, p = 0.89), and a high proportion of correctly classified observations (83.5%, sensitivity 87.5% specificity 78.1%). In particular, the odds ratios reported in Table 3 indicate that for a unit increase in the FCT score, holding all other variables constant, the odds of accepting WHOMS increased by 173%, indicating a very strong relationship. Both age and education years still maintain an independent, although weaker, association with acceptability (results indicate a reduction by 9% and an increase by 32% in the odds of accepting WHOMS for a unit increase, respectively).

Table 1: Acceptance or refusal by 97 cancer inpatients to compile the questionnaire using a mobile phone as related to patient characteristics

Characteristics	**Accepted** (n = 56) %	**Rejected** (n = 41) %	**Total** (n = 97) % (n)
Gender			
Male	57	43	31 (30)
Female	58	42	69 (67)
Age (years)			
Mean (SD)	45 (13.0)	61 (9.2)	52 (13.9)
Years of education			
Mean (SD)	12 (3.5)	7 (3.4)	10 (4.2)
Primary tumor site			
Colon-rectum	55	45	32 (31)
Uterine or ovarian	50	50	14 (14)
Breast	59	41	35 (34)
Other	67	33	19 (18)
Setting/surgical unit			
Senology	59	41	35 (34)
Gynaecologic	50	50	14 (14)
Endoscopy	60	40	15 (15)
Colo-rectal	47	53	18 (17)
Melanoma & sarcoma	71	29	18 (17)
Communication technology use *The number of patients who used a particular technology at least once in the week prior to hospital admission.*			
Mobile phone call			
Yes	66	34	82 (80)
No	18	82	18 (17)
Sent SMS message			
Yes	95	5	41 (40)
No	32	68	59 (57)
Internet			
Yes	89	11	37 (36)
No	39	61	63 (61)
Email			
Yes	90	10	32 (31)
No	42	58	68 (66)

Table 2: Mobile phone-based compilation of the questionnaire by 56 patients

Compilation	**% (n)**
Complete	61 (34)
Partial (1–5 items missing)	39 (22)
Failed (the number of patients unable to compile the questionnaire, or left more than 5 questions unanswered)	0 (0)
Items missing (complete or partial compilation)	
Pain	0 (0)
Lack of energy	2 (1)
Worry	2 (1)
Weight loss	2 (1)
Cough	7 (4)
Difficulty sleeping	4 (2)
Shortness of breath	11 (6)
Problems with urination	2 (1)
Lack of appetite	2 (1)
Difficulty concentrating	27 (15)
	Mean (DS)
Compilation time (minutes)	1 (1.3)

Table 3: Association between WHOMS acceptability and patients' characteristics

	Univariate logistic regression models results		Multivariate logistic regression model results	
Characteristics	**OR (95% CI)**	**P***	**OR (95% CI)**	**P***
Gender	1.06 (0.45–2.54)	NS	--	
Age (years)	0.88 (0.83–0.92)	0.000	0.91 (0.85–0.97)	0.005
Years of education	1.50 (1.27–1.77)	0.000	1.32 (1.07–1.62)	0.008
Primary tumor site			--	
Colon-rectum	1	--		
Uterine or ovarian	0.82 (0.23–2.91)	NS		
Breast	1.18 (0.44–3.14)	NS		
Other	1.64 (0.49–5.51)	NS		
Setting/surgical unit			--	
Senology	1	--		
Gynaecologic	0.70 (0.20–2.44)	NS		
Endoscopy	1.05 (0.30–3.62)	NS		
Colo-rectal	0.62 (0.19–2.00)	NS		
Melanoma & sarcoma	1.68 (0.48–5.84)	NS		
Communication technology use				
Mobile phone	9.16 (2.42–34.64)	0.001	--	
Sent SMS messages	41.17 (8.93–189.66)	0.000	--	
Internet	12.33 (3.87–39.32)	0.000	--	
Email	12.67 (3.50–45.87)	0.000	--	
FCT score	--	--	2.73 (1.38–5.43)	0.004

*Wald test

Of the 41 patients that declined to answer the questionnaire, 37 refused due to inexperience, incapacity or idiosyncrasies regarding mobile phones. Examples of comments were: "I don't know how to use them", "I can't understand these things", "I don't like using this equipment", "I'm afraid I'll break it", "I wouldn't know where to put my hands","If it were necessary I would ask my son, who's good with that sort of thing, for help", "I'd tell my husband what to answer on his mobile phone", "I don't want a mobile phone, the computer's at home but it's my son's and I don't want him to read about my illness", "It would be too tiring for me if they sent me a questionnaire everyday." The other four patients refused on physical and psychological grounds. Examples of comments from these patients were: "I'm in too much pain at the moment", "I don't feel well", "I'm too worried about my test results", "I'm too worried, tomorrow I have to be operated."

Of the 56 patients that attempted the questionnaire, some spontaneous comments were: "It's really easy!", "In the 16 months that I've been going back and forth from hospital the only flaw I have had has been trying to contact the doctors from home. I believe it's extremely useful!", "I don't think I'll have any problem filling it out at home. Let's hope that the doctors go to see how the patients are doing!". One lady, after completing the questionnaire, decided to try a second time using the symptoms of her husband who was suffering from benign prostatic hyperplasia. In another case, after completing the questionnaire, the patient commented he was a doctor and that he would be interested in using WHOMS at his own specialist clinic. Only three patients owned the same model mobile phone as that used in this study. All three of them were immediately successful and it took them much less time to compile the questionnaire compared to other patients.

Discussion

In this field test study, the number of patients who refused to use a mobile phone to complete the questionnaire proved to be higher than expected. The reasons for refusal were usually related to the patient's unfamiliarity with this form of communication technology. Preoccupation due to an imminent operation and physical pain were also given as explanations for refusal.

The sample population comprised cancer patients with a mean age of 52 years. The number of patients who used mobile phones (82%) was unexpectedly high and was more than twice the number of internet users (37%). The latter are included (with the exception of one patient) among those who used a mobile phone, therefore the

complimentary quota of around 20% use a fixed line only.

As expected, older age, lower number of education years, and in particular, lack of familiarity with new communication technologies were the most predictive factors for test refusal.

The absence of compilation problems for those who accepted to fill in the questionnaire confirmed the user-friendliness of the system for people familiar with modern communication technologies. The last question was associated with the highest amount of missing data (27%). This was probably due to the selection field being too close to, and indistinguishable from, the button used to confirm results.

The data generated in the present pilot study must be viewed cautiously in terms of the use of this WHOMS for communicating with patients at home. Firstly, the responses were from patients staying in the hospital, not from patients who had returned home. Furthermore, the questionnaire was designed to be particularly brief and easy. However, it was promising that there was a high percentage of successfully completed questionnaires given that all but three patients were completely unfamiliar with the mobile phone model used.

On the basis of the results obtained from this first study, we are currently introducing modifications aimed at improving the system. In particular, we are investigating multichannel approaches so as to offer WHOMS functions through palm computers, speech recognition and interactive voice responder (IVR) to provide a better interface and wider choice.

The WHOMS described in this study is being developed for monitoring patients at home and in clinical practice. It is likely to be more readily applied in hospitals, because it is easier to oversee questionnaire compilation by patients while they are in hospital. It is also likely to be more readily applied in HRQOL research, as only a part of the system is used since no medical intervention is requested on the basis of the data collected. HRQOL research with repeated measures can be completed with a very small amount of missing data. The system allows automatic inclusion of data in the electronic database, avoiding possible errors in data entry.

Conclusions

It is difficult to monitor patient symptoms and quality of life at home with paper-pencil questionnaires. This difficulty can be largely overcome through developments in telemedicine, telehealth (or e-health) and home telecare [32]. Numerous computer-based approaches have been useful in reporting patient conditions [33-36]. Although use of the Internet is one of the best ways to carry out distance health monitoring, it is still used only infrequently. For people over sixty, amongst whom chronic illnesses are more common [37,38], WHOMS has the advantage of offering both internet and mobile phone options to patients.

Medical and nursing staff are increasing their use of mobile phones during home visits in order to provide a smooth and speedy connection with care centres. Increasingly, programs are being established where telephones are used directly by the patient to monitor and pass on vital information concerning blood pressure, cardiac pulsation or ECG, so that any anomalies can result in fast medical intervention [39,40]. Furthermore, monitoring of the patient's quality of life/satisfaction/needs/treatments compliance can be achieved using standardised questionnaires created for patient use. Patients recently discharged following surgery, the elderly, those suffering chronic/evolving pathologies and terminally ill patients can communicate from a distance with their medical team, including the family doctor. In many cases the compilation of these questionnaires through video communication will provide for doctors a more up-to-date picture of the patient's state of health, and may allow the solving of problems without requiring the patient or carer to move locations. Any problems coping with the new communications technology are likely to be even less frequent when working with children and adolescents patients.

The present study demonstrated the majority of patients agreed to use a mobile phone-based wireless health outcomes monitoring system. Furthermore, 100% of these patients successfully completed the questionnaire. These are the first steps required in the process of seeking to apply this system to standard clinical practice. The next steps are to demonstrate the system's usefulness for patients and/or providers, and demonstrate provider acceptance and use of the system.

List of abbreviations

FCT score Familiarity with Communication Technology score

GPRS General Packet Radio Service

HRQOL Health-Related Quality of Life

IVR Interactive Voice Responder

MMS Multimedia Messaging Service

MMSC Multimedia Messaging Service Centre

PHP Hypertext Preprocessor

SMS Short Message Service

SMSC Short Messaging Service Centre

WAP Wireless Application Protocol

WHOMS Wireless Health Outcomes Monitoring System

XHTML eXtended HTML

Competing interests

Reply always keeps the focus on innovation and know-how: wireless technology and programming devices are key drivers of Reply business development in order to build advanced and effective mobile solutions. Company's investments have always been done according to this point of view, like in WHOMS, where Reply joined together technological experience and scientific knowledge to help people. Up to now, everything's been done thanks to the enthusiasm of Marcello Tamburini, his staff and Reply people. We didn't get any revenues, just costs, but we strongly believe it can be a big sales opportunity for the future, apart from being a way to improve patients quality of life, using a common device as mobile phones.

Authors' contributions

EB directed the project and provided critical revision of the manuscript, including important intellectual input. FC developed the WHOMS in collaboration with SLC and wrote the original draft of the manuscript. MT suggested the original system, reviewed the literature and wrote the sections dealing with HRQOL assessment. ML and MT tested the system with patients. CB performed the statistical analyses. All authors approved the final paper.

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