CRANFIELD UNIVERSITY

OLUSEUN ADEOGUN

INFORMATICS FOR DEVICES WITHIN TELEHEALTH SYSTEMS FOR MONITORING CHRONIC DISEASES

SCHOOL OF APPLIED SCIENCES

PhD
Academic Year: 2010 - 2011

Supervisors: Dr J.R. Alcock and Dr A. Tiwari

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This thesis is submitted in partial fulfilment of the requirements for the degree of PhD

ABSTRACT

Preliminary investigation at the beginning of this research showed that informatics on point-of-care (POC) devices was limited to basic data generation and processing.

This thesis is based on publications of several studies during the course of the research.

The aim of the research is to model and analyse information generation and exchange in telehealth systems and to identify and analyse the capabilities of these systems in managing chronic diseases which utilise point-of-care devices.

The objectives to meet the aim are as follows: (i) to review the state-of-the-art in informatics and decision support on point-of-care devices. (ii) to assess the current level of servitization of POC devices used within the home environment. (iii) to identify current models of information generation and exchange for POC devices using a telehealth perspective. (iv) to identify the capabilities of telehealth systems. (v) to evaluate key components of telehealth systems (i.e. POC devices and intermediate devices). (vi) to analyse the capabilities of telehealth systems as enablers to a healthcare policy.

The literature review showed that data transfer from devices is an important part of generating information. The implication of this is that future designs of devices should have efficient ways of transferring data to minimise the errors that may be introduced through manual data entry/transfer.

The full impact of a servitized model for point-of-care devices is possible within a telehealth system, since capabilities of interpreting data for the patient will be offered as a service (c.f. NHS Direct).

This research helped to deduce components of telehealth systems which are important in supporting informatics and decision making for actors of the system. These included actors and devices. Telehealth systems also help facilitate the exchange of data to help decision making to be faster for all actors concerned.

This research has shown that a large number of capability categories existed for the patients and health professionals. There were no capabilities related to the caregiver that had a direct impact on the patient and health professional. This was not surprising since the numbers of caregivers in current telehealth systems was low.

Two types of intermediate devices were identified in telehealth systems: generic and proprietary. Patients and caregivers used both types, while health professionals only used generic devices. However, there was a higher incidence of proprietary devices used by patients. Proprietary devices possess features to support patients better thus promoting their independence in managing their chronic condition.

This research developed a six-step methodology for working from government objectives to appropriate telehealth capability categories. This helped to determine objectives for which a telehealth system is suitable.

Keywords:

Point-of-care, informatics, data processing, long term conditions care, chronic care, point-of-care testing, medical device, PSS, product-service system, glucometers, information exchange, model, telehealth, capability, capabilities, functionality, system, chronic diseases, actor-centric, categories, diabetes, advice, intermediate device, types, location, user, healthcare, policy

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PUBLICATIONS

Edited versions of the chapters have been published, submitted or will be submitted as follows:

Chapter 2 Adeogun, O., Tiwari, A. and Alcock, J.R., “A Review of Informatics for Decision Support in Point-of-Care devices for Long Term Conditions Care”. *International journal of medical informatics* (to be submitted)

Chapter 3 Adeogun, O., Tiwari, A. and Alcock, J. R. (2010), "Informatics-based product-service systems for point-of-care devices", *CIRP Journal of Manufacturing Science and Technology,* vol. 3, no. 2, pp. 107-115.

Chapter 4 Adeogun, O., Tiwari, A., Alcock, J. R. (2011), “Models of Information exchange for UK telehealth systems”, *International journal of medical informatics*, vol. 80, no. 5, pp. 359-370.

Chapter 5 Adeogun, O., Tiwari, A., Alcock, J. R., “Capabilities of telehealth systems”, *Journal of the American Medical Informatics Association* (to be submitted)

Chapter 6 Ajai, O., Tiwari, A. and Alcock, J. R. (2009), “Evaluation of the state-of-the-art in informatics in glucometers”, *Informatics for Health and Social Care,* vol. 34, no. 3, pp. 171-179.

Chapter 7 Adeogun, O., Tiwari, A., Alcock, J. R., “Intermediate devices in telehealth systems: types available, where they are found and who uses them”? *International journal of medical informatics* (submitted)

Chapter 8 Adeogun, O., Tiwari, A., Alcock, J. R. (2011), “Capabilities of Proprietary Intermediate Telehealth Devices”, *Telemedicine and e-Health.* (accepted)

Chapter 9 Adeogun, O., Tiwari, A., Alcock, J. R., “Applying capabilities of telehealth systems to a healthcare policy”, *International Journal of Technology Assessment in Health Care.* (to be submitted)

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LIST OF ABBREVIATIONS

AST	Alternative site testing
CDSS	Clinical decision support system
CHF	Congestive heart failure
COPD	Chronic obstructive pulmonary disease
DSS	Decision support system
ECG	Electrocardiogram
EPR	Electronic patient record
ETL	Extraction Transformation Loading
FDA	Food and Drug Administration
GP	General practitioner
GPRS	General Packet Radio Service
HCU	Hand-carried Cardiac Ultrasound
ICU	Intensive care unit
LOC	Lab-on-a-chip
MeSH	Medical subject headings
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National health service
PCT	Primary Care trust
POCT	Point-of-care Testing
PSS	Product-service system
TAT	Test turnaround Time
TSA	Telecare services association
UML	Unified modeling language
VTE	Venous thromboembolism
WHO	World Health Organization

1 Introduction

1.1 Background

The administration of healthcare has been traditionally based on health professionals playing the most active role. Speedie et al. (2008) emphasised that existing care models should not be replicated by using new technologies but the development of new models is needed.

The global drivers advocating this change in healthcare administration are: the ageing population and a change in demographics since people are living longer in many developed societies (Department of Health, 2008b; World Health Organization, 2004, 2008c; Saranummi et al. 2006; Wakefield, 2003); the upsurge in the use of technology to access information (information is widely available to the general public and the internet has made this easier, with healthcare not being exempted) (Department of Health, 2008b); the advancement of science (recent discoveries have enabled scientists to have a greater understanding of diseases and their treatment) (Department of Health, 2008b); and the rise in certain conditions due to change in lifestyle (obesity related diseases, cancer and other chronic conditions are becoming prevalent) (Department of Health, 2008a, 2008b).

A multi-faceted approach (which considers multiple research techniques) is required in responding to these challenges which may involve the development of new care delivery models, the use of technology and a change in the mindset of individuals about healthcare.

1.2 Motivation

At the beginning of this research, initial investigation showed that informatics on point-of-care devices was limited to basic data generation and processing.

Decision support for patients rarely occurred at the point of use of the device. Instead data were usually transferred to an external source.

This research sought to understand how information could be generated from point-of-care devices to support patients in making decisions about their health. It also considered the components (actors and devices) involved in the process of patients generating data to receiving information.

The findings from this research will help in planning healthcare systems in the future that will comply with the trend of government requirements to empower patients.

1.3 Overall Context

This thesis covers information systems as an aid to providing decision support to patients with chronic diseases. Although this thesis is not focussed on knowledge management, the author covers an aspect of knowledge in the literature with regards to supporting decision making for patients. The aspect of literature covering knowledge considers how data is translated to information and then knowledge. Data refers to a set of elements (Saint-Onge, 1996). Information is when data has been organised into a structure, thereby providing context for the data (Saint-Onge, 1996). Knowledge shows understanding of the information (Saint-Onge, 1996). There are two aspects of knowledge: (i) explicit (this is formal and systematic; it can be communicated methodically) and (ii) tacit (this may be based on an individual's experience and may be difficult to express and formalise) (Nonaka, 1991).

1.4 Link to thesis chapters

This thesis is a compilation of publications written during the course of this research. The thesis considers the state-of-the-art in current models of delivering healthcare and proposes methods of how these may be improved to meet the changing demands worldwide to bring about a change in its delivery.

One way in which healthcare delivery can be changed is through telehealth and that is one of the main themes within this research. The other themes encompassing this research are: point-of-care devices, long term conditions, medical and health informatics and decision making/decision support. Section 1.4 defines the terminology used in this research, while section 1.6 provides details of each of the chapters of the thesis and how they are linked together.

1.5 Terminology

This section defines the terminology used in this research. They are: point-of-care devices, telehealth and telemedicine, long term conditions, medical and health informatics and decision making/decision support.

1.5.1 Point-of-care devices

Medical devices are used to diagnose, screen, monitor or treat patients. Their primary aim is not ‘pharmaceutical activity’, but rather a tool to ‘deliver a service’ (Summerhayes and Sivshankar, 2006). Medical devices range from hearing aids, to artificial implants in the joints, to ECG (electrocardiogram) machines and ICU (intensive care unit) monitors (Summerhayes and Sivshankar, 2006). Biomedical devices have a biological focus and therefore involve laboratory based features, i.e. such devices would be able to carry out similar experiments as in a standard laboratory, for example, identifying biomarkers in a biological sample.

According to the Medical Subject Headings (MeSH) (2011a), point-of-care systems offer “laboratory and other services to patients at the bedside” which may include “diagnostics and laboratory testing”. Point-of-care testing (POCT) has been defined as “diagnostic testing at or near the site of patient care” (Kost, 2002). POCT has also been defined by Price and Hicks as “assays of blood and other fluids”, not carried out in a central laboratory, but rather close to the patient to give results to facilitate a rapid change in patient care (1999). Hicks et al. (2001) added that such tests could also be done by the patients themselves.

Therefore it can be inferred from the descriptions that point-of-care devices are a subclass of medical devices used to carry out diagnostic tests. The description implies that the facilities of a conventional laboratory may be brought to patients irrespective of their location. For instance, patients located in a non healthcare setting will be able to benefit from a point-of-care device.

There is a margin of error associated with POCT. According to Meier and Jones (2005), sources of error include: “the operators’ incompetence, non adherence to test procedures and use of uncontrolled reagents and equipment”. They added that the following increased the likelihood of errors: “incoherent regulation, rapid result availability and immediate therapeutic implications”. A recent example of errors on a point-of-care device was in a news article recalling a point-of-care device for prostate cancer because it gave people an inaccurate measurement (BBC, 2009). POCT errors therefore suggest that they should not be used in isolation but used to give an initial indication to enable the appropriate decision to be made which may include further testing.

1.5.2 Telehealth and telemedicine

Telehealth is defined as “the use of information, computing and telecommunications technologies to provide” health related services when health professionals and patients are separated by a distance (Fitzmaurice, 1998). Koch (2006) added that telehealth has developed from telemedicine but also includes “health promotion and disease prevention”.

Telemedicine is the use of "advanced telecommunication technologies to exchange health information" and to provide services irrespective of location (Reid, 1996; Picot, 1998).

Anecdotal evidence suggests that differences exist between telehealth and telemedicine: Global Media (2011) suggested that telehealth includes both clinical and/or non-clinical services whereas telemedicine refers to clinical services only; the Telecare Services Association (TSA) suggested that telehealth refers to remote patient monitoring of an individual's condition at home, while telemedicine relates to health professionals consulting at a distance (TSA, 2011).

In literature, the terms have been used interchangeably and therefore both have been considered in this research.

A recent government report on healthcare showed that in order for the NHS (National Health Service) to be sustainable in the future, its focus must change to improving people's health rather than treatment alone (Department of Health, 2008b). Although the concept of telehealth has been available for some time and its benefits known on small scale projects, there is limited peer-reviewed literature supporting its efficacy on a wider scale. During the course of this research, the UK government conducted a large scale project to see the impact of telehealth and telecare[1]. However the full impact is yet to be published.

1.5.3 Long term conditions

Long term conditions have been defined by the UK Department of Health as conditions which cannot be currently cured but can be managed through "medication and other therapies" (Department of Health, 2008a). It was

[1] Telecare is the delivery of "health and social care services to people in their own home" through telecommunications technologies. It is "characterised by continuous, automatic and remote monitoring of real time emergencies and lifestyle changes over time in order to manage the risks associated with independent living" (Brownsell and Bradley, 2003).

estimated that 15.4 million people in England have a long term condition (Department of Health, 2008a). Examples of such conditions include: hypertension, asthma, diabetes, coronary heart disease, stroke and transient ischaemic attacks, chronic obstructive pulmonary disease (COPD) etc. The named conditions are the most prevalent in England (Department of Health, 2008a). Figure 1-1 shows five long term conditions linked by arrows. This was achieved by analysing different conditions and how they are currently being managed. The image illustrates that some of the diseases are risk factors for developing other conditions.

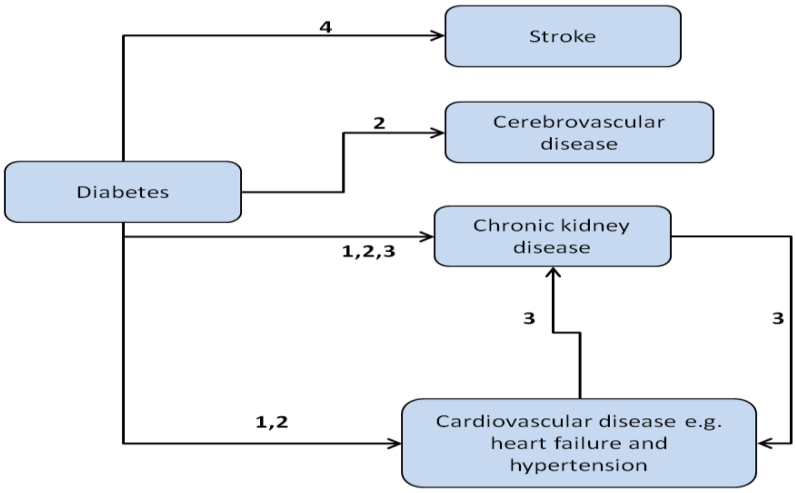


Figure 1-1 – Risk factor links between chronic conditions. (1: Nichols and Moler (2010); 2: Adler et al. 2000; 3: Whaley-Connell et al. 2008; 4: Kissela et al. 2005)

1.5.4 Medical and health informatics

Informatics can be defined as a method of processing stand-alone data into information thus allowing it to be interpreted for a specific purpose. It is the application of computational methods to data in order to: classify them; store in a repository by making associations in the data; retrieve the data in an efficient manner when needed (efficient, in this context denotes speeding up the rate at which a process occurs to deliver the information needed); and disseminate the data effectively to the resource requiring it (Merriam-Webster, 2011c).

The main emphasis is that tasks that would normally take a significant length of time, using manual methods, are carried out efficiently and speedily, using informatics, thus saving time and allowing more complex sophisticated analysis to be carried out.

Health is the general well-being of the body (Merriam-Webster, 2011a), while medicine is an intervention used to restore, preserve or treat a disease or condition affecting a person's health (Merriam-Webster, 2011b). Medical informatics or health informatics is the application of computational methods to aid in maintaining the general well-being of the body. This may be to help in diagnosing conditions and/or proposing the best type of treatment to give to a patient. There are different definitions for medical informatics, however the following provides a good summary: "the scientific field that deals with biomedical information, data and knowledge - their storage, retrieval and optimal use for problem solving and decision making" (Shortcliffe and Blois 2001).

Informatics covers several sub domains (MeSH, 2011b) which are shown in Table 1-1. This research considers medical and health informatics since both terms have been used interchangeably in the past.

Sub domain name	Description
Dental informatics	“The application of computer and information sciences to improve dental practice, research, education and management”.
Medical informatics	“The analysis and dissemination of data” to different areas of healthcare and medicine.
Nursing informatics	Supporting systems within nursing.
Public health informatics	Application of information and computer science and technology to the practice and research of public health i.e. considering populations rather than individuals.

Table 1-1 – Sub domains of informatics (MeSH, 2011b)

1.5.5 Decision making/decision support

Decision making is the combination of cognitive processes that are considered before making a conclusion about the appropriate action to take (Dictionary.com, 2011).

A decision support system (DSS) has been defined as a class of computerised information system that supports business and organisational decision-making activities (Information Builders, 2011). It may be based on a set of algorithms. For instance, one may need to make a choice between several solutions and a DSS may be able to ascertain the optimal solution thus helping the user to make an informed choice. DSSs have benefits associated with them and these include increasing the efficiency of arriving at a solution and improving problem solving.

A clinical DSS (CDSS) uses patient data to generate specific advice (Wyatt and Liu, 2002). Hunt et al. (1998) expand the definition of a CDSS to an automated process for comparing patient-specific “characteristics” against a “computerised knowledge base” where “recommendations are presented to the provider at the time of clinical decision making”. This definition implies that CDSS are designed for health professionals as the primary user. Other examples found in literature of DSSs used in healthcare are shown in Table 1-2.

More literature is available for health professionals (rather than for patients) as the primary users of decision support systems. However, this research focuses more on empowering the patient in becoming the primary decision maker in managing their long term condition. This is not to say that health professionals will be excluded from the decision making process but rather providing a supporting role to patients so that they have a better understanding of their condition.

Use of DSS	**Primary user of DSS**	**Reference**
Observing patient blood glucose levels.	Health professional	Ford, 2007
Gait[2] analysis in rehabilitative medicine.	Health professional	Wu et al. 2007
Supporting trainee nurses in clinical decisions.	Health professional	Fortier et al. 2005
Monitoring post triage patients.	Health professional	Curtis et al. 2008
Supporting informed decision making for the type of prenatal[3] test for foetal abnormalities.	Patient	Nagle et al. 2006

Table 1-2 – Examples of DSSs used in healthcare

1.6 Research goals

1.6.1 Research context

This research is set within the context of a crossover project in Cranfield University between Product-Service Systems (PSSs) and Micro Manufacturing. The aim of the crossover project is to “develop methodologies to facilitate the design of PSSs in which a complex micro-integrated device forms the physical core of the system”.

[2] Gait: a person’s manner of walking (Oxford Dictionary, 2011a).
[3] Prenatal: the period before birth (Oxford Dictionary, 2011b).

A PSS is an "integrated product and service offering that delivers value in use" (Baines et al. 2007). Micro Manufacturing produces devices at the micro scale level. An example is a blood separating device which could be applicable in developing a future point-of-care device that could be used to analyse a pregnant woman's blood for conditions that may affect the unborn baby.

This research considers informatics as an aid to service delivery for point-of-care devices.

1.6.2 Research aim

To model and analyse information generation and exchange in telehealth systems and to identify and analyse the capabilities of these systems in managing chronic diseases which utilise point-of-care devices.

1.6.3 Research objectives

Six objectives have been defined to help meet the research aim and they are as follows:

1. To review the state-of-the-art in informatics and decision support on point-of-care devices.
2. To assess the current level of servitization of point-of-care devices used within the home environment.
3. To identify current models of information generation and exchange for point-of-care devices using a telehealth perspective.
4. To identify the capabilities of telehealth systems.
5. To evaluate key components of telehealth systems.
    a. Point-of-care devices.
    b. Intermediate devices.

6. To analyse the capabilities of telehealth systems as enablers to a healthcare policy.

1.6.4 Research approach

A multidimensional approach was used to tackle the objectives. This was necessary to enable the models of information generation and exchange within telehealth systems to be captured and to identify the capabilities of such systems. It is illustrated in Figure 1-2.

The thesis begins with a literature review to understand the state-of-the-art in informatics pertaining to point-of-care devices.

Review of literature

A critical literature review was carried out to identify how information was obtained and presented to users of point-of-care devices in order for them to make informed decisions about their health.

The process involved a systematic searching of electronic databases (Scopus, ISI Web of Knowledge) using a few keywords initially: informatics and point-of-care devices. The titles and abstracts of the literature retrieved in the search were scanned to identify relevant ones. The search was refined to include a combination of the following keywords: state-of-the-art, bioinformatics, biomedical devices, decision support, decision making, health informatics, informatics, medical devices, point-of-care devices and point-of-care.

The major themes emerging from the literature were decided based on the nature of the topics covered in the literature. These themes were point-of-care devices, data processing and communication, decision support systems and human issues. A simple hierarchical health informatics model (Desrosieres, 1998) (which comprises three parts: data, information and knowledge) was found and literature was presented under these three parts.

A separate literature review was carried out to outline the current level of servitization for POCT devices using glucometers as a focus. The literature used in this sector were similar to those of the first literature review, however they were viewed from the perspective of point-of-care devices providing services to users. Questions on factors influencing the choice of users and additional features they would like to see in future glucometers were added to three online forums to receive feedback from users of glucometers.

It was ascertained that glucometers were supplied as products with additional functionalities. It was proposed that in future, they could be supplied within a result-oriented PSS, whereby more services could be provided through them.

A review for telehealth was incorporated in the background of the studies carried out.

Studies

Five major studies were undertaken in this research.

Study 1. A survey of 11 UK based telehealth organisations was completed.

An online search was carried out using the following keywords: point-of-care devices, telehealth, telemedicine, eHealth, home telehealth solutions UK, telemedicine services and telehealth companies. This helped to identify UK organisations offering telehealth services. Symbols were invented to represent telehealth offerings diagrammatically since there were no formal tools with flexibility to represent entities and information exchange routes.

Content analysis was carried out on the organisations' documentation to ascertain the entities involved in exchanging data and information. Once the diagrammatic representation of the telehealth offering was drawn, it was sent to each organisation in the form of a questionnaire to ascertain whether the details in the diagrams were accurate. The questionnaires were sent by email to appropriate contacts in the organisation. Each organisation was asked to make modifications if the diagrams were incorrect.

On return of the questionnaire, by 6 of 11 organisations, the diagrams were modified.

Study 2. Capabilities of existing telehealth offerings (study 1) were derived by analysing their characteristics.

The list of capabilities was complied by content analysis of each telehealth offering diagram and recording the flow of data and information through the system. Once the list of capabilities were compiled, similar ones were grouped together based on a hierarchical methodology. This method ranked actors (human entities) higher than other entities of the system. Entities initiating actions were considered above entities affected by outcomes. The categories of capabilities were then represented in diagrams for easier viewing.

A subset of key components identified in the baseline model[4] of telehealth offerings was evaluated. This subset was based on the types of devices used within the offerings since the research had a foundation which considered devices. The purpose of these studies was to understand the role of the devices in generating information.

Study 3. The glucometer was chosen as a case-study for evaluating point-of-care devices because it was ubiquitous and represented the state-of-the-art of point-of-care devices used within the home environment. 100 glucometers were evaluated through examination of their manuals and manufacturer documentation. A set of informatics criteria to ascertain the quantity, types of information and advice provided to the patient was noted in a table before being analysed.

Study 4. Intermediate devices are identified in this research as one of the key components of telehealth systems. They are defined in this research as

[4] Baseline model: Model representing the entities that were common to all telehealth offerings (Adeogun et al. 2011a).

connectors between point-of-care devices, patients and health professionals. These were investigated using two approaches. The first, considered the different types available, where they could be used and who used them in telehealth systems. This involved scanning the telehealth offerings (study 1) and constructing a diagram showing each intermediate device located in between two other entities. These diagrams were analysed and the data from this were summarised in tables.

The second considered capabilities of a specific type of intermediate device – proprietary[5] devices. In this, all the proprietary devices used in evaluated telehealth offerings were considered. Three more intermediate devices were added to the evaluation following an internet search. Questions were composed to ascertain the following about the devices: setup/configuration, available features, inputs and outputs. The results were analysed.

Study 5. Telehealth is considered in this research as one solution in changing the current delivery of healthcare, therefore, the capabilities of telehealth systems (study 2) were applied to a UK government health report. The UK was chosen since this research is based here.

A six-step methodology emerged from identifying objectives in the report to applying capabilities of telehealth systems to them. The six steps are as follows: (i) identifying the government objective; (ii) summarising what the government objective entails; (iii) extrapolating the actions proposed by the government to meet the objective; (iv) assessing whether a telehealth system is feasible for the objective; (v) proposing actions to meet the government objectives; and (vi) matching equivalent capabilities of telehealth systems to the proposed actions.

A questionnaire was constructed showing the first three steps applied to all objectives. The questionnaire then asked potential respondents whether a telehealth system was a feasible solution for the objective and what would be expected capabilities. A short presentation was recorded (using Windows

[5] Proprietary device: a device designed to fulfil a specific role of exchanging data/information between entities of telehealth systems (Adeogun et al. 2011a).

Movie Maker) to accompany the questionnaire. The questionnaire and the recording were added to a website and the link was disseminated to potential respondents via email. The questionnaire was sent to a total of 14 people who were health professionals, telehealth service providers and telehealth researchers. Six of them replied.

Validation

Validation was performed for individual studies where appropriate.

For study 1, the diagrammatic representations of the telehealth offerings were evaluated by sending questionnaires to all organisations concerned. As a result of the feedback, the diagrams were refined.

For studies 3 and 4, organisations were contacted and data gathered about the devices were refined.

For study 5, experts within the telehealth industry and health professionals validated the results through a questionnaire. The questionnaire showed steps 1-3 of each government objective and then asked respondents to decide whether a telehealth system is possible in step 4. The respondents were also asked to provide reasons for their answers.

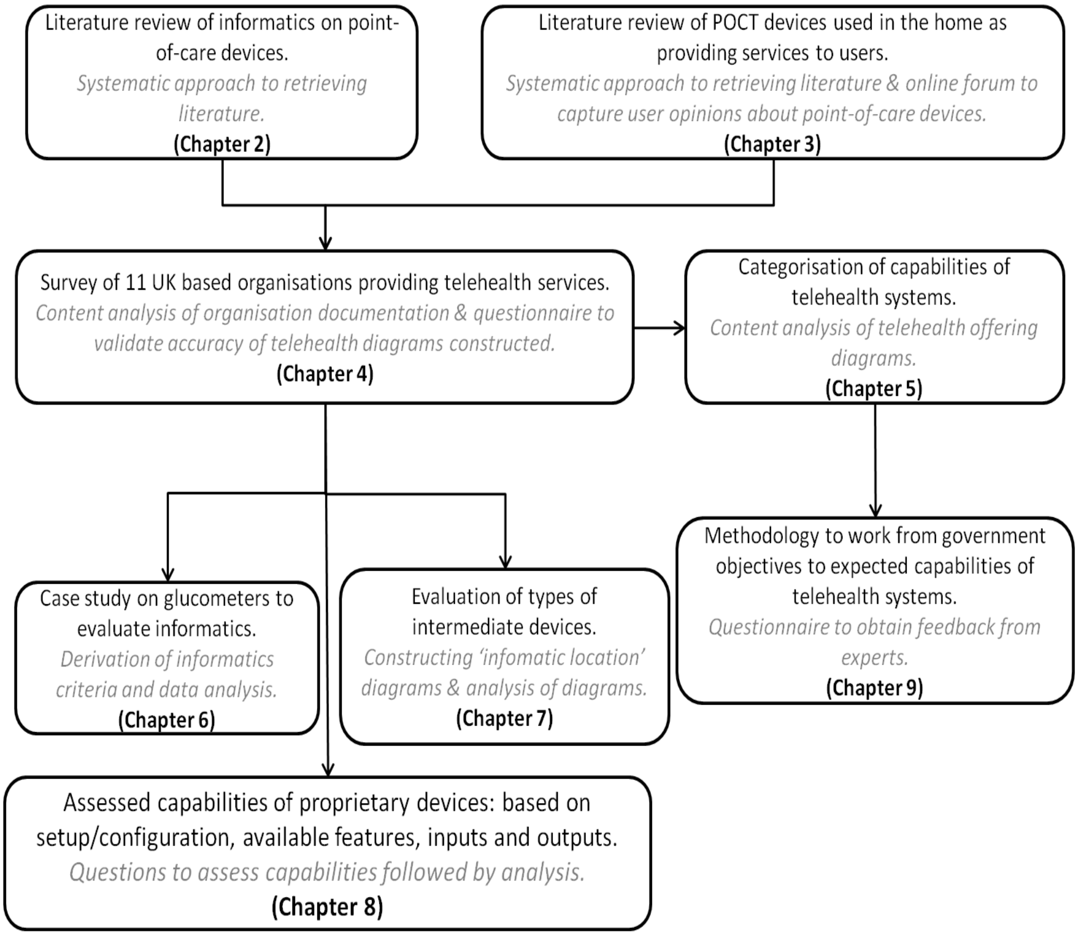


Figure 1-2 – Approach followed in this research (the details of methods used are shown in grey)

1.7 Thesis Structure

This section provides details of each of the chapters of the thesis and how they are linked together. This thesis is a compilation of publications written during the course of this research. It comprises 12 chapters.

1.7.1 Introductory chapters

Chapter 1 is the introduction and sets the scene for the thesis. It provides the background to the research, the research goals and the approaches used in the research. It also shows the overall storyline of how the chapters are related and fit into the research.

Chapter 2 is the literature review (part 1) which details an in-depth and critical analysis of literature. It outlines the current state-of-the-art of informatics on several point-of-care devices suitable for managing chronic conditions.

The outcomes of the literature review revealed that information synthesis on point-of-care devices was limited and data were usually transmitted to an external location in order for information to be provided to users.

Chapter 3 is the second literature review which considers point-of-care devices as a means of providing a service (in the form of information) to users. In this chapter, it was ascertained that point-of-care devices are supplied as products with additional functionalities. The level of servitization of point-of-care devices can be increased through a result-oriented PSS.

1.7.2 Studies

Chapter 4 sought to investigate where information was generated, following the discovery that data from point-of-care devices were transferred to an external location (chapter 2). This led to an identification of the arrangement of entities forming telehealth systems. Although telehealth systems are used in many parts of the world including both developed and developing countries, a decision was made to focus on systems within the UK only, due to time constraints. 12 telehealth systems were evaluated. The outcomes of the chapter include the discovery of models of information exchange within these systems: the baseline, dominant and fully-featured models. The baseline model showed entities common to all 12 telehealth systems. The dominant model showed entities present in more than 6 of the telehealth systems. The fully-featured model is a hypothetical model comprising all the entities and their functionalities.

The subject of the overall research considers informatics to aid decision support when patients use devices to monitor their health and this chapter showed that point-of-care devices do not exist in isolation but are part of a telehealth system. Certain entities were common to all telehealth systems and a decision was made to further evaluate these in chapters 6 to 8.

Chapter 5 showed how capabilities could be derived from telehealth systems. These were derived through content analysis of each telehealth offering diagram. They were categorised based on perspectives of actors in the system. The trend of patient centric capabilities related to providing data (i.e. test results and responses to questions) to systems. Caregivers were present in only 4 of 12 existing offerings, therefore no real trend was observed. For health professionals, the trend was for them to review the patient's result to support decision making about the patient's health therefore prompting a change in the care plan at an earlier, rather than a later stage.

There were some capabilities that were not directly related to actors and these were grouped into separate capability categories. Their main aim was to save results and transfer results to another component of the telehealth system. This implies that information transfer within telehealth systems is important in order for it to be used by other entities.

Chapter 6 was a case-study on glucometers to investigate information and advice provided to users. Glucometers are point-of-care devices used by people suffering from diabetes to aid in managing their condition (whilst away from their health professional). 100 glucometers from 27 manufacturers were evaluated and it was found that informatics was limited to averaging of data. Other information was also provided to users and these were short messages when unexpected results occurred. Data could be downloaded to a computer in many cases to be further analysed by health professionals. The outcome of this chapter supported the details obtained in the literature review (chapter 2) and models of telehealth systems (chapter 4) that advanced information synthesis occurred away from the glucometers.

Chapter 7 assessed the types, locations of use and users of intermediate devices within telehealth systems. There are two types of intermediate devices: generic[6] and proprietary[7] types. Generic devices currently in use are mobile phones, personal computers, television and landline phones. Proprietary devices are specifically developed to be used within telehealth systems. The chapter did not provide a case on the suitability of devices; rather it showed two distinct characteristics of the devices; which was their availability as proprietary or generic and their ability to display data.

Chapter 8 further evaluates intermediate devices by considering proprietary types. The goal of the chapter was to assess the features they exhibit and to identify the clustering of attributes in current devices. The devices exhibited similar features. Inputs to devices came from point-of-care devices and patients. Outputs were sent to a software application or an external server. The evaluation showed that intermediate devices have three main roles: displaying information to the patient; receiving data manually/automatically; forwarding results and questionnaire responses to another entity.

Chapter 9 considered the UK government proposals for the future direction of healthcare administration. The chapter aimed to identify the key objectives and whether there was a role for telehealth and its capabilities (chapter 5) in delivering the objectives. This was achieved through a systematic methodology, by considering the explanation of the objectives and how telehealth systems could be used to meet them. One of the outcomes of this chapter showed that telehealth systems were suitable for some but not all of the objectives. In addition, the government could use the results as a starting point for implementing telehealth systems, but other aspects of the system need to be evaluated i.e. effectiveness and cost. Healthcare providers could also see how they could adapt their current practices to comply with the proposal.

[6] Generic devices are devices designed originally for other purposes but are adapted for reuse within telehealth systems.
[7] Proprietary devices have been designed to fulfil a specific role of exchanging data/information between entities of telehealth systems.

1.7.3 Summary

Chapter 10 is an overall discussion of the main findings of the research. It concludes with a summary of the limitations, further work of the research and conclusions.

2 A Review of Informatics for Decision Support in Point-of-Care Devices for Long Term Conditions Care

Abstract

This literature review presents an evaluation of informatics on point-of-care devices in terms of their role in the provision of data, information and knowledge, in particular for chronic care applications. It considers whether sufficient information is provided on the devices to allow users of devices to make informed decisions on managing their health.

Whilst on-device generation of data was the norm, information was generated off-device by associated software. Current emphasis was on educating and training users in how to interpret results. However, information synthesis was found to be very limited, with a lack of semantic interoperability and knowledge morphing capabilities.

Decision Support Systems (DSSs) aimed at the health care professional as user have been considered at the generic level, but little yet exists in DSS in which point-of-care devices play a role. DSSs aimed at patients barely yet exist. Reasons for this are discussed.

2.1 Introduction

2.1.1 Scope of the review

The 2006 UK Department of Health report *Our health, our care, our say: a new direction for community services*, places renewed emphasis on the education and empowerment of patients with long term conditions (Department of Health, 2006c). The goal of this is that people are ‘fully informed about their condition and are better able to manage it’.

This goal is set against a context of 15 million individuals in England with long term health needs and the desire of those with long term conditions for advice and support about technologies that will promote their independence.

Implicit in being able to manage their condition is that patients will be making decisions about their own health. This ‘taking control’ is encouraged in the report by such initiatives as an ‘Expert Patients Programme’, with training from people with personal experience of long term illness. For example, in one case study, peer adviser groups were established to pass expertise on to people who had developed diabetes.

The report also notes the role that assistive technologies already play and will play in the future, an increasing role in patient support.

The paper considers the example of current medical devices which allow diagnostic testing at or near the point-of-care – which for patients with long term needs will often be their own home.

2.1.2 Aim of review

To review informatics in point-of-care devices for decision support available in literature.

2.1.3 Research Questions

This paper addresses the following research questions:

- How is current technology for those with long term needs used to aid patients in managing their conditions?
  - Following the theme of empowering patients to better manage their own conditions, it considers what data and information is currently available to patients from such devices.

  - It then considers who is primarily responsible for making the decisions about the patient's health.
- How might future technologies empower patients?
  - Looking further into the future, it identifies what informatics, present on devices, might further empower patients, by using the example of research on current 'decision support systems' in health care.
- What are the research gaps between current informatics and those which decision support systems would require?

2.1.4 What this review does not cover

One question left relatively unaddressed in *Our health, our care, our say: a new direction for community services,* is the complex issue of how far such empowerment should go. In other words how far should patients be encouraged in "taking control" of their health? This question is also outside the remit of this review. Rather the question considered here is, how the current state-of-the-art in technology would help patients in taking control and what improvements might have to be made in relevant informatics in order to increase patients' abilities to manage their own conditions.

Also unaddressed in this review paper are telehealth and telecare systems in which a health professional plays a role within the total system. Whilst such systems have advantages in terms of convenience, accessibility and cost, management of the condition is still primarily within the control of the health professional, not the patient. Instead, the scope of this review covers informatics either on or off devices up to the point where data is manipulated by external software. The device, and/or external software, can be considered as providing a service to the patient in the form of information. Figure 2-1 shows this in diagrammatic form.

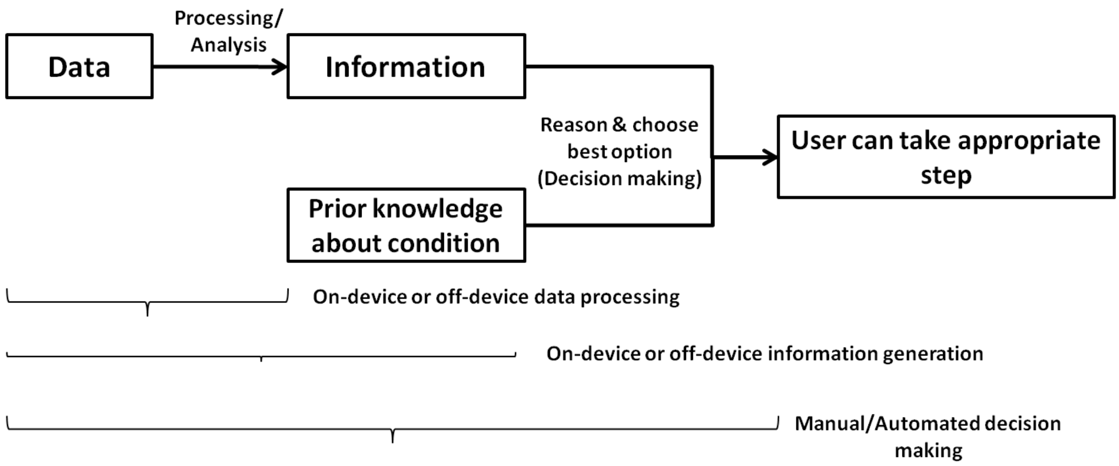


Figure 2-1 – The domains investigated in this review and their linkages

2.1.5 Background

2.1.5.1 Point-of-care devices

Point-of-care devices can be classified in terms of functionality into two categories: firstly, testing and secondly, treatment or therapeutic devices. Table 2-1 shows examples of some of the point-of-care devices that were reviewed in this report, their function and what they measure.

Point-of-care testing (POCT) has been defined as 'diagnostic testing at or near the site of patient care' (Kost, 2002). Tests can be carried out immediately and results obtained instantly without the need to send the patient's biological sample to the laboratory where it might take a number of days to analyse before the results are obtained.

Hicks et al. (2001) expanded the definition of POCT to cover tests carried out by the patient themselves. However, patients' use of POCT devices are primarily condition-monitoring rather than for diagnosis, for example, peak flow meters help people suffering from asthma to monitor their breathing volume.

Point-of-care devices for therapy primarily provide a means of administering medication to the user while at the same time helping the patient to control their condition on a regular basis. One example is an insulin pump which releases insulin periodically into the body to help maintain a regular blood glucose level. It also releases insulin on demand in cases when the patient has eaten (Roche, 2008a; Medtronic, 2009a).

More recently, point-of-care devices for condition monitoring and treatment or therapy have appeared. This is particularly relevant to the device by Medtronic (REAL-Time Continuous Glucose Monitoring Kit) which offers continuous monitoring of glucose in the body Medtronic, 2009b). The device works in conjunction with the insulin pump which receives the blood glucose data wirelessly at a regular interval (every minute) to give the user an accurate picture of their condition. Alarms on the monitoring device can alert the user when extreme results occur. A caveat is given that the users should still confirm their results through a glucometer before modifying their therapy.

The devices covered in this review were mainly POCT since the aim was focussing on patient self managing their condition.

POCT Device	Function	Diagnosed Condition	Reference
Glucometer  (LifeScan, 2008a)	Measures the concentration of blood glucose.	Hypoglycaemia or hyperglycaemia.	(Cohen et al. 2006; Weitgasser et al. 1999)
Blood Pressure Monitor  (Omron, 2009)	Measures blood pressure.	Hypertension.	(Mengden et al. 1998)
Peak Flow Meter  (QuickMedical, 2008)	Measures expiratory volume of the lungs.	Assessing lung function in those suffering from asthma.	(PDS/Ferraris Respiratory, 2004)
Blood gas monitoring device  Physicians Office Resource (2008)	Monitors blood pH, oxygen concentration, carbon dioxide concentration and the concentration of certain electrolytes.	Several medical conditions when patient is in critical care.	(Hosokawa et al. 2000; Randolph et al.2000)
Hand-carried cardiac ultrasound device  (Sonosite, 2008)	For echocardiographic images.	Assessing cardiac function.	(Salustri and Trambaiolo, 2002)

Table 2-1 – Examples of point-of-care testing devices

2.1.5.2 Point-of-care device informatics

"Point-of-care device informatics", a term used in this review, is the application of computational techniques to point-of-care devices to help provide information for diagnosis, treatment or monitoring of patients with a particular medical condition. It therefore includes informatics for POCT.

2.2 Methodology

The methodology of this review uses to some extent the approach described by (Talmon et al. 2009), although the method used here relates to developing guidelines to writing evaluation reports, some of the principles can be used. In that paper, the authors, considered a set of terms and their descriptions, these were presented and discussed with colleagues at a workshop to allow feedback and refinement of the terms before developing the final guidelines.

The methodology of this paper began with a keyword search. A summary of each of the publications were noted and this was followed by the organisation of the literature found based on the major themes identified. Majority of literature found described the assessment of other features of point-of-care devices such as accuracy, efficiency and relevance rather than informatics. Relevant literature were then organised and reviewed based on an informatics model found in literature.

As this review was part of a time limited research, the authors could not go ahead to obtain feedback from external audiences to refine the search terms. However, the authors did refine their search terms accordingly to find more relevant literature focussing on informatics of point-of-care devices.

2.2.1 Keyword search

Electronic databases such as Scopus and ISI Web of Knowledge were used as search engines to find articles used in this review. The keywords used were: state-of-the-art, bioinformatics, biomedical devices, decision support, decision making, health informatics, informatics, medical devices, point-of-care devices, point-of-care and future of healthcare. Different combinations of the keywords were used to search for literature.

The search covered literature available between January 2008 and August 2009.

2.2.2 Organisation of literature

2.2.2.1 Major themes identified

The major themes were decided based on the nature of the topics covered in the literature. These themes were point-of-care devices, data processing and communication, decision support systems and human issues. The literature found were tabulated.

2.2.2.2 Organising literature based on informatics model

Desrosieres (1998) described a simple hierarchical health informatics model which comprises three parts: data, information and knowledge (Figure 2-2). Data resides at the bottom of the hierarchy and consists of facts which on their own do not have meaning. Information however, provides the context to the data.

This model when applied to the context of the topic of this review (empowering patients) suggests that data (results) generated by patients through a point-of-care device requires them to understand their condition and interpret this data in order to be able to better manage it.

The literature found were organised into three groups based on the three parts found in the simple informatics model (Desrosieres, 1998). Those showing data, those describing information and those explaining decision support for patients.

This model was chosen since it represented the preceding steps that would be needed for a decision making process.

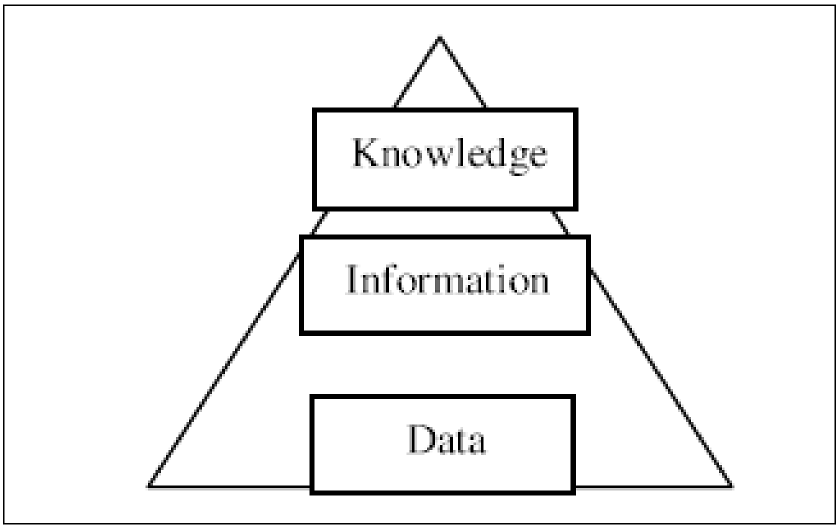


Figure 2-2 – A simple health informatics model (Desrosieres, 1998)

2.3 An informatics model applied to point-of-care devices

The results are divided into three parts. Informatics of point-of-care devices is initially considered from the data viewpoint. Secondly, information provided by the device and its associated software is shown. The third part reviews the current state of appropriate decision support systems in healthcare. Most of the point-of-care devices reviewed represent those used by health professionals and mainly within the hospital, while few of the examples show patients using devices. This therefore prompts that the shift in perspective towards a more patient centric use of such devices is limited in publications currently available.

2.3.1 Data

The data available from point-of-care devices is reviewed here in terms of its accuracy, its efficiency in achieving desirable clinical outcomes, its relevance, data storage and transfer issues. Also considered are issues related to the interoperability of data as it is exchanged.

2.3.1.1 Accuracy of data

Ho et al. (2004) evaluated five glucometers used in neonatal care for their accuracy in detecting low blood glucose in newborns. Data generated on the device was sufficient to conclude that results could not be used exclusively and a laboratory test was still required (Ho et al. 2004).

Weitgasser et al. (1999) carried out a study comparing older generation with more recent glucometers, specifically comparing their accuracy and precision. The authors used error-grid analysis to determine data accuracy. Error-grid analysis is clinically most relevant when considering accuracy of glucometers. More modern glucometers were more accurate, despite requiring smaller blood volumes. This was attributed to technological improvements. Although no details of these improvements were provided, improved sensitivity of the test is likely to be the most important factor.

Randolph et al. (2000) conducted a study considering whether results obtained from the i-STAT blood analyzer would be consistent and accurate irrespective of its location of use. This was undertaken to check its suitability in giving accurate results when transferring patients between hospitals. In order to check the precision of results, duplicate analysis of samples from patients were carried out prior to and during the transfer. Data generated on the device was sufficient for interpretation by the users and it was not analysed further.

Cohen et al. (2006) compared the accuracy and precision of glucometers used in Australia. Accuracy was determined by simultaneously analysing blood samples from the patient using a reference method and the glucometers. Precision was determined through the calculation of the coefficient of variation of the control solutions. The authors also noted that precision and accuracy were both significantly improving in more recent generations of glucometers.

2.3.1.2 Efficiency of generating data

Kendall et al. (1998) investigated whether the clinical outcome of patients was affected when a point-of-care blood analyzer was used compared with the hospital laboratory in the accident and emergency department of the hospital. Details were not provided of whether data analysis occurred directly on the device. Using the point-of-care blood analyzer reduced the time doctors spent waiting for results of blood tests. The shorter time however did not improve the clinical outcome of patients thus indicating that the time taken to wait for results did not have an impact on the treatment of patients (Kendall et al. 1998).

Prause et al. (1997) investigated whether pre-hospital patient care could be improved through the use of a point-of-care device for measuring blood gases. The device was used by health professionals working in emergency medicine. The results obtained showed that they could manage cardiac failure more quickly because data was provided quickly and reliably from the device. A typical test for electrolytes took 70 s while obtaining blood gases took 160 s. There were some cases (although the number was not given) when recalibration of the device was needed and this took a further 25 s.

Additional features such as faster test results (between 20 – 60 s) and memory functionality (storage for up to 300 results) and a smaller size were noted to describe the enhancement of new generation glucometers compared with old ones (Weitgasser et al. 1999).

Evidence on the timeliness of data related to the speed of generating results on devices; however the key aspect of this depends on whether users of point-of-care devices act on the data quickly.

2.3.1.3 Relevance to test requirements

Salustri and Trambaiolo (2002) described a hand-carried cardiac ultrasound (HCU) device which provided 2-D details on features of the heart. These included: size of the chambers, ventricular hypertrophy (which can result from hypertension) and ejection fraction; size and dynamics of inferior vena cava. In a case-study comparing measurements of standard echocardiography and HCU for screening hypertensive patients, Salustri and Trambaiolo (2002) concluded that HCU devices could be used for diagnosing ventricular hypertrophy because sufficient detail was provided on the device to enable health professionals to interpret the images.

Biehl and Velten (2008) indicated that generic challenges within primary care affecting the development of point-of-care devices are related to developing precise and 'robust' devices that are straightforward to use. Biehl and Velten (2008) also add that automatic calibration and the ability to test multiple components are advantageous.

2.3.1.4 Storage of data

Burkhart et al. (2007) carried out a study over a period of 16 weeks evaluating how regular peak flow monitoring would affect children suffering from asthma. The authors found that the children's awareness of their condition was increased since the following were reduced: the number of asthma episodes, the number of visits to the health professional or clinic due to asthma problems and the number of school days missed. The Accutrax personal diary spirometer was used to measure peak expiratory flow and forced expiratory volume in 1 second. The device recorded both the date and time and provided storage facilities for the results although users were asked to manually record the data into a diary initially.

A report by PDS/Ferraris Respiratory (2004) described a hand held lung function monitor which could measure the peak expiratory flow (PEF) to indicate whether the user was likely to face an asthma attack. One of the features present on the monitor was memory facilities to store the results.

The data from the GlucoPhone (an integration of a glucometer and a mobile phone) was stored in a server that was linked to a website which was available to patients, parents and health professionals (Carroll et al. 2007).

A recent review of 100 glucometers by the authors investigating informatics on modern glucometers available between 1998 and 2008 showed that all glucometers had memory facilities thus indicating that blood glucose results do not need to be manually recorded by users (Ajai et al. 2009). In addition to blood glucose results, averages were calculated based on the stored values and these ranged from 7, 14, 21, 30, 60 and 90- day averages.

2.3.1.5 Transfer of data from devices

The Accutrax personal diary spirometer used in the Burkhart et al. (2007) study had the capability for results to be downloaded to a computer for further analysis, after users had been trained. However, the medium of downloading was not noted in the study (i.e. via wireless or wired connections).

Cohen et al. (2006) noted that the download feature on glucometers was being used thus removing the need for manual recording of the data in a logbook. This demonstrated that further data analysis could be done to provide information to users on the trends identified within their data. A caveat was given that users however needed to maintain the right date and time on their glucometer to ensure its accuracy. There was a tendency that the date and time needed to be reset the first time the glucometer was used and when batteries were changed.

A pilot study considering a prototype device known as the GlucoPhone which helped adolescents in monitoring blood glucose levels was investigated by Carroll et al. (2007). The authors established that users found the device easy to use and it helped in better diabetes management. On carrying out the test, data was initially displayed on the phone before it was transferred to a server.

A hand held lung function monitor by PDS/Ferraris Respiratory (2004) also had the capability to download results to external software where trends could be seen from the data.

Prause et al. (1997) explained that the blood analyzer had the functionality to download the results thus providing the scope for data to be manipulated away from the device however details of how the data was utilised was not given.

Apostolopoulos et al. (2007) conducted a study to investigate the usability of technology in aiding patients in self management of diabetes. To transfer the results to the health professionals, patients were given the option of either downloading their results themselves, sending it via the internet, phoning the health professional at the clinic with their results or sending their results via SMS using a mobile phone. Data was not further analysed on the device hence the need for a software application.

Finkelstein et al. (2000) described asthma patients using a spirometer which measured the volume of air inspired and expired by the lungs. Users initially entered answers to questions which categorised their symptoms based on a scoring method learnt by them into a palmtop computer. On completing the questions, users were prompted to perform spirometry tests. A button on the spirometer downloaded the results into a palmtop computer. Data was also transferred to a central clinical information system for further analysis.

The OneTouch UltraSmart glucometer allowed results to be downloaded from the device to a PC where software (OneTouch Diabetes Management Software) was used to further manipulate the data.

A non-invasive glucose monitor known as the ‘GlucoWatch Biographer’ was approved by the FDA (Food and Drug Administration) in 2001 (FDA, 2001). However it is no longer being manufactured therefore limited information was available. It was designed to complement rather than replace finger-prick tests. Its purpose was to obtain glucose levels readings at regular intervals (i.e. every 20 minutes) and track patterns therefore detecting trends. It had a capability to transfer results to a computer.

2.3.1.6 Interoperability of devices

Garguilo et al. (2007) examined interoperability in the context of medical devices for acute and continuing care within the hospital environment. The authors identified that a generic communication standard was needed. However, they noted that several standards existed for different layers for communication of devices and medical systems. Schrenker and Cooper (2001) noted that in order for devices to exchange data, “they must speak the same language grammatically and semantically”.

Standards exist for communication of medical devices and these are classified under the ISO/IEEE 11073 family of standards. The ISO/IEEE 11073 standard defines the “information model”, which includes the device attributes, range of values and the way data is accessed. Part 10417 of the ISO/IEEE 11073 standard defines communication for plug-and-play interoperability between glucometers and data handling devices such as mobile phones, computers, personal health appliances and set-top boxes (ISO/IEEE, 2009). Part 30200 of the ISO/IEEE 11073 standard, defines a standard for medical devices that connect with a cable to a data handling device (ISO/IEEE, 2004a). Part 30300 of the ISO/IEEE 11073 standard defines a standard for wireless communication through infrared (ISO/IEEE, 2004b). Although the ISO/IEEE 11073 standard is for new devices, existing devices can also be modified to comply with it.

These standards are targeted at ensuring that data obtained from medical devices can be “archived, retrieved and processed” using a range of applications without the need of a wide range of software for data conversion and without compromising data integrity or misplacing data.

2.3.2 Information

In this section, information available from point-of-care devices is briefly summarised in terms of information analysis, storage, presentation of information and timeliness of information. In contrast to data, relatively little peer-reviewed literature is available concerning information and point-of-care devices.

2.3.2.1 Information analysis

LifeScan (2008b) provided diabetes management software for data retrieved from OneTouch glucometers. After the data has been downloaded, a summary is provided to the user. It includes the total number of results transferred, the number of duplicate results, unsuitable or unsupported results. The software allows glucometer results to be analysed to identify trends over different time periods.

2.3.2.2 Storage

According to the National Institute of Diabetes and Digestive and Kidney Diseases (2001), some of the features of the 'GlucoWatch Biographer' included: an alarm to alert the user if the blood glucose level is outside the normal range and a memory function thus implying storage of information. One can infer that a computational algorithm which may involve statistical techniques would be implemented on the device to help detect patterns in the results.

2.3.2.3 Presentation of information

The OneTouch UltraSmart glucometer (LifeScan, 2006) allowed data to be annotated on the device based on diet, medication, exercise and the individual's general health. It also displayed the following message on the device when the result was lower than the predefined target, "Do you need a snack"? In addition, OneTouch UltraSmart displayed a graph to allow users to see the trends of their data by displaying a graph on the glucometer.

In a study by Carroll et al. (2007), blood glucose results were stored off-device on a server. They were accessible via a website, on which the results could be presented in several different formats. The authors concluded that the GlucoPhone was helpful to users in managing their condition because they contacted their doctor less frequently and the device was also easy to use.

The OneTouch Diabetes Management Software by LifeScan (2008b) had eleven different reporting formats to visualise the data. They included: logbook, summary, pie chart, glucose trend graph, standard day, data list, health checks, average readings, exception, insulin and histogram. Some of the reports produced by the software used colour, shading and typefaces to highlight data that were outside the specified ranges. The following features were available once users had concluded viewing their data: printing, emailing or faxing the report to their health professional. This meant that health professionals could have access to patient results before the next scheduled appointment with patients but this was at the discretion of the patient.

2.3.2.4 Timeliness of information

St-Louis (2000), noted that a benefit of POCT was provision of “immediate access” to information since some of the steps associated with standard laboratory testing are removed; as a result, the ‘test turnaround time’ (TAT) is reduced. The shortening of the TAT implies that users of POCT devices will receive information to make decisions on their health quickly.

Kendall et al. (1998) also showed that POCT increased the speed of decision making because results were generated in a quicker time.

2.3.3 Decision support systems in health

In this section, the current state of decision support systems in health is reviewed. It considers, health professionals role in decision-making, how health professionals are assisted with decision tools and finally assisting patients with decision tools.

2.3.3.1 Health professionals role in decision-making

The expertise of the health professional rather than computational methods helped to diagnose patients with a heart condition in the paper by Salustri and Trambaiolo (2002).

In a 2003 patent, a diabetes management system was proposed which incorporated the use of a mobile phone to transmit glucometer results to a health professional. The health professional then provided advice to the patient regarding the type of treatment they should administer Moerman et al. (2003). Again in this scenario, support is provided through the expert opinions of health professionals rather than through devices.

2.3.3.2 Assisting health professionals with decision tools

Sullivan and Wyatt (2005a) described an example of how decision support tools were being used to aid and complement the clinical diagnosis of a doctor within a GP surgery. A clinical information system providing decision support to the health professional (GP) was described. The article described how informatics resources could be used in patient management by considering the patient’s overall health rather than only the symptoms presented by the patient at a particular consultation.

The electronic system provided a means of highlighting issues through the use of prompts. In addition, alerts could also be triggered by the system informing the doctor that the new symptoms recorded could also affect the management of the patient’s long term condition, hence allowing “proactive” rather than reactive care.

Sullivan and Wyatt (2005a) further discuss the advantages of computerised guidelines over paper ones. These included accessibility of information; reduction of ambiguity of information; customizing guidelines to suit the patient; and sending prompts to the doctor. In summary, Sullivan and Wyatt (2005a) give a warning that although a variety of other information sources are available to patients, they must not be used in isolation and a doctor was still needed to help clarify issues.

Liu et al. (2006) considered a decision tool as “an active knowledge resource utilizing patient data to generate case-specific advice supporting decision-making about patients by health professionals, patients or those caring for them”. This definition suggested that the use of decision tools within health care could be extended from a sole use by health professionals alone to others. Liu et al. (2006) provide some reasons why decision tools may not have been used in the past. These included:

Health professionals already operating best practice and using a DSS would not enhance patient treatment.

The output provided by the DSS was inaccurate or it did not provide enough details to influence health professionals in changing their practice.

The DSS did not produce a useful output in the time health professionals needed to make a decision.

2.3.3.3 Assisting patients with decision tools

Ruland (2004) noted that patients should be involved in decision-making on their health, but that the issue of safety needed to be considered. Literature suggested that the main causes of error relate to unavailability of relevant data; “misinterpretation of data” and “ineffective communication” (Reason, 1992). Ruland (2004) considered the more recent development of decision aids that have helped to support shared decision-making between patients and health professionals. Decision aids should allow people to choose the appropriate option, based on the information available, by improving their knowledge of the condition, but without at the same time raising their anxiety levels (O’Connor et al. 1999).

Gustafson et al. (1999) also noted the need for information to aid people diagnosed with prolonged conditions in their decision-making. Gustafson et al. (1999) described a computerised DSS that enabled patients to access multiple information sources in order to make informed decisions.

The PDS/Ferraris (2004) report about the device for measuring PEF noted that patients could be trained in interpreting the results obtained based on guidelines provided by health professionals.

Burkhart et al. (2007) discussed a manual decision support system for managing asthma. A written guideline in the form of a traffic light system was provided for each person in the study for them to manually compare actual PEF with expected PEF results so that necessary actions could be taken. The result range which was specific to each individual was based on their recordings in the diary. A PEF value below 50% of the individual's personal best was classified into the 'red' region and it signified that medical assistance was urgently needed, while a PEF value between 80% and 100% of their personal best was classified into the 'green' region as it represented good asthma management. This type of monitoring allows for real-time decision support for the patient.

Similarly, in a study by Apostolopoulos et al. (2007) investigating self management of diabetes, where patients were trained in how to draw conclusions and manage their condition from their blood glucose test results on a daily basis. After transferring the results, it was not clear in the report of the study whether health professionals could then provide real-time advice or whether patients received feedback at a later date. It seemed that the primary decision-maker was the patient since monitoring was on a daily basis.

2.4 Discussion

The goal of "point-of-care device informatics" is to help provide data, information and knowledge for diagnosis, treatment or monitoring of patients with a particular medical condition. Translating knowledge into actions by patients will require that their decisions are supported.

2.4.1 Improvements for data

Efficiency of generating data is a factor for consideration in point-of-care device informatics and technology will play a role in this. For devices solely used by patients, results need to be provided in a timely manner so that patients will be able to draw conclusions from them in a short time frame without delay. The same rule of efficiency is also applicable to devices used by health professionals.

Data storage is an important aspect of providing historical data to the patient, however access and security issues must be considered to ensure patient confidentiality and so that patient data is not tampered with or accessible to unauthorised personnel. Data must be stored in a structured way to ensure that it can be retrieved in an efficient manner.

2.4.2 Sufficiency of information

Memory functionality on point-of-care devices is the closest to information generation, as stored results once reviewed, form the basis of information presented to users to help them take the necessary step in the management of their health. An example of this was seen in glucometers for diabetes monitoring.

A consideration is the level of detailed information provided on point-of-care devices as this will vary depending on the intended users of the devices. For example, devices for health professionals may be designed to display more detail and use medical vocabulary since they have more expertise and experience to interpret data than the ordinary user. Only appropriate information should be presented to users so that they are not overloaded with unnecessary details. This level of detail could be determined by seeking advice from health professionals. If the device is capable of displaying reports, the views of reports should be customisable to the user's preference.

Transfer of data was the key to generating information and this was seen from the devices reviewed. Software external to the device was used to manipulate data so that it could be presented in multiple ways to users. Future devices could incorporate faster data transfer by using faster connections. A wireless connection is also suggested as a feasible solution since it makes the whole process more seamless thus following the trend of new generation devices. Compliance of devices to existing standards for connectivity is essential to promote interoperability, prevent the use of many types of software applications and avoid data corruption.

It is therefore necessary to define the meaning of sufficient information in the context of using point-of-care devices as it varies on the user of the device. Even within the same category of users, there will be varying degrees of knowledge as newly diagnosed patients monitoring a long term condition may need more support at the early stages than someone who may have established a regular routine. Another issue to consider is whether or how this information could be quantified, in the sense that quantification would add further value for the user. However that is beyond the scope of this paper.

Most point-of-care devices seen in this review are fulfilling a basic requirement of providing a result (measurement) for the condition they are designed to monitor.

2.4.3 Information synthesis

Shepherd (2007) defined information synthesis as obtaining information from numerous sources to combine it to generate something new. In the context of point-of-care devices, data generated from the device can be brought into contact with a knowledge source related to the condition being tested and an algorithm can then be applied to generate new information. Information synthesis sounds straightforward theoretically; however, Shepherd, raised two issues regarding its practical aspect. Firstly, “semantic interoperability” which refers to ensuring that information exchange between systems is understandable. This means terminology between devices and information systems must be standardised to ensure the accuracy of information exchange. Secondly, “knowledge morphing” which is an “intelligent fusion of contextually and functionally related knowledge objects that may exist in different representations". "Semantic interoperability" and "knowledge morphing" will play an active role in a DSS for point-of-care devices because information generated on them will need to be customised for the users that is, the information given as output must be relevant to either the patient or health professional depending on who is requesting the information.

From this review, limited evidence of information synthesis was found taking place on point-of-care devices. In order for this to happen, a proposal is that after data transfer to external software, both the data and other known facts about the condition being monitored can be combined to produce information for users to make informed decisions.

2.4.4 Knowledge and decision support

It is argued here that the knowledge domain relevant to point-of-care devices lies with integrating a level of decision support or associated software on them; however, limited evidence was found supporting this happening on devices, though, DSSs already exist in health care for health professionals. Literature also demonstrated the use of decision support tools for health professionals although a caveat is given that they must not be used in isolation, rather as a guide. Literature demonstrating decision support tools for patients was limited but it will be an emerging area in the future since examples were seen of patients being trained in how to interpret their results for both asthma and diabetes management.

2.4.4.1 Decision support for health professionals

From the literature reviewed, no expert systems were found existing on devices; however semi-automated DSSs existed in which the user had to make a judgement about the suggestions proposed. Health professionals could play a part in helping to develop advanced automated DSSs. Their input would be vital in limiting unnecessary errors that may be introduced through computer programs. Where fully-automated systems cannot be used, dedicated health professionals could be devoted to analysing the data.

Ethical issues also require consideration, as automated decision support from devices, if inaccurate, may cause a less optimal course of action to be taken, which may ultimately affect a patient’s well-being.

From the decision-making process in arriving at a diagnosis, as described by Sullivan and Wyatt (2005b), the diagram in Figure 2-3 was constructed as a generic decision-making process. It describes the steps taken to make an informed decision.

The patient presented their symptoms and the doctor observed other indications during assessment of the patient. Both of these are considered before arriving at a possible diagnosis. The process of reaching a diagnosis can either be by hypo-deductive reasoning or inductive reasoning depending on the level of experience of the doctor.

A possible diagnosis enables the doctor to continue with the appropriate procedure to treat the patient; however a differential diagnosis (i.e. other diagnoses which may also result from the symptoms presented) may also be made at this time.

Subsequently, the patient may be further examined and/or medical tests may be carried out to confirm the illness. This results in a particular action or treatment being administered to the patient. Sometimes multiple conditions present similar symptoms; hence the initial diagnosis may be incorrect thus resulting in a loop where another possible diagnosis is given. Incorporating a part of this process into a computerised DSS may aid in speeding up the overall decision-making process.

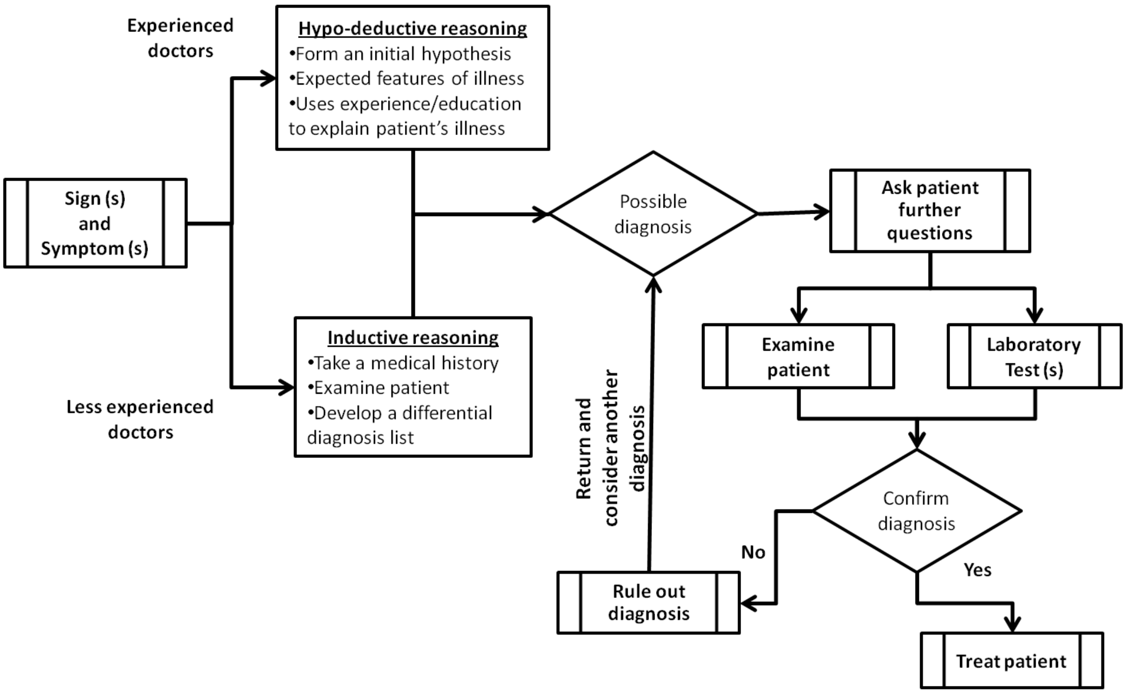


Figure 2-3 – Example of a decision-making process by the health professional

2.4.4.2 Decision support for patients

In the case of providing a computerised decision support tool for patients using point-of-care devices, the same principle used when doctors make a diagnosis may be applied. A glucometer is used as an example. Currently, their mode of operation is they provide blood glucose results to the user. If decision support could be incorporated on the device it could take the following form.

Into the glucometer would be incorporated a range of expected values that have been predefined and agreed by both patient and health professional. The user performs the test which is recorded and stored in the glucometer. Depending on whether the result meets the requirements will then determine the subsequent steps. If a result within the given range is seen, there is no need for the patient to take an action. However, if an extreme or out of range result is obtained, a set of questions could be posed to the patient to help ascertain the cause of such a result. The predefined result range could be combined with a DSS algorithm and possible suggestions of how the patient could improve their result would then be displayed.

Figure 2-4 is a flow chart of the steps which would be required in such a process. To date, such a system does not exist on glucometers. The closest to it, involves the tagging or annotation of results to allow further discussion of results when the patient visits their health professional.

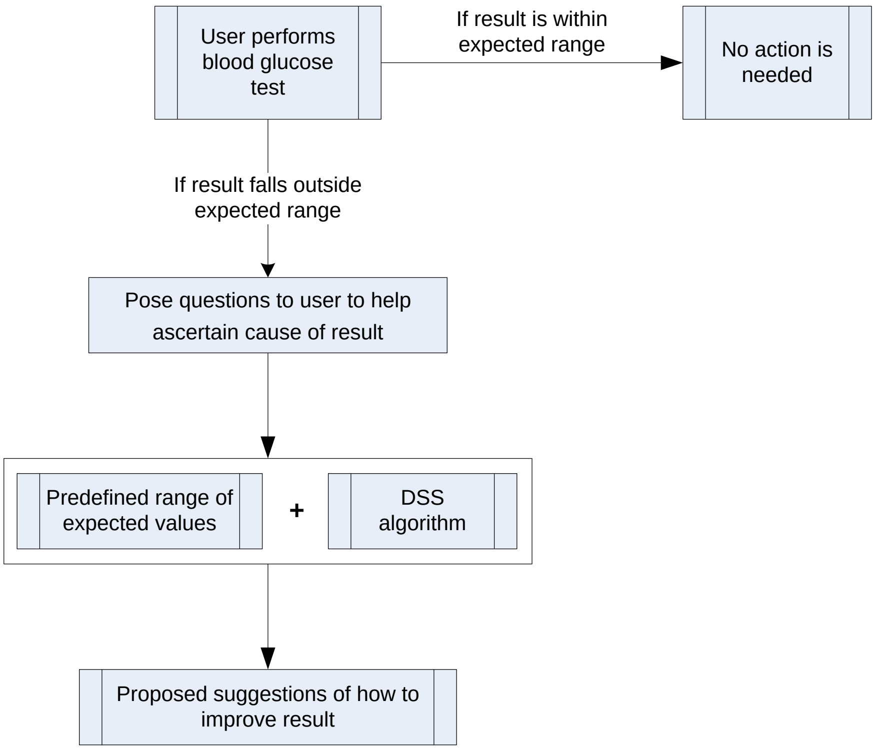


Figure 2-4 – A proposal of on-device decision support for patients

Although a description has been given of a possible method of incorporating decision support on devices, evidence from literature suggested that data was transferred to external software to provide information to the patient. It is therefore suggested that in order for decision support to be fully functional, it could only occur away from the device.

2.4.4.3 Features of a decision support system

A DSS, whether simplistic or complex, is suggested for all the devices mentioned in this paper as it would help to provide initial suggestions to aid users in determining the most appropriate diagnosis and as a result, the optimal therapy can be administered. Decision support could also play a role in the external software used to manipulate the data as it could help enhance decisions made by health professionals.

The approaches seen in the literature to support users making appropriate decisions were as follows: The functionality to download data from point-of-care devices to external software so that it could be further manipulated. This facility existed in glucometers, spirometers and blood gas analyzers; providing access to results via a web portal; educating and training users in how to interpret results. This is a way of empowering patients to enable them to manage their health consistently.

2.4.4.4 Factors limiting decision support on point-of-care devices

One hypothesis for the limitation of on-device information display may be that existing point-of-care devices are limited in the computational technology they can incorporate. Mobile phones and PDAs are small devices with advanced technology, as they are portable and can have sophisticated functionalities; hence their usage as data transfer aids for point-of-care devices could be incorporated into the overall system for decision support. However regulatory boards exist (FDA [USA] and MHRA (Medicines and Healthcare products Regulatory Agency [UK])) of which approval is required before new medical devices can be released for general usage.

There may also be an economical reason if the state-of-the-art technology has a potential to be expensive, it may not be affordable to users. Biehl and Velten (2008) proposed lab-on-a-chip (LOC) technology for POCT devices due to their compact size. However the challenges that must be overcome are the cost of development and approval from governing bodies.

2.5 Conclusions

This paper reviewed the current state of “point-of-care device informatics” i.e. data, information and knowledge that could empower patients with long term conditions to better manage their health.

For data, important issues identified were: the efficiency of generating data, the availability of structured data storage, timely access to data and data security.

Information had to be sufficient, a meaning that will vary even within user groups. Memory functionality, the level of detail and appropriateness of information were important issues. To generate adequate information, data transfer off a point-of-care device was of key importance, because of the lack of on-device information generating capability. However, information synthesis was found to be very limited, with a lack of semantic interoperability and knowledge morphing capabilities.

Providing knowledge on devices relates to incorporating decision support on them. Decision Support Systems (DSS) aimed at the health care professional as user have been considered at the generic level, but little yet exists in DSS in which point-of-care devices play a role.

DSS aimed at patients barely yet exist. The current emphasis is on educating and training users in how to interpret results. Aspects which limit patient-oriented DSS include: patient safety, on-device computational power, technological complexity, regulatory approval and device ergonomics. A patient-oriented DSS will help empower them to play a greater role in their health.

3 Informatics-Based Product-Service Systems for Point-of-Care Devices

Abstract

Informatics related to point-of-care devices denotes the ability to translate stand-alone biological data into meaningful information that can be interpreted to enable and support users in taking the most appropriate steps to aid in managing their health. This paper considers small point-of-care devices used outside healthcare environments, and presents glucometers as an example. The paper seeks to evaluate the current level of servitization of point-of-care testing devices and considers whether they are, or could form, the product-core of a product-service system. The type of product-service system, its informatics requirements, and the services such a system could provide are also considered.

3.1 Introduction

3.1.1 Point-of-care biomedical devices

Medical devices are used to diagnose, screen, monitor or treat patients. Their primary aim is not 'pharmaceutical activity', rather a tool to 'deliver a service' (Summerhayes and Sivshankar, 2006).

Point-of-care systems offer, according to the National Institutes of Health, 'laboratory and other services to patients at the bedside' which may include 'diagnostics and laboratory testing' (MeSH, 2011a). Point-of-care testing (POCT) has been defined as 'diagnostic testing at or near the site of patient care' (Kost, 2002). Point-of-care devices form a sub-class of medical devices used to carry out these tests. This paper concentrates on such devices.

The benefits of point-of-care testing rely on the increase in the speed of processing and analysis of biological samples, the speed at which data from the tests may be obtained by the user, or healthcare professional and therefore, the more timely use of this information as an aid to reach diagnosis and treatment.

Examples of commercially available POCT devices and their associated services include:

- Blood gas monitoring devices: to monitor blood pH, oxygen concentration, carbon dioxide concentration and the concentration of certain electrolytes, as an aid in diagnosis for several medical conditions.

- Blood glucose monitoring devices: to measure the concentration of glucose as an aid to diagnosing hypoglycaemia or hyperglycaemia.

- Cardiac marker monitoring devices: to identify markers in the blood as an aid in diagnosing patients with acute coronary syndrome, venous thrombo-embolism and congestive heart failure (Roche, 2008b).

- Haemoglobin monitors: to measure haemoglobin concentration in the blood, as an aid to the diagnosis of anaemia.

- Hand-carried cardiac ultrasound devices: for obtaining echocardiographic images for the assessment of cardiac function (Salustri and Trambaiolo, 2002).

Point-of-care devices can be used in different settings including: the healthcare environment, the home environment and remote locations such as at the scenes of accidents and in battlefield situations. Point-of-care devices used within the healthcare environment tend to be large and fixed in a permanent location. Those used in the home and in remote locations tend to be smaller, compact, transportable and sometimes disposable.

3.1.2 Medical/Health informatics

'Medical informatics' or 'health informatics' are interchangeable terms used to describe the application of computational methods to aid in maintaining the general well-being of the body. Informatics is the application of computational methods to data in order to:

- Classify them.
- Store in a repository once classified.
- Retrieve the data in an efficient manner when needed. The method of storage will also ensure that they can be retrieved in an efficient manner, e.g. by creating indexes in the data or making associations in the data. Efficiency in this context denotes speeding up the rate at which the process occurs to deliver the information needed.
- Disseminate the data effectively to the resource requiring it.

Informatics related to POCT devices refers to analysing the data generated from it to aid interpretation by the user, so that they are able to make the most appropriate decision regarding the subsequent steps to aid the management of their condition effectively. Informatics will help the user identify the changes that may be needed for their diet, medication and current lifestyle habits.

3.1.3 Product-service systems

A product-service system (PSS) 'is an integrated product and service offering that delivers value in use' (Baines et al. 2007). In a PSS, the product and the service are considered as a single offering. A PSS can be classed as a special form of 'servitization' in that it emphasises utilization or performance more than simple product ownership.

Three sub-classes can be discerned within PSS: product-oriented PSS – the product is sold to the customer but with additional services; use-oriented PSS – the use or availability of the product is sold to the customer, not the product; result-oriented PSS – a result or capability is sold to the customer, not a product, though the product is still required to support this capability (Baines et al. 2007).

A service can be described as something done in relation to a product. It may come in the form of maintenance or the supplying of extra products/parts. Baines, et al. describe it as an activity done for others with an economic value (2007). Services provided through point-of-care devices should aid in diagnosing, monitoring and improving the health of the user.

'Servitization' is defined as the development 'of product identity based on material content to a position where the material component is inseparable from the service system' (Morelli, 2003). PSS can be seen as an example of servitization of products.

In PSS terms, point-of-care devices would be the product in the offering. For such products, the degree of servitization of a PSS offering would strongly depend on the level of health informatics support for services associated with the device. This may govern whether a point-of-care device has the capability to form part of a PSS without redesign and if so, at which level (product-oriented, use-oriented or result-oriented) the PSS may function.

3.2 Aim

This paper concentrates specifically on the concept of PSS for those POCT devices designed for use in the home environment.

It investigates the following questions:

- What is the current level of servitization of POCT devices for home use?
- What are the driving forces to change this level of servitization?

- How does this level of servitization compare to that required for a result-oriented PSS offering?
- What informatics resources are in place or would be required in these devices to support a result-oriented PSS?
- What would be the benefits to users of such new services?

3.3 The current model of usage of home environment point-of-care devices

Glucometers are used on a regular basis by people with diabetes to monitor their blood glucose concentration and to identify if it is within an appropriate range. Both hypo- and hyperglycaemic glucose concentrations carry severe medical risks.

Glucometers serve as an interesting example of the current model of use of POCT in the home environment because:

- They are relatively ubiquitous as examples of point-of-care devices.
- Their rate of innovation as products is relatively high. For example, Weitgasser, et al. (1999) compared four old generation and four new generation models of glucometers in terms of their ‘analytical’ performance. They found that newer devices were smaller, more aesthetically pleasing, easier to use and gave more accurate results (Weitgasser et al. 1999). They noted that the improvement in functionality could be attributed to technical improvements in glucometers and the lower blood volumes used for measurement.
- They provide a clear example of a situation in which informatics-based services would be of benefit to the user. Nobel has discussed how improved information generation and exchange is needed to help reduce the ‘morbidity and mortality’ of diabetes (Nobel, 2006). Monitoring diabetes is particularly suited as an application for informatics because ‘its management is characterised by quantifiable outcomes’ (Nobel, 2006). Informatics would aid

in improving those methods that may currently be manual and un-automated. Calculations needed to ascertain a diagnosis could be computed quickly thus allowing treatment to be administered to patients at a quick rate.

Currently, glucometers are bought as a complete, packaged product consisting of the glucometer, a lancet, test strips and control solutions. The cost of a glucometer and accessories currently ranges from £5.11 to £16.39 (ChemistDirect, 2010). The test strips supplied in the pack are limited; hence the user has to make an additional expense to replace them. Operating instructions are provided through a user manual. Therefore, users generally do not need technical support when using glucometers apart from when the glucometer malfunctions. An example of this is when incorrect units of measurement, for a particular user's country, are displayed on the glucometer. In such a case, the user is simply instructed by the manual to return the glucometer to the manufacturer for an exchange.

In a recent study by the authors the state-of-the-art in informatics in glucometers was evaluated (Ajai et al. 2009). This established that many glucometers provided other information in addition to blood glucose concentration. The majority of the glucometers provided error messages indicating that part of the testing procedure had not been followed properly. These included: faulty test strips, the size of the blood sample provided and the temperature at which the test was carried out. Certain glucometers displayed a graphical representation of blood glucose concentration plotted against time so that users could monitor trends.

A number of glucometers had data management software, which provided off-device data analysis. This included statistical analysis of the data and the facility to generate trend graphs and the ability to easily identify outliers in the data. An 'electronic logbook' facility was also present to allow the users to record their results and medications (Ajai et al. 2009).

Some glucometers were supplied with extended measurement functionalities above those of blood glucose measurement. In a survey of 100 glucometers, 11% provided other functionalities. 8% allowed a blood pressure measurement to be obtained. 1% measured the Ketone level in the blood, while 2% measured Uric acid.

The observations noted above suggest that glucometers are currently operating as stand-alone products and do not yet form the product core of product-service systems. However, the extension of informatics and measurement functionalities by a number of manufacturers suggests that the degree of sophistication of this example of POCT devices is tending towards the point where their future incorporation into PSS could become a reality.

3.4 Drivers for change

In this section, three sets of drivers for change are considered. Firstly, drivers from the literature, for example the ageing population, secondly, drivers from government, the UK government is taken as an example and thirdly drivers from user expectations.

3.4.1 Drivers from literature

Wakefield noted that there were multiple drivers for change in healthcare (Wakefield, 2003) and some of these were echoed by Saranummi et al. (2006). Although the drivers by Wakefield (2003) were mentioned in relation to the nursing sector, they could also be applicable to POCT devices. They included:

- Cultural diversity (Wakefield, 2003) – society is becoming increasingly multicultural with more integration between different races and ethnic origins. Consequently, healthcare services are being tailored to meet this transition.
- Ageing population ((Wakefield, 2003), (Saranummi et al. 2006)) – the trend in the age of members of society is generally becoming older. The World Health Organization (WHO) notes that an ageing population is a challenge that will impact the current century and requires ‘joint approaches and strategies’ (2008c). A WHO report noted that healthcare for older people should ensure that they remain independent and continue to play a role in their families and communities (2004). Thus, healthcare ought to be adapted to look after this

group of the society, as they will need long-term care. As a result, care can be provided to patients in a number of alternative settings rather than the traditional healthcare environments.

- New services and technologies (Wakefield, 2003) – Wakefield noted that the challenge of time and distance within healthcare was ‘irrelevant’ because of the use of technology (2003). Information technology has been successfully applied in other industries such as banking, travel and communications, for instance, people are able to monitor their bank accounts and carry out transactions online through the internet; however healthcare informatics is still lagging behind (Altman, 1997). Although this statement is not applicable to traditional healthcare environments (hospitals/GP surgeries), within the home, healthcare informatics is not advanced as highlighted by the evaluation of glucometers (Ajai et al. 2009). In most glucometers, informatics was limited to simple data processing (averaging). Health informatics for the home therefore needs to be streamlined to improve the delivery of services to the level of other sectors.
- Change in lifestyle habits (Saranummi et al. 2006) – Nowadays, people are interested in playing a more active role of managing their health which has been made possible by easier accessibility of information (Department of Health, 2006a). In an information-driven society where people desire information at their fingertips in any location, informatics will help to improve access to information by allowing the wireless transfer of data between sources etc.

3.4.2 Plans by UK Government regarding changes in healthcare

A number of white papers by the UK Department of Health highlighted plans to change the administration of healthcare. These are: *Saving Lives: Our Healthier Nation* (Department of Health, 1999), *Choosing Health: Making healthy choices easier* (Department of Health, 2004)*, Our health, our care, our say: a new direction for community services* (Department of Health, 2006a). The relevant aspects of these white papers are detailed in the subsections below, along with a consideration for the purposes of this paper of what these imply for future health services. These future services are listed as questions that need to be used as a form of assessing whether they meet the aims of the government.

Statement	"Reducing risk and staying healthy" (Department of Health, 1999).
What this means in more detail	Making lifestyle changes such as: eating a healthy diet, reducing/stopping smoking, taking regular exercise, controlling one's body weight and avoiding excess alcohol. Public education campaign on stopping smoking and smoking cessation services.
For future services	Are the services helping the user reduce the risk of developing a long term condition or to stay healthy? Is information provided to the user about different diseases? Is information provided about how the user can improve their diet or other lifestyle habits and what could be done to reduce the risk of developing the disease? Is information presented to the use in the most suitable manner?

Table 3-1 – Action point 1 from *Saving Lives: Our Healthier Nation*

Statement	"More effective treatment" by providing access to specialist services (Department of Health, 1999).
What this means in more detail	Creating National Service Frameworks (NSF) for several conditions including diabetes, coronary heart disease (CHD) and chronic obstructive pulmonary disease (COPD). A NSF helps to establish requirements for care and provides information about the "best" treatment and service based on evidence available. It also outlines the strategy that organisations should follow (NHS Choices, 2008). Improving the control of certain conditions which are risk factors for some diseases by educating people, reviewing the screening process and partnering with the food industry to explore reducing unhealthy ingredients within processed foods.
For future services	Are there specific services for different long term conditions? Are the services accessible by the people who require it? Are health professionals able to deliver a more focussed service? Is the rate at which the patient is receiving appropriate information fast enough thus helping to prevent exacerbations?

Table 3-2 – Action point 2 from *Saving Lives: Our Healthier Nation*

Statement	“Integrated action” (Department of Health, 1999).
What this means in more detail	A whole generation approach is needed to improve lifestyles and reduce risk factors. Tackling underlying social, economic and environmental conditions (by reducing health inequality through better education). More effective, high quality health services. Healthy citizens initiative (through NHS Direct).
For future services	Is the service affordable to all? Are there adverts through multiple forms of media to inform the general public about the services?

Table 3-3 – Action point 3 from *Saving Lives: Our Healthier Nation*

Statement	"Support informed choice" (but exercise a special responsibility for children who are too young to make informed choices themselves) (Department of Health, 2004).
What this means in more detail	Raising awareness about issues related to healthy living which includes: food and lifestyle choices (exercise, smoking and alcohol consumption). Ensuring information is available to all members of society by presenting information in many formats to suit the audience and ensuring clarity about message being communicated. Individual's actions must not affect health of other members of society. Provision of facilities enabling members of society to have more choice for healthier lifestyle e.g. local leisure centres, local shops selling healthy food.
For future services	From the analysis of the results entered by the user, does the service provide the possible options of the steps which the user should take? Does it raise awareness about how healthy living could improve their subsequent results? Does it have the facility to present information in a number of formats depending on the type of user? Does it provide information about local services and other facilities that may be relevant to the user? Does it provide information about other types of support that may be available to the user?

Table 3-4 – Principle 1 from *Choosing Health: Making healthy choices easier*

Statement	"Personalisation of support to make healthy choices" by ensuring that people from all classes of society have access to information, support and services (Department of Health, 2004).
What this means in more detail	"Building information, support and services around people's lives". Ensuring equal access is provided to users.
For future services	In addition to the analysis of results, from additional inputs (dietary and lifestyle information) entered by the user, does the service provide personalised options to the user?

Table 3-5 – Principle 2 from *Choosing Health: Making healthy choices easier*

Statement	"Working in partnership to make health everybody's business" (Department of Health, 2004).
What this means in more detail	Engaging the whole of society irrespective of status in issues related to health.
For future services	Does the service provide suitable information to other members of the society and not only those with a long term condition? Are other people contributing to promoting the service (not just health professionals)?

Table 3-6 – Principle 3 from *Choosing Health: Making healthy choices easier*

Statement	"Putting people more in control of their own health and care" (Department of Health, 2006a).
What this means in more detail	People will take more responsibility of their health and care. Evidence shows that "care is less effective if people feel they are not in control".
For future services	Are people aware of the steps involving the control of their condition? Are they aware of additional resources/support available to them and how to reap the benefits?

Table 3-7 – Theme 1 from *Our health, our care, our say: a new direction for community services*

Statement	"Enabling and supporting health, independence and well-being" (Department of Health, 2006a).
What this means in more detail	Empowering people by educating them so that they are more knowledgeable about their long term condition. Training people in how to monitor their condition and recognize warning signs early. Raising awareness of the services available. (50% of people with long term conditions are not aware of the services (i.e. treatment options & care plan) (Department of Health, 2006b). The information should be easily accessible to different members of the society. E.g. leaflets, interactive games (for the younger population), pre-programmed software on mobile phones, computer applications for health. Provide support locally or remotely (videos, online forums etc) so that patients know who to contact for help and advice.
For future services	Are users well informed about their long term condition? Is information readily/easily accessible to patients? What is the mode of communicating/presenting this information? Can users contact a health professional or designated carer? Are patients aware of all the services available to them and how to use them? Are patients able to make decisions regarding the next course of action to take based on their results?

Table 3-8 – Theme 2 from *Our health, our care, our say: a new direction for community services*

Statement	"Rapid and convenient access to high-quality, cost-effective care" (Department of Health, 2006a).
What this means in more detail	People should not have to wait a long time to receive treatment/care. Healthcare should be delivered in a proactive than reactive manner i.e. Push rather than Pull. More care is given to people within the community rather than in general hospitals. Healthcare could be customized/personalised for groups/individuals. Options will be provided for patients as to how and where to receive care. Healthcare services provided ought to be flexible (not everyone is available on a 9-5 basis). Examples can be seen of pharmacies being placed within supermarkets which stay open past usual working hours.
For future services	Are the services available on a flexible time basis (24/7)? What is the response time for patients to receive feedback on their results? Who provides the service? What effect does this have on the response time?

Table 3-9 – Theme 3 from *Our health, our care, our say: a new direction for community services*

3.4.3 User choices and expectations

The final set of drivers detailed here are those of user expectation. This was investigated using the specific example of the blood glucometer.

Three online forums (Diabetes.co.uk, (2010), Diabetes Forum, (2010) and Diabetes Buddies, (2010)) for people with diabetes were used a means of obtaining information. Two questions were posed to the users with the aim of ascertaining the factors that influenced their choice and features they wanted to see in future glucometers. They were:

Firstly I'd like to get some of your opinions on the glucometers you use and what factors influenced your choice?

Secondly, if you had the opportunity to influence the design of future glucometers that would be released into the market:

- *What kind of features would you like them to have that they don't currently possess?*
- *What extra information on blood glucose monitoring do you want your glucometers to provide?*

Figure 3-1 shows the factors influencing user's choice of glucometer, while Figure 3-2 shows additions for the development of future devices. In each case, the responses have been grouped into five categories based on the emerging themes from the responses. They were 'usability', 'aesthetics', 'information', 'technology' and 'cost'.

In terms of the factors influencing users' choices, there were more comments on the usability and aesthetics of the device than for the other three categories. Whereas, in terms of future devices, the comments centred on usability, information and technology.

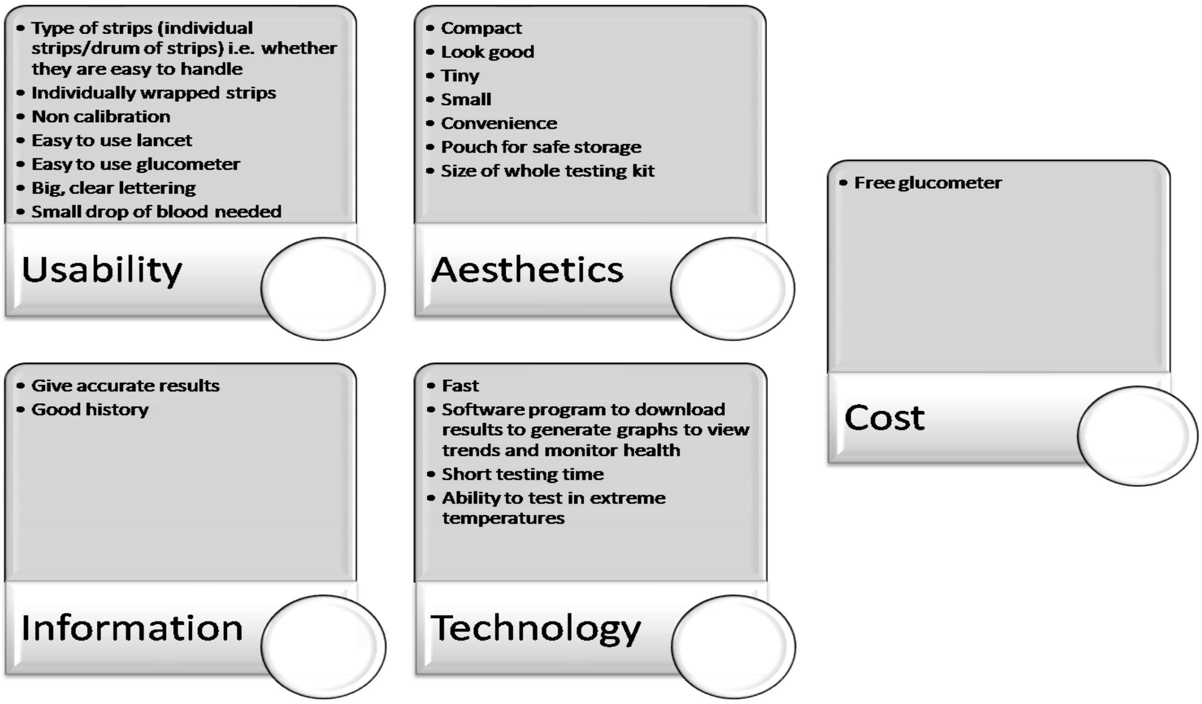


Figure 3-1 – User comments showing factors influencing their choice of glucometer

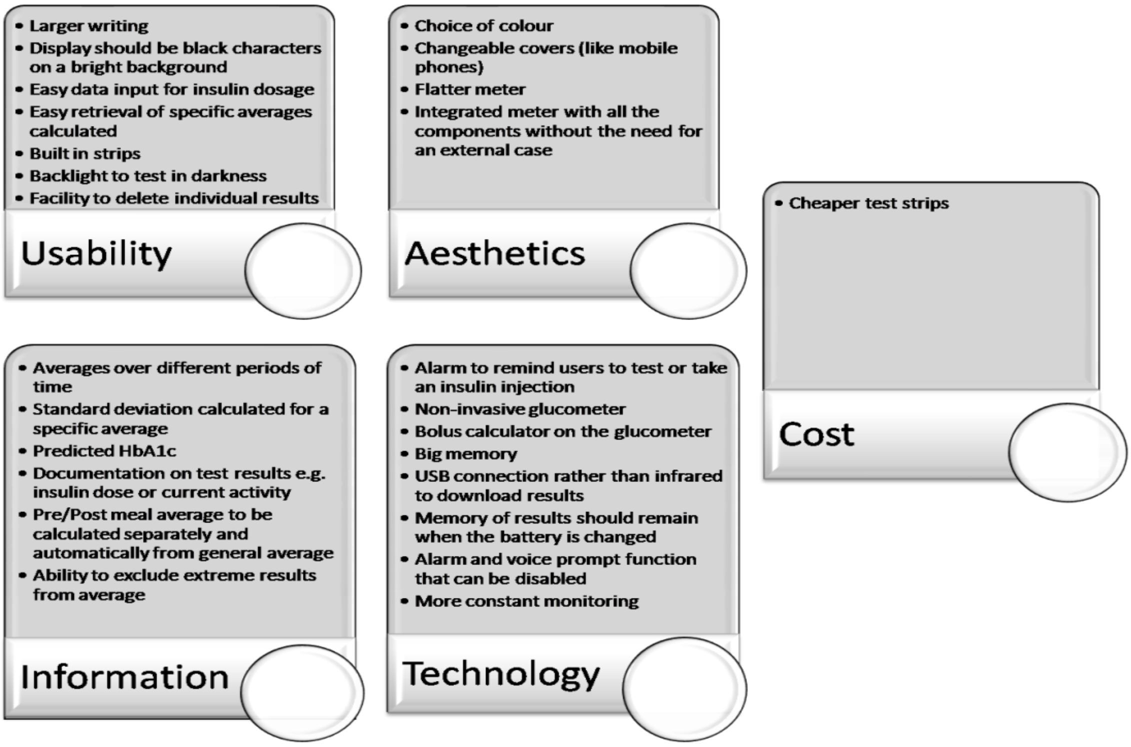


Figure 3-2 – User comments showing features that users would prefer to be incorporated in future glucometers

3.5 Use- and Result-oriented PSS for Point-of-care testing devices

3.5.1 Examples of services

Whitney (2008), noted that the development of concepts for providing information services within healthcare will be enhanced if issues are considered from a combination of the users and the companies. It is a necessity to recognise the needs from both perspectives in order to ensure that the point-of-care device and the service provided are suited to users.

Whitney (2008), also provided two interesting examples of generic future services: a ‘medication management system’ and a ‘diet assistance program’ for patients with cardiac conditions.

In the medication management system example, a service would be provided that would allow users to monitor the medication they are taking. It would remind the user to take the medication and notify them of when it had been taken, in order to prevent missed doses or overdosing. In the diet assistance example, an integrated application that monitored diet, exercise and medication for a user was envisaged. This would form the basis of a service customised to individual users. The service would offer advice, based on the individual's monitored information, on how the user could achieve and maintain a healthy lifestyle (Whitney, 2008).

Returning to the example given in the previous section it is interesting to consider what services could be provided based on a POCT device such as a glucometer. Several services that could be provided using a PSS approach are:

- Reminders for the patient to carry out their test (cf. alarm function).
- The result of the blood test (currently state-of-the-art).
- An option to allow users to input the diet and current lifestyle habits they have as health professionals can provide advice to users on ways to improve this (diet assistance). (A commercial example of this approach currently exists and is briefly discussed in the next section).
- An automated report on a regular basis (either weekly or monthly), providing feedback to user of trends in their result. This should be accompanied with advice from health professionals, or information systems, on the progress of the user and how they can maintain and improve their health condition (condition monitoring).
- The logging of extreme results, so that if there is a regular occurrence, the user is prompted to contact their health professional. Alternatively the health professional may be alerted through an automated process to contact the patient. Streamlining this would provide real-time advice to patients (acute condition alerts).

The first two services already exist in glucometers; the third and fourth services are appearing on modern glucometers while the final service has emerged through the gaps found in the literature. In principle, the above services could also be applied to other POCT devices.

3.5.2 Advantages of POCT Devices in a PSS

Selling the use or the capability of a POCT device would involve leasing it to the users which has a number of advantages. In this scenario, the manufacturer owns the POCT device and is responsible for the maintenance of it. The user therefore pays for the use of the POCT device and its services without the need of owning the product. The user is provided with the most recent version of the POCT device. Instead of a one-off payment by the user, there will be a smaller cost to lease the POCT device, however glucometers are relatively inexpensive and therefore the cost of leasing them could be waived. The major cost to the user is the test strips which they will be responsible for.

The POCT device is returned to the manufacturer when a new model is released or improvements are added.

3.5.3 Informatics resources required for POCT devices to support a move towards more servitization

A core part of the result-oriented PSS approach towards POCT devices will involve the use of informatics. Health informatics on POCT devices used within the home environment will need to process data quickly in order to underpin service provision. However, owing to insufficient medical expertise at the point of use, a bottleneck in service-provision is likely to occur. Data will therefore need to be transferred to an external location where advice may be obtained from health professionals who must then contact the user.

A candidate for an approach to solving the problem of this bottleneck in service provision is the 'telemedicine' approach. Telemedicine may be defined as 'the delivery of healthcare and the exchange of health information across distances' comprising reaching a diagnosis, providing treatment, transferring knowledge and skills to other health professionals and enhancing ongoing research (Eren et al. 2008; Croteau and Vieru, 2002).

Bryant et al. (2006) have proposed a 'medical monitoring and patient advisory service' within the home. This system would offer medical advice through a rule-based decision support system.

GlucoCom (manufactured by Cardiocom) is an example of a glucometer that has adopted the telemedicine approach. The glucometer is linked to another device, which then transfers the blood glucose results to an online system. Health professionals have access to their patients' data and they can offer 'timely' advice concerning changing their medication and monitoring their health (2008).

From the examples, one can deduce that the following additional health informatics resources are needed to enable POCT devices to move to a higher degree of servitization. They include:

- Additional devices to aid transfer of results from the point-of-care device.
- Secure databases to store the patient data.
- Fast and reliable long-range wireless technology such as GPRS to allow data transfer remotely.
- An efficient computational algorithm for cleaning and analysing the raw data entered by the patient. An algorithm for cleaning data is known as ETL (Extraction Transformation Loading) (Galhardas et al. 2001). The process includes assigning a unique identity to each record, parsing the data, removing duplicates, checking the data type assigned is correct. This process can be repeated several times to ensure data accuracy. However, to reduce inconsistencies in data, the POCT device could be designed in a way that data is validated on entry into the system thus reducing ambiguity and allowing efficient data/information transfer and exchange. Statistical techniques could be used to analyze data.
- Effective synchronisation of data must also be ensured to prevent inconsistencies arising in the database.
- Dedicated health professionals to provide on-demand advice to users. They may not necessarily be in a fixed location; however they do need to have

access to communication resources enabling them to send messages quickly and efficiently to the patients.

3.5.4 Challenges of POCT Devices in a PSS

Using POCT devices to become part of a PSS comes with certain challenges which need to be overcome and these include: The options of the POCT device provided to the user are limited to the manufacturer stock. The user is often fined a huge levy if damage occurs to the product. There is a usability issue, in that the user has to learn how to use a new device when upgrades have been made. Specifically for POCT devices involving the handling of blood, there is a health and safety issue as such devices are designed for personal use. The device cannot be used by another individual until it has been decontaminated. An assessment of the cost effectiveness of sterilizing equipment ought to be carried out to ascertain the viability of this approach.

The infrastructure must exist to enable the informatics capabilities to be delivered to the users. Standards will be needed to ensure adherence and quality control of the services within the infrastructure. A change in people's mindset in their approach to healthcare is also needed as people will need to be willing to accept the new forms of information delivery. The cost of delivering a streamlined service may also be high to begin with due to the overhead incurred to build the infrastructure. Data protection in terms of its storage and transmission to ensure the confidentiality of users. Data should be encrypted when it is stored and secure protocols could be used during data exchange.

3.5.5 A proposed example of an informatics system required for a result-oriented PSS based on POCT devices

A proposed view of an informatics system for a PSS for home care point-of-care testing devices is seen in Figure 3-3. It involves the transfer of the user's results remotely to a temporary database. A software application is then used to clean and analyse the data before it is saved to a central database. Data is stored securely in the database through encryption and is password protected, thus it can be accessed only by authorised personnel.

Health professionals can access the database periodically or may be alerted through the system whenever new results are added to the database that appear to be outliers or show an inconsistency to regular results. The alerts will be governed by a set of predefined triggers. Each alert will be assigned a priority level from low to high. Low priority alerts may be viewed at a later stage while high priority alerts require immediate attention. Alternatively, two sets of health professionals could be included in the system. Low priority alerts could be channelled through the system to less experienced health professionals, while more experienced health professionals would only receive high priority alerts.

Advice is then provided to the patient via a wireless communication link and received on their glucometer.

An important question for the use of POCT devices as part of a result-oriented PSS is whether it would possible to fully automate the actions of point-of-care devices and their supporting informatics. Based on the current level of informatics, it is likely that semi-automation would be possible but not full automation. In contrast to trained health-care professionals, current point-of-care devices do not have the ability to reason through all the available scenarios and options they are presented with. Furthermore, occasionally health professionals need to obtain a second opinion before making final decisions regarding a patient’s diagnosis and currently, this is unlikely to be within the capabilities of a fully automated system.

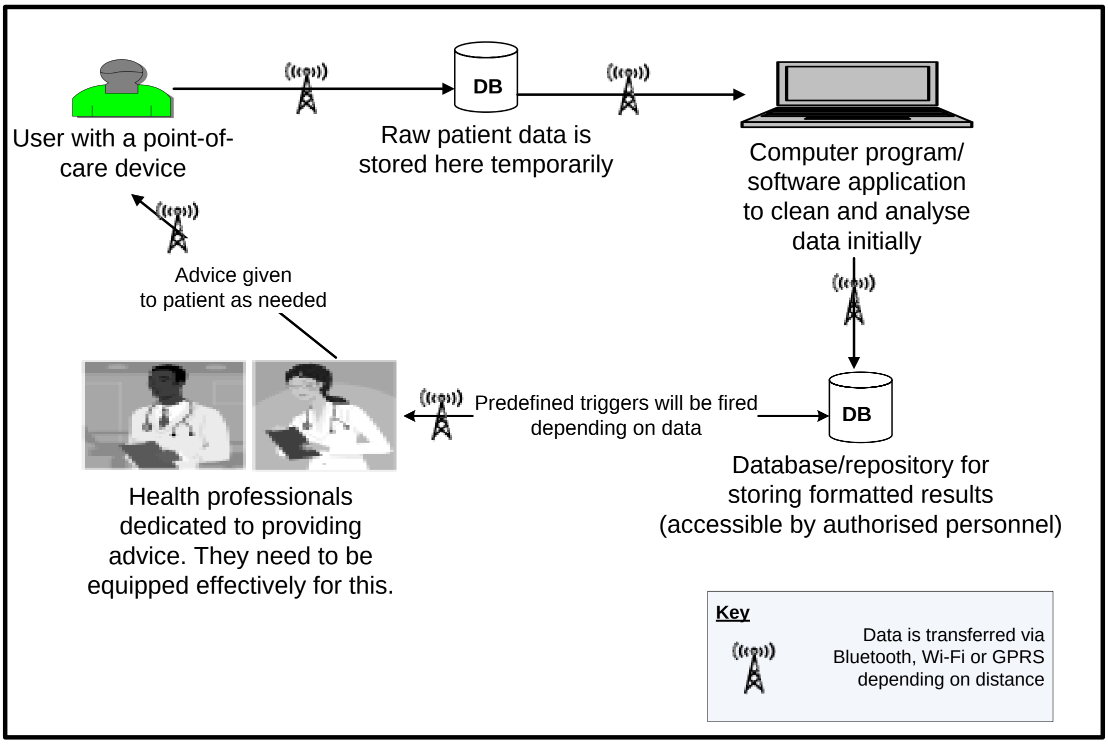


Figure 3-3 – A proposed view of PSS for home care devices

3.6 Limitations and future work

This paper has concentrated primarily on POCT devices used in the home environment with a focus on glucometers. Many other POCT devices could have been included and this shows the limitations of this paper. In addition, there are limited publications on informatics relating to POCT devices.

The research could be further extended to cover POCT devices that are used in healthcare and in remote environments.

3.7 Conclusions

The current level of servitization for POCT devices, such as glucometers, has been considered in this paper.

From the three sub-classes of PSS, it was initially ascertained that glucometers were currently supplied as products with some additional functionalities such as the ability to carry out other measurements for blood pressure, ketone and uric acid concentration. It was established that the services affiliated to POCT devices relate to the level of information that the device provided to its users.

A “use-oriented” PSS model was not suggested, as in this model the usage of the POCT device is sold, i.e. the device is still owned by the manufacturer and the customers lease the device. (This is not to say that the services required from these devices are not user-oriented.) POCT devices used in a home environment are not suited to leasing as they are generally solely for personal use and are not designed for use by multiple users. This is a health and safety issue to aid in avoiding transfer of infections, which is key in monitoring health and caring for a patient.

Hence, a result-oriented PSS has been proposed and its suitability discussed within the context of POCT devices. This was the most appropriate model applicable to improve the level of servitization for POCT devices such as glucometers.

Whilst some services, such as providing reminders to carry out a test, already exist, POCT still has some way to go in order to reach the requirements for a result-oriented PSS model. The availability of informatics resources will aid in reaching this goal, as highlighted by this paper.

Whilst this paper has concentrated on informatics requirements for POCT-device based services to users, it has been highlighted throughout that actors such as health professionals are likely to have an important role in the service provision. Therefore, there is an intimate relationship between the systems and system constraints, within which these health professionals have to operate, such as local and national health organisations and the possible and efficient provision of services. The interaction of health professionals with POCT devices therefore, forms an important future domain of study, without which it is unlikely that the service-potential of POCT-based PSS will be fully achieved.

4 Models of Information Exchange for UK telehealth systems

Abstract

Aim: The aim of the paper was to identify the models of information exchange for UK telehealth systems.

Methodology: Twelve telehealth offerings were evaluated and models representing the information exchange routes were constructed. Questionnaires were used to validate the diagrammatical representations of the models with a response rate of 55%.

Results: The models were classified as possessing four sections: preparing for data transfer, data transfer, information generation and information transfer from health professional to patient.

In preparing for data transfer, basic data entry was automated in most systems though additional inputs (i.e. information about diet, lifestyle and medication) could be entered before the data was sent into the telehealth system.

For the data transfer aspect, results and additional inputs were sent to intermediate devices, which were connectors between point-of-care devices, patients and health professionals. Data were then forwarded to either a web portal, a remote database or a monitoring/call centre.

Information generation was either through computational methods or through the expertise of health professionals.

Information transfer to the patient occurred in four forms: email, telehealth monitor message, text message or phone call.

Conclusion: On comparing the models, three generic models were outlined. Five different forms of information exchange between users of the system were identified:

patient-push, system-stimulation, dialogue, health professional-pull and observation. Patient-push and health professional-pull are the dominant themes from the telehealth offerings evaluated.

4.1 Introduction

4.1.1 Definitions of telehealth

Telehealth is defined as “the use of information, computing and telecommunications technologies to provide” health related services when health professionals and patients are separated by a distance (Fitzmaurice, 1998). Koch (2006) has added that telehealth developed from telemedicine but has extended to “health promotion and disease prevention”.

Telemedicine has several definitions: the practice of medicine between health professionals and patients when they are not in the same location (Merriam-Webster, 2010); the exchange of information between multiple health professionals as a means of training and education (American Telemedicine Association, 2010); facilitating clinical consultations through an electronic medium e.g. through the telephone, videoconference and email (Wyatt and Liu, 2002); using telecommunications technologies for exchanging health information and also the provision of services (Reid, 1996).

In summary, the goal of telehealth is to provide medical care at a distance in an efficient manner via a number of media.

4.1.2 Benefits of telehealth for point-of-care devices

Devices which enable testing and also aid in delivering a form of therapy near a patient are known as point-of-care (POC) devices (MeSH, 2011a). Glucometers (Benjamin, 2002; Apostolopoulos et al. 2007) and peak flow meters (PDS/Ferraris Respiratory, 2004) are examples of point-of-care testing (POCT) devices used within the home for monitoring long term conditions such as diabetes and asthma respectively. At subsequent appointments with their health professional, results recorded by patients can be reviewed and patients may be informed to either maintain or alter their current lifestyle routines (NHS Choices, 2010a; NHS Choices, 2010b).

Point-of-care devices are not limited to being used in a specific location as they can be used in the home of the patient, the GP surgery or in hospitals (Price and Kricka, 2007). Coupling this feature with telehealth therefore extends their functionalities.

The case for telehealth being used in conjunction with point-of-care devices is based on perceived benefits such as the following:

- Helping to improve patient compliance with medication. Mao et al. (2008) described how a mobile pharmacy service system utilizing SMS was used to help improve medication compliance. Text messages were sent to patients reminding them to take their medication prior to the time it was due to be taken. It demonstrated that patients found the messages helpful in complying with their medication.
- Helping to empower patients as they become more knowledgeable and confident about managing their condition. Franklin et al. (2008) described a system known as “Sweet Talk” which was designed to help young people with diabetes manage their condition through text messaging. Personalized messages reminding patients of their goals were sent to them based on their profiles. The patients were also encouraged to send in messages with relevant information about diabetes.
- Speeding up the rates of change of medication. Brown et al. (2004) showed that patients with diabetes may need to change their medication and the time taken to do this may be between 27 and 35 months, however this time could be reduced through telehealth since regular updates of the patients’ results could help health professionals make changes to medications quickly.
- Supplementing care provided to patients in between visits to health professionals. Azar and Gabbay (2009) noted this to occur when they investigated whether electronic uploading of glucose results was an advantage compared with manual methods. They found that although

telehealth did not make an impact on diabetes management by people with type 1 diabetes, it helped those with type 2 diabetes to manage their condition (Azar and Gabbay, 2009).

4.1.3 Drivers for telehealth

Speedie et al. (2008) noted two assumptions of current delivery of care to patients which will be altered by telehealth. They are: provision of care to patients is in a fixed “geographic” location and as “episodic” visits. The UK Department of Health also advocates that technology can be used to improve the delivery of healthcare by allowing remote patient monitoring. This allows patients to stay in their own homes rather than restricting them to a hospital setting (Department of Health, 2008c). To support this, the Department of Health is currently running a program known as ‘Whole System Demonstrators’ which is investigating the effect of telehealth and telecare systems on the monitoring of patients and how they may improve patient lifestyles (The King’s Fund, 2010). Prior to the UK Department of Health program, several systems have emerged to deliver healthcare remotely. Some of these are being offered as pilot projects while others have been deployed on a larger scale. The UK was therefore selected as it provided several choices of telehealth systems that have been deployed.

4.1.4 Motivation

There is little available in the literature on different offerings of telehealth. Kruger (2009) has described three different models, “basic”, “advanced” and “cloud-based” representing information flow schemes between components of “eHealth” systems. eHealth systems refer to telehealth systems using the internet only as a means of exchanging information and therefore cannot be applied generically. Telehealth, however as defined in Section 1.1 extends to other forms of telecommunications technology. This paper is therefore an analysis of telehealth offerings rather than eHealth offerings with the aim of identifying its overall structure and the data/information flows that are present.

4.1.5 Research questions

This paper aimed to derive models of information exchange for telehealth offerings which are currently available.
The paper posed three research questions concerning telehealth systems.

1. What are the paths of information transfer in the telehealth offerings?
2. What types of entities form part of telehealth offerings?
3. Can a standard model of information transfer in a telehealth offering be established?

4.2 Methodology

The criteria for selection of the data set of the paper were restricted to offerings available in the UK and those based on point-of-care devices, specifically those devices which could be used in the home.

An online search was performed through Google to identify what telehealth systems were currently available in the UK. The keywords used in the search included: point-of-care devices, telehealth, telemedicine, eHealth, home telehealth solutions UK, telemedicine services and telehealth companies. As the paper's focus was on telehealth, telecare was excluded as a search term.

The UK Telemedicine and E-health Information Service (TEIS) provided by the University of Portsmouth (2004) was also a useful resource in identifying organisations within the UK offering telehealth.

4.2.1 Modelling the telehealth offerings

Company documentation of each offering was evaluated. The sub-sections of each telehealth system were defined and the routes for the generation and exchange of information between sections of the telehealth system were identified.

Each offering, comprising the system sub-sections and the information exchange routes, was depicted diagrammatically. Formalised tools such as UML data flow diagrams or IDEF0 were considered for this task, but they lacked the necessary flexibility to represent section types and information exchange. Therefore, symbols based on the type of entities identified were defined. This symbol set is shown in Table 4-1.

Where the direction of information flow could be discerned this was given a direction arrow in the symbol set. In certain cases an assumed direction of information transfer is given where this could be inferred from but was not explicitly mentioned in the information available.

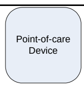
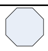
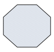
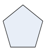
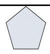
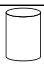
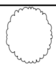
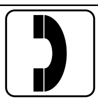
Symbol	Meaning
	Patient
	The point-of-care device labelled appropriately with the right name
	Generic intermediate device that displays data (e.g. mobile phone)
	Proprietary intermediate device that displays data (e.g. telehealth monitor)
	Generic intermediate device that does not display data (e.g. landline phone)
	Proprietary intermediate device that does not display data
	Health professional
	Caregivers (usually non health professionals)
	Database
	Portal (Web/Online interface)
	Call centre
 EPR	Electronic Patient Record (EPR) or Electronic Medical Record (EMR)
	Firewall
——→	Direction of data/information transfer
·······→	Direction of assumed data/information transfer. (Some aspects of the diagrams were not explicitly specified hence assumptions were made as to when data transfer occurred).
	List of multiple tasks that can happen in an entity

Table 4-1 – Key to symbols used to draw telehealth offerings

4.2.2 Validation of the telehealth offerings

To validate the diagrammatic depiction of the offerings as being accurate representations of the companies' telehealth offerings, questionnaires were sent to the organisations via email. The questions posed asked the organisations to make changes to the diagrams as needed.

4.3 Results

This section provides information about the defined entities used to depict the offerings and the organisations surveyed. The detailed description of each of the 12 telehealth offerings referred to as offering A to L can be found in the supplementary material (Appendix A).

4.3.1 Entities

Eleven entities were identified as being present across the offerings: the patient, point-of-care devices, intermediate devices that had data display capabilities, such as telehealth monitors and mobile phones, intermediate devices that did not have data display capabilities, health professionals, caregivers, databases, ‘web portals’, call centres, electronic patient records (EPRs) and firewalls.
The above entities are defined as follows:

- Patients are the primary users of the system.
- Point-of-care devices enable testing or therapy to be administered at the patient’s location; examples are glucometers and blood pressure monitors.
- Intermediate devices are defined here as connectors between point-of-care devices, patients and health professionals. Some are generic devices that have been adapted to a telehealth system, for example mobile phones; others are proprietary devices.
- Health professionals are doctors or nurses.
- Caregivers provide a form of care to the patient but are not necessarily a health professional.
- Databases are used for storing results from the devices.

- Portals are web-based interfaces available to both patients and health professionals to view current and historical results obtained from the point-of-care devices.
- Call centres are central locations used to receive phone calls to aid in the administration of a product or service.
- EPRs are defined as electronic records of the patient’s medical history usually accessible only to health professionals.
- Firewalls are part of a computer system which provide security by preventing unauthorised access and allowing authorised communications.

4.3.2 Organisations evaluated

Eleven organisations were found to offer telehealth services currently in use within the UK (AxSys Technology Ltd (2010), Broomwell HealthWatch (2010a, 2010b), Docobo (2008a), Entra Health Systems Ltd (2009) /MyGlucoHealth (2010), Intel (2009, 2010a), Philips (2010), Project E-vita (2009), Telehealth Solutions (2010a, 2010b), OBS Medical Ltd (2010), Tunstall (2010c) and Tynetec (2010a). Twelve offerings were identified as one organisation offered two systems.

The telehealth systems were all used for monitoring one or more chronic conditions namely: asthma, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), diabetes and hypertension. One offering was for managing a single condition, while eleven were for managing multiple conditions.

4.3.3 Baseline model

A baseline model (Figure 4-1) for information exchange was deduced from the telehealth offerings. For readability, it is shown in this section to enable the function of each entity to be seen through each telehealth offering, however further details of how it was derived are shown in Section 4.3.

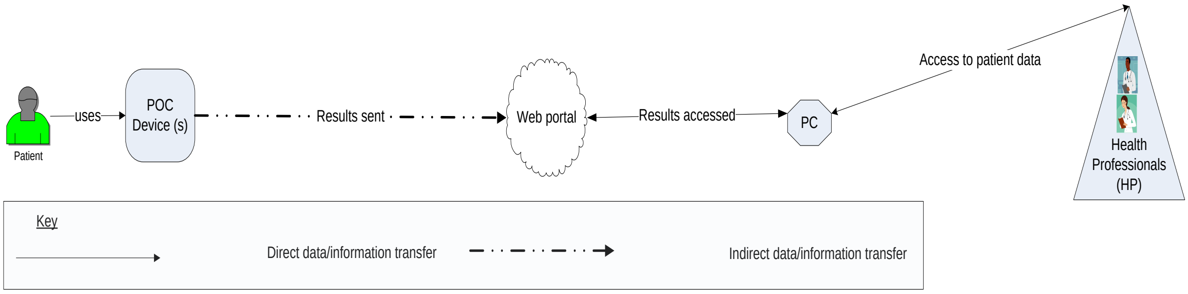


Figure 4-1 – The baseline model for information exchange: all systems have these functions

4.3.4 Validating results

The time period given to receive the responses back from the organisations was two months and 55% of them (offerings B, D, E, H, I, L) responded within this time frame. All the diagrams for which feedback was received were modified with significant changes made to offering D and I.

4.3.5 Constraints by organisations when implementing telehealth offerings.

When the organisations were asked whether they had any constraints in the design of their system, B, D and J provided information that they were not operating under explicit constraints when implementing the telehealth system.

For offering E, the constraints were small, light and simple devices suitable for use by elderly people. In addition, they had to be suitable for connecting to a telephone line.

The remaining organisations did not respond or return their questionnaire.

4.3.6 Standards

Descriptions of four of the offerings stated that they used standards. Offering B had medical devices with EN60601 certification of safety and performance of the medical device (2006). Offering C and E used medical devices that were certified to ISO 13485 a standard for quality control (British Standards Online, 2003). Offering C also had ISO 9001 certification (British Standards Online, 2008). The glucometer in offering A and intermediate device in offering I carried the CE mark thus showing conformation to “essential requirements” within Europe for health, safety and environmental protection. The intermediate devices in offering B and I had FDA approval which meant that they were suitable for use in USA (see Table 4-4 for details).

4.4 Discussion

Tabulated comparisons of the offerings are given in Table 4-2 to Table 4-6. Table 4-2 shows the types of chronic diseases being managed by the telehealth offering. Table 4-3 represents the comparisons of the sections of the offerings prior to the transfer of data within the telehealth system. Table 4-4 represents comparisons when the user transfers data into the telehealth system. Table 4-5 shows the comparisons of the offerings based on information generation and transfer of information to the patient. Table 4-6 compares how data is stored and accessed in the offerings.

4.4.1 Comparing the telehealth offerings

4.4.1.1 Chronic diseases being monitored

Table 4-2 shows the range of chronic diseases that could be monitored by the different telehealth offerings available. Some systems could monitor additional conditions that were not necessarily chronic and these have been represented as ‘other conditions’. For two of the telehealth offerings, the conditions were not specified.

Type of condition being monitored	Offering A	Offering B	Offering C	Offering D	Offering E	Offering F	Offering G	Offering H	Offering I	Offering J	Offering K	Offering L
Diabetes	✓	✓	✓			✓	✓	✓	✓			✓
Congestive heart failure (CHF)		✓		✓	✓	✓		✓				
Chronic heart failure							✓		✓			✓
Chronic obstructive pulmonary disease (COPD)		✓	✓	✓	✓	✓	✓	✓	✓			✓
Hypertension		✓	✓			✓	✓	✓				
Asthma			✓		✓	✓						
Other conditions		✓		✓	✓		✓					
Unspecified										✓	✓	

Table 4-2 – Comparison of the information path diagrams – chronic diseases being monitored

4.4.1.2 Preparing for data transfer

Table 4-3 shows that for all the telehealth offerings, the primary user of the point-of-care device was the patient. Offering D also provided a service allowing health professionals to be primary users. The testing process was initiated by the patient in nine of the systems while the intermediate device prompted patients to perform their test in three offerings (G, H, I).

		Offering A	Offering B	Offering C	Offering D	Offering E	Offering F	Offering G	Offering H	Offering I	Offering J	Offering K	Offering L
Users	Primary user of point-of-care (POC) device is patient	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Primary user of POC device is health professional (HP)				✓								
Testing process initiated:	By patient (P) or by device prompting patient (D)	P	P	P	P	P	P	D	D	D	P	P	P
POC device types	Number of types of devices supported	1	6	4	5	1	5	8	6	5	3	5	4
Before data transfer	Users see results prior to getting feedback from a HP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Users provide additional inputs		✓	✓		✓	✓	✓	✓	✓		✓	✓
	Manual (M) or automated (A) data entry	A	A	M	A	A	A	A	A	A	A	A	A/ M

Table 4-3 – Comparison of the information path diagrams – preparing for data transfer stage

4.4.1.3 Data transfer from patient to a health professional

As shown in Table 4-4, the first stage of information exchange began with the transfer of data from the point-of-care device to an intermediate device. Following this, data were then transferred to either of the following locations: a web portal i.e. an online web interface: offerings (A, B, C, G, H, J); a remote database: offerings (E, F, I, L); and a monitoring/call centre: offerings (D, K). In offerings (E, F, I, L), data were forwarded to a web portal after being initially transferred to a remote database.

		Offering A	Offering B	Offering C	Offering D	Offering E	Offering F	Offering G	Offering H	Offering I	Offering J	Offering K	Offering L
Results transferred through intermediate devices that display data	Proprietary intermediate device		✓			✓	✓	✓	✓	✓	✓	✓	
	Adapted intermediate device	✓	✓	✓	✓	✓							✓
Results transferred through intermediate devices that do not display data	Proprietary intermediate device				✓						✓		✓
	Adapted intermediate device				✓								
Mode of data transfer:	Through wireless communicatio n	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Through cables	✓	✓					✓					✓

Table 4-4 – Comparison of the information path diagrams – data transfer from patient to health professional

4.4.1.4 Information generation and information transfer from health professional to a patient

Table 4-5 illustrates the results discussed in the next two sections. The second stage of the information path relates to the translation of data into information of which two methods were noted in the evaluation.

4.4.1.5 Information generation through computational methods

In this scenario, data was retrieved from a server before being analysed through predefined algorithms which can be configured by health professionals. This was seen in 11 offerings (A, B, C, E, F, G, H, I, J, K, L), where the results are initially analysed through software. From this, alerts can be sent to the health professionals when unexpected results occurred (all cases apart from offerings C & J). In offering B, health professionals were also alerted when new data were added. Results were presented to the health professionals in a colour coded format in four offerings (B, G, H, I). This enabled high priority results to be addressed quickly.

It is important to note that the colour coded signals alerting the health professionals may occasionally have false positives and false negatives, however the organisations do not provide details of their algorithms to generate the alerts therefore it was difficult to assess this.

4.4.1.6 Information generation through experts

In this scenario, no computational algorithms were used to analyse results in order to arrive at the patient diagnosis. Rather, the expertise of the health professional sufficed in making a decision which was sent back to the patient. This was demonstrated in offering D where GPs sent the patient's ECG results via the telephone and cardiology experts interpreted the ECG results and provided immediate feedback to the GP.

4.4.1.7 Information transfer from health professional to a patient

In all cases, results were accessed by health professionals via a PC. Although in offering D, health professionals had a more real-time contact with the patient, since the results were transmitted over the telephone line and discussed immediately.

The traffic light colour coded system in offering B helped to identify urgent and extreme cases that may be missed if a manual method was employed. In some cases they passed on a message to the patient regarding the status of their result.

All the offerings evaluated followed the pattern of indirect data transfer in which another device other than the point-of-care device utilised transmitted the results to a portal or server. Indirect data transfer is also known as ‘store and forward’ and it is generally suitable for non-emergency situations (Myers, 2003).

		Offering A	Offering B	Offering C	Offering D	Offering E	Offering F	Offering G	Offering H	Offering I	Offering J	Offering K	Offering L
Roles of HP	Number of types of HP	1	1	2	2	2	1	2	1	2	1	1	2
	Description of the role of 1st HP	Clinician	Physician	Specialist nurse	GP	GP	Clinician	GP	Clinician	GP	Care agency personnel	Healthcare professional	Nurse
	Description of the role of 2nd HP			GP/nurse	Cardiology expert	Specialist		Clinician		Specialist			Specialist
Modes of contact	HP alerted if extreme results encountered	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓
	HP contacts patient indirectly i.e. through a message		✓	✓		✓	✓	✓	✓	✓		✓	✓
	Feedback provided to patient via (phone call [p], text [sms], email [e], telehealth monitor message [tmm])	e, sms	tmm	sms	p	tmm	tmm	tmm	tmm	tmm		tmm	tmm
	HP contacts patient directly				✓					✓			✓
	Message to remind patient:	To test & to take medication	To take medication				To test	To test	To test	To test		To take medication	To take medication
	Patient can contact HP directly				✓				✓				
User Interface	Portal (web/online interface)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 4-5 – Comparison of the information path diagrams – information generation and information transfer to patient

4.4.1.8 Data storage and accessibility

The comparison of data storage and accessibility characteristics of the offerings is given in Table 4-6. Offerings (A, B, F, K) utilise an EPR provided by the organisations which has the medical history of the patient. The essence of storing this historical data was for reference purposes when a patient's medical history is being tracked. Offering F and H provided two databases for storing data. In offering H, the databases were physically stored in different locations to aid data recovery during disasters and to support accessibility to data and guarantee data safety when applications fail to function thus providing extra security.

		Offering A	Offering B	Offering C	Offering D	Offering E	Offering F	Offering G	Offering H	Offering I	Offering J	Offering K	Offering L
Data storage	Data repository					✓	✓		✓	✓			✓
	Electronic Patient Record	✓	✓				✓					✓	
Accessibility to data	Secured access to data by HP			✓			✓	✓	✓	✓			✓
	Patients can access stored data	✓		✓		✓	✓		✓	✓			✓
	Caregivers can access patient data	✓					✓		✓			✓	
Other	Firewall						✓						
	Uses standards		✓	✓		✓				✓			

Table 4-6 – Comparison of the information path diagrams – data storage and accessibility

4.4.2 Features of baseline, dominant and fully-featured models

4.4.2.1 Baseline model

The baseline model (Figure 4-1) shows that five entities were common to all the offerings: the patient, point-of-care device, web portal, PC and health professional. In the baseline model, patients use a point-of-care device to generate results; the results are sent to a web portal, where they were accessed through a PC (an intermediate device) by the health professional.

4.4.2.2 Dominant model

The dominant model (Figure 4-2) represents the entities that were present in more than six of the offerings. In addition to the entities found in the baseline model, the dominant model included additional intermediate devices and remote databases. Results from point-of-care devices are sent via an intermediate device to either a remote database, before being accessible through a web portal, or directly to the web portal.

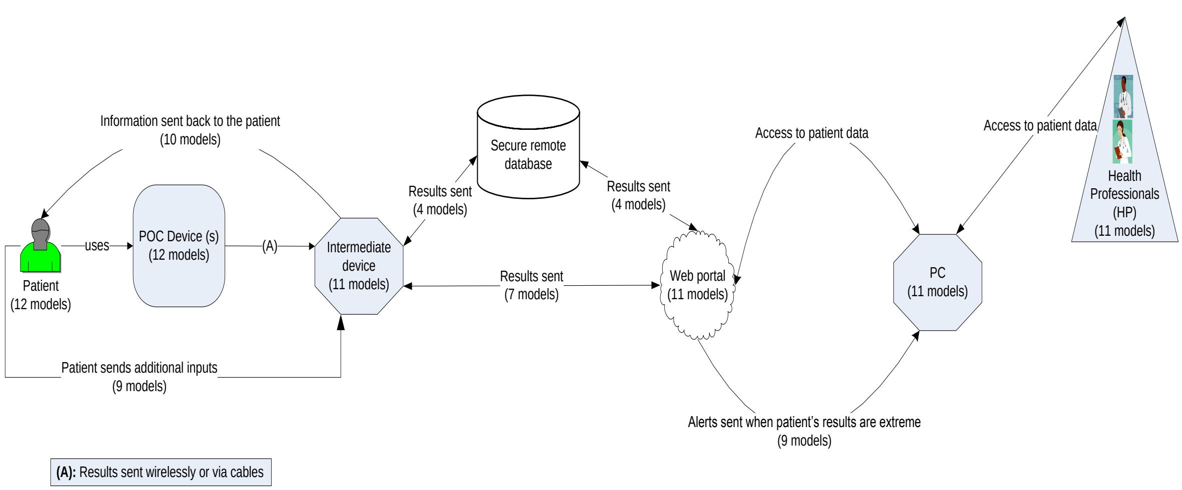


Figure 4-2 – The dominant model showing the entities that appear in more than 6 of the offerings

4.4.2.3 Fully-featured model

The “fully-featured” model representing all the defined entities along with their functionalities observed from all the offerings is shown in Figure 4-3. Each of the 12 telehealth offerings exhibited useful features that would aid information exchange, although as expected, they were not all present in each offering, hence this fully-featured hypothetical model shows the complexity of the possible capabilities. The main differences between this and the baseline model are:

- Patients were reminded to either carry out their test or to take their medication.
- The intermediate device could initiate the testing process thus helping the patient to comply with regular monitoring.
- Results from point-of-care devices and responses to questionnaires (data) were sent wirelessly or via cables to the intermediate device.
- A telephone link was added to enable the patient to speak to the health professional to aid in answering queries during the testing process.
- Patients could access their results through the web portal and also through the intermediate device.
- Results and data were encrypted before being transferred from the intermediate device that displays data to a database.
- For an intermediate device that does not display data, results were sent via a landline telephone to a call centre to be interpreted by health professionals. The interpreted information was transferred to a remote database to be stored.
- For data sent to a call centre, interpreted results were communicated to the patients through a landline telephone.
- Results and data were sent through a firewall and stored further in another remote database to increase security.
- Results and data were accessible to health professionals through a web portal via a PC.

- Health professionals could: create triggers on the patients' records; set up personalised schedules for the patients; review and analyze patients' results; and provide suggestions to patients on how to improve their results. They have additional privileges which allow them to filter the patient's result based on its priority level.
- Alerts were sent to health professionals via mobile phones or PCs when patient's results were unusual.
- Specialists were available in the system so that they could be consulted by general practitioners to exchange information about the patient.
- An EPR was added to allow health professionals to update the patient's records.
- Caregivers were integrated into the system to help track the patient's condition and provide additional support to patients to enable compliance to routine.

From the above it can be seen that the main difference between fully-featured, dominant and baseline systems is the number of service elements for patients and health professionals that the fully-featured model adds to the system. It seems likely that telehealth providers can and will seek to differentiate themselves from competitors via such service provision.

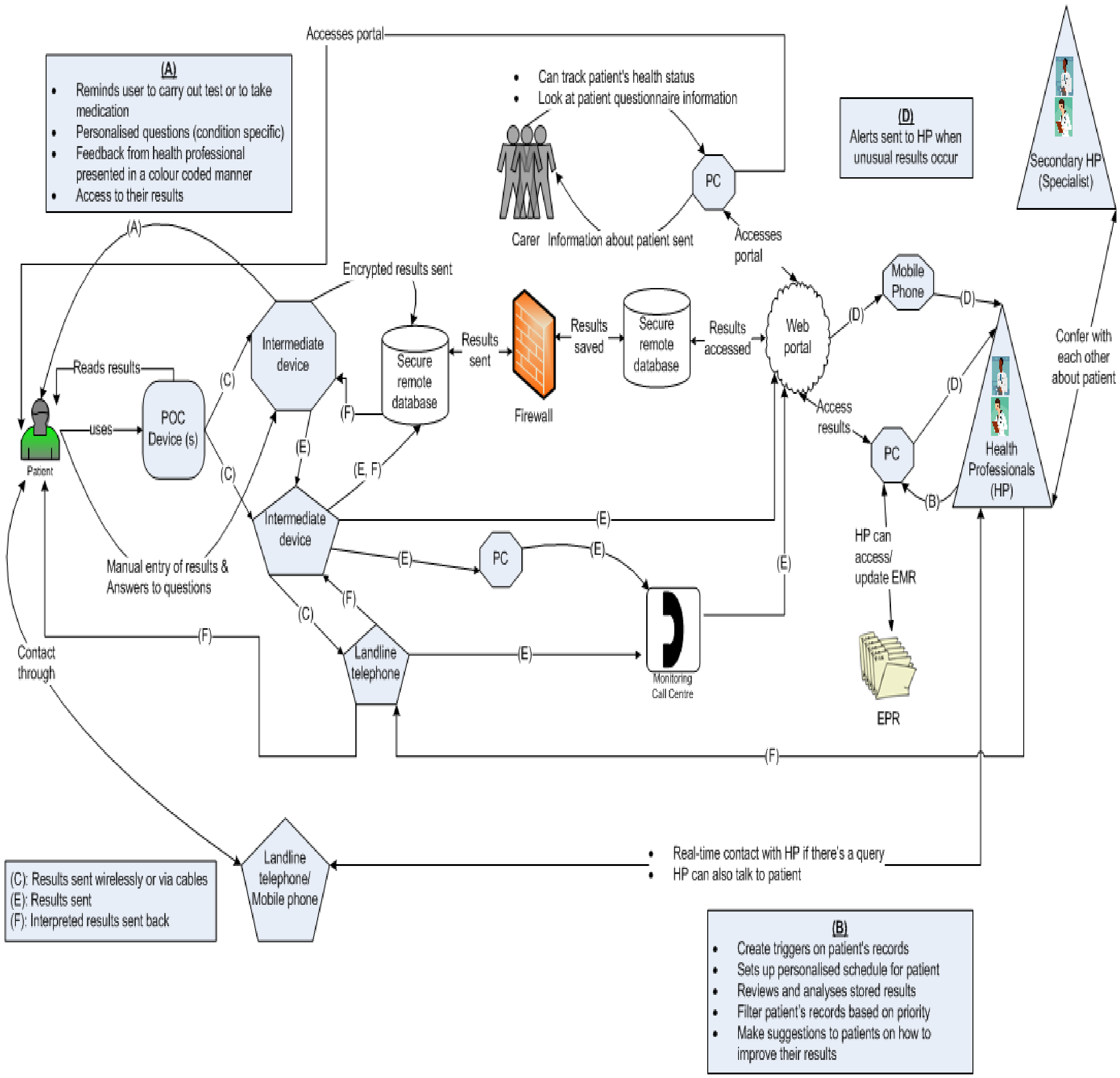


Figure 4-3 – A model comprising functionalities observed in all the offerings for information exchange

4.4.2.4 Forms of information exchange in telehealth systems

From this evaluation, different ways of information exchange between users of the system have been identified. They are listed in the order that information flows through:

- **Patient-push:** The testing process was initiated by patients, who send their test results to health professionals. Examples of this are seen in all offerings apart from (G, H, I) and in the baseline, dominant and fully-featured model.
- **System-stimulation:** Patients are prompted to carry out their test or take their medication through reminders. Examples of this are seen in offerings (B, F, G, H, I, K, L) and in the fully-featured model.
- **Dialogue:** Patients and health professionals have a live dialogue either on the phone or through video conferencing to discuss results and progress of patients. Examples of this are in offerings (D, I, H) and in the fully-featured model.
- **Health professional-pull:** Health professionals set up alerts to be informed when patients' results arrive each time or when patients' results are outside specified limits. Examples of this are seen in all the offerings apart from (C & J) and in the dominant and fully-featured model.
- **Observation:** Caregivers can access information about the patient thus checking their compliance with monitoring and encouraging the patient. Examples of this are seen in offerings (A, F, H, K) and in the fully-featured model.

Patient-push and health professional-pull are the leading themes from these approaches.

4.5 Strengths and weaknesses of the study

The strengths of the study are: providing an overall structure of telehealth offerings for managing chronic diseases by showing the entities used. Highlighting the commonality in the characteristics of telehealth offerings. It has shown three generic models of telehealth offerings of which the level of complexity is based on the requirements of the telehealth system.

The weaknesses of the study are: the effectiveness of such telehealth offerings has not been evaluated. The telehealth models refer to the management of chronic diseases and may not be applicable to other areas of healthcare without further work.

4.6 Conclusion

The paper presented models of information exchange in the UK telehealth industry with specific focus on telehealth offerings containing point-of-care devices.

The models were classified as possessing four sections: preparing for data transfer, data transfer, information generation and information transfer from health professional to patient.

In preparing for data transfer stage, the testing process was initiated by the patient in most systems. Most of the systems also provided automated data entry. Additional inputs, apart from the result, could be entered in most systems before the data was sent into the telehealth system.

For the data transfer stage, results and additional inputs were sent to an intermediate device, which were connectors between point-of-care devices, patients and health professionals. Data were then forwarded to either a web portal, a remote database or a monitoring/call centre.

The information generation stage took two forms: (i) information through computational methods where data was analysed through predefined algorithms and alerts were triggered when unusual results occurred; (ii) information through the expertise of health professionals. GPs could confer with specialists to discuss the patient's health and progress. Information transfer to the patient occurred in four forms: email, telehealth monitor message, text message or phone call. Health professionals were alerted when unusual results were recorded by patients. Reminders were sent to patients in some offerings to either carry out their test or to take their medication.

A further aspect for the offerings included data storage and accessibility. Databases were explicitly identified in five of the offerings and four of the offerings also used

Electronic Patient Records (EPRs). Data were encrypted in some cases to provide additional security before it was stored.

Five different forms of information exchange between users of the system have been identified: patient push, system-stimulation, dialogue, health professional-pull and observation. Patient-push and health professional-pull are the dominant themes from the telehealth offerings evaluated.

On comparing the offerings, a baseline model was outlined comprising five of the 11 defined entities. The main difference between the ‘fully-featured’ and baseline model is the addition of numerous service elements to the system, for both patients and health professionals. It seems likely that telehealth providers can and will seek to differentiate themselves from competitors via such service provision.

5 Capabilities of telehealth systems

Abstract

Capability is defined in this paper as the ability of a system entity to perform an action. Limited evidence was found of a systematic review of capabilities present in current telehealth systems. Therefore this paper aims to consider capabilities of telehealth systems from the perspective of the actors involved. Perspective is taken as what the actors are likely to see in the system though their views were not obtained.

12 existing telehealth offerings previously evaluated for managing chronic diseases were used to compile the capabilities (Adeogun et al. 2011). They were then grouped into categories based on the three actors identified: patient, caregiver and health professional. Non-actor capabilities were grouped into a separate category. A capability diagram was used to represent the categories of capabilities identified for each actor and the non-actor entities.

55 individual capabilities were compiled from existing telehealth offerings. This resulted in 18 categories for the patient, two categories for the caregiver, 14 categories for the health professional and six categories for non-actor entities.

The trend of patient initiated capabilities in existing telehealth offerings relates to providing data (i.e. test results and responses to questions) and taking a more active role in managing their condition.

Caregivers were present in only four existing offerings therefore no real trend was observed. In addition, they had no direct impact on other actors of the system.

For health professional initiated capabilities, the trend was for them to create/modify patients care plans; review the patients’ results and be alerted about unusual results. These actions promote a change in the care plan at an earlier, rather than later stage.

The non-actor capabilities resulted in two outcomes: results being saved and results being transferred to another component of the telehealth system. This implies that information transfer within telehealth systems is important in order for it to be used by other entities.

5.1 Introduction

5.1.1 Aim of paper

In this paper the current capabilities of telehealth systems for the management of chronic diseases are defined and categorised based on the existing state-of-the-art in actual systems. The aim of the paper is to consider the capabilities of telehealth systems from the perspective of the three classes of actors present in these systems: the patient, the caregiver and the health professional. Perspective is taken as what the actors are likely to see in the system though their views were not obtained. It seeks to show what capabilities are visible to each of these classes of actors and also the variance of these capabilities between current systems.

An understanding of these capabilities should help to formalise current systems, highlight capability gaps in such systems and therefore, facilitate better design of future systems. The target audience for this paper is therefore, telehealth systems providers, telehealth systems researchers and health professionals interested in using such systems for managing patients with chronic diseases.

5.1.2 Definition of capability

For the purposes of this paper it is necessary to define capability. Capability is taken as the ability of a telehealth system entity to perform an action. It is taken as having five parts: the action itself, the telehealth system entity used to initiate the action, the system entity used as a channel to perform the action, the system entity on which the action is performed and the final outcome as a result of the action.

The eleven system entities considered here are those that have been identified in telehealth systems in a previous study by the authors (Adeogun et al. 2011a): patient, point-of-care device, intermediate device (with data display capabilities), intermediate device (without data display capabilities), health professional, caregiver, database, web portal, call centre, electronic patient record (EPR) and firewall.

A summary of previous studies relevant to telehealth system capabilities is shown in Table 5-1. None of these studies represent a systematic review of the capabilities present in current telehealth systems, rather certain aspects of particular capabilities are described, usually for a single telehealth system.

Article Name	Authors	Year	What is the system designed for	Where telehealth system is used
Internet-Based home asthma telemonitoring	Finkelstein et al.	2000	Asthma	Home
Managing asthma with mobile phones: A feasibility study	Holtz & Whitten	2009	Asthma	Home
Telehealth and diabetes monitoring	Blanchet	2008	Diabetes	Home
A Comparison of web-based and paper-based self management tools for asthma: Patients' opinions and quality of data in a randomised crossover study	Cruz-Correia et al.	2007	Asthma	Home
Medication compliance—Helping patients through technology: Modern "smart" pillboxes keep memory-short patients on their medical regimen	Naditz	2008	Medication compliance	Home
Application of health informatics in the education of diabetic patients for the improvement of self management and reporting to specialists	Apostolopoulos et al.	2007	Diabetes	Home
Patients' engagement with "Sweet Talk" – A Text Messaging Support System for Young People With Diabetes	Franklin et al.	2008	Diabetes	Home
Mobile phone technology in the management of asthma	Ryan et al.	2005	Asthma	Anywhere
A randomized controlled trial of the effect of real-time telemedicine support on glycemic control in young adults with type 1 diabetes	Farmer et al.	2005	Diabetes	Anywhere

Table 5-1 – Telehealth studies showing the management of chronic diseases

5.2 Methodology

In this paper, capabilities are derived from existing telehealth offerings currently available for the management of chronic diseases (Adeogun et al. 2011a). In most cases these systems include the use of point-of-care devices for self testing.

The derivation of current capabilities was undertaken as a three stage process. Firstly, for each current telehealth offering, the capability (action, initiating entity, channel entity, entity on which action is performed and outcome) of each system was characterised and then tabulated.

Secondly, similar capabilities were grouped into categories, based on the actor with which the system capability interacts.

Thirdly, diagrammatic representations of the actor centred view of telehealth system capabilities were constructed.

Finally, representations of the variance between systems that an actor would perceive when using each system’s full capabilities were produced.

The methodology of each stage is explained in more detail below. The methodology is presented at a detailed level with the aim that others could reproduce this work using the same data set. (The primary data set can be found in the on-line supplementary material of (Adeogun et al. 2011a)).

5.2.1 Compile capabilities

Each telehealth offering was scanned for details of the mode of data/information exchange by following the information path through the system. Capabilities were then compiled using the following steps.

1. The action was noted.

2. The system entity initiating the data/information exchange was noted.
3. The system entity used as a channel (where available) was noted.
4. The system entity on which the action is performed was noted.
5. Finally, the outcome of the capability was noted. It was written in the form of a system entity achieving ‘something’.
6. This information was used to derive an initial capability list: each item on the list is composed of five attributes: action – initiating entity – channelling entity – receiving entity – outcome.
7. Each capability was named and the telehealth offerings (labelled A to L) in which it was found were noted. (The telehealth offering labels used here are the same as in (Adeogun et al. 2011a), so that a reader may compare the total system with this capability analysis if he or she wishes.)

5.2.2 Identify categories

From the compiled list of capabilities, similar ones were grouped together. Similarity was judged via a hierarchical methodology as detailed below.

1. Three main actors are found in telehealth systems (patient, caregiver and health professional) (Adeogun et al. 2011a). The order of precedence assigned to them was: patient > caregiver > health professional. Patients were recognised as the most important actor because the central goal for healthcare is to benefit them by improving their health and well-being. Caregivers were considered as of greater system importance than health professionals as they are closer in the system to the patient.
2. Actors were used to group capabilities. At the highest level of grouping, whether the actor is the initiator of the action, or the system is designed such that it is intended that the actor is affected by the action was then used to group capabilities. This approach yielded the following order for categorisation: 1) patient as initiator > 2) outcome affects patient > 3) caregiver as initiator > 4)

outcome affects caregiver > 5) health professional as initiator > 6) outcome affects health professional. Capabilities which were not initiated by nor had a direct effect on any actor were placed in a final category.

3. From the previous step, the actions relating to the same actor were combined. E.g. items 1 and 2 were placed in the same group (designated P); items 3 and 4 were placed in the same group (designated C); and items 5 and 6 were placed in the same group (designated H); capabilities that were not directly influenced by an actor were placed in a final group (designated S).
4. The capabilities in the four groups derived from step 3 were sorted by action and similar actions were assigned to a set. These sets were considered as categories of capabilities. Names were assigned to each category.
5. Capabilities in the final group – those that did not involve actors - were sorted into sets by their outcome, followed by the action, to arrive at their final categories.

5.2.3 Representations of actor centric capabilities

The categories of capabilities, as derived above, were represented in “capability diagrams” using the following steps.

1. The entity initiating the action or affected by the outcome was represented by an oval shape.
2. Categorised capabilities were represented in different shapes depending on the initiating entity.
    a. For patients: a rectangle with a rounded corner was used.
    b. For caregivers: a hexagon was used.
    c. For health professionals: a pentagon was used.
    d. For non-actor entities: a bevelled rectangle was used.

3. Capability groups that the entity initiates were depicted to the right of the initiating entity; the capability groups that affect the entity were depicted to the left. Similarly, an arrow pointing away from the entity meant that the entity initiates the action; while an arrow towards the oval meant that the outcome of the capability affects the entity. See, for example, Figure 5-1.
4. To indicate variance between current telehealth systems, mini capability diagrams were constructed for each telehealth system evaluated by (Adeogun et al. 2011a) and then tabulated.

5.3 Results

From the telehealth offerings evaluated, 55 individual capabilities were listed. The details of each capability and its corresponding category can be found in the supplementary materials appendix in Table B-1 - Table B-4. Each table represents one of the four groupings: patient, caregiver, health professional and non-actor entity.

The results section is divided into five parts. In section 5.3.1 – 5.3.4, the capability categories 'seen' by the different actors and non-actors are presented. Section 5.3.5 gives the capability categories available in each of the current telehealth offerings.

5.3.1 Patient

27 capabilities are related to the patient and they were grouped into 18 categories (Table B-1). Figure 5-1 shows the categorised capabilities for the patient in pictorial form.

Nine of 18 categories are initiated by the patient.

Eight of 18 categories are initiated by other system entities but had an outcome that affected the patient. These can be placed into two groups: those initiated by the health professional; those initiated by other system entities. System entities which initiate an action only are 'intermediate devices', web portal and EPR. The caregiver does not initiate any categories of actions which require the patient to act and vice versa.

One category appears on both sides of Figure 5-1 as it is initiated by and affects a patient. This is 'P9-Patient has real-time communication with health professional'.

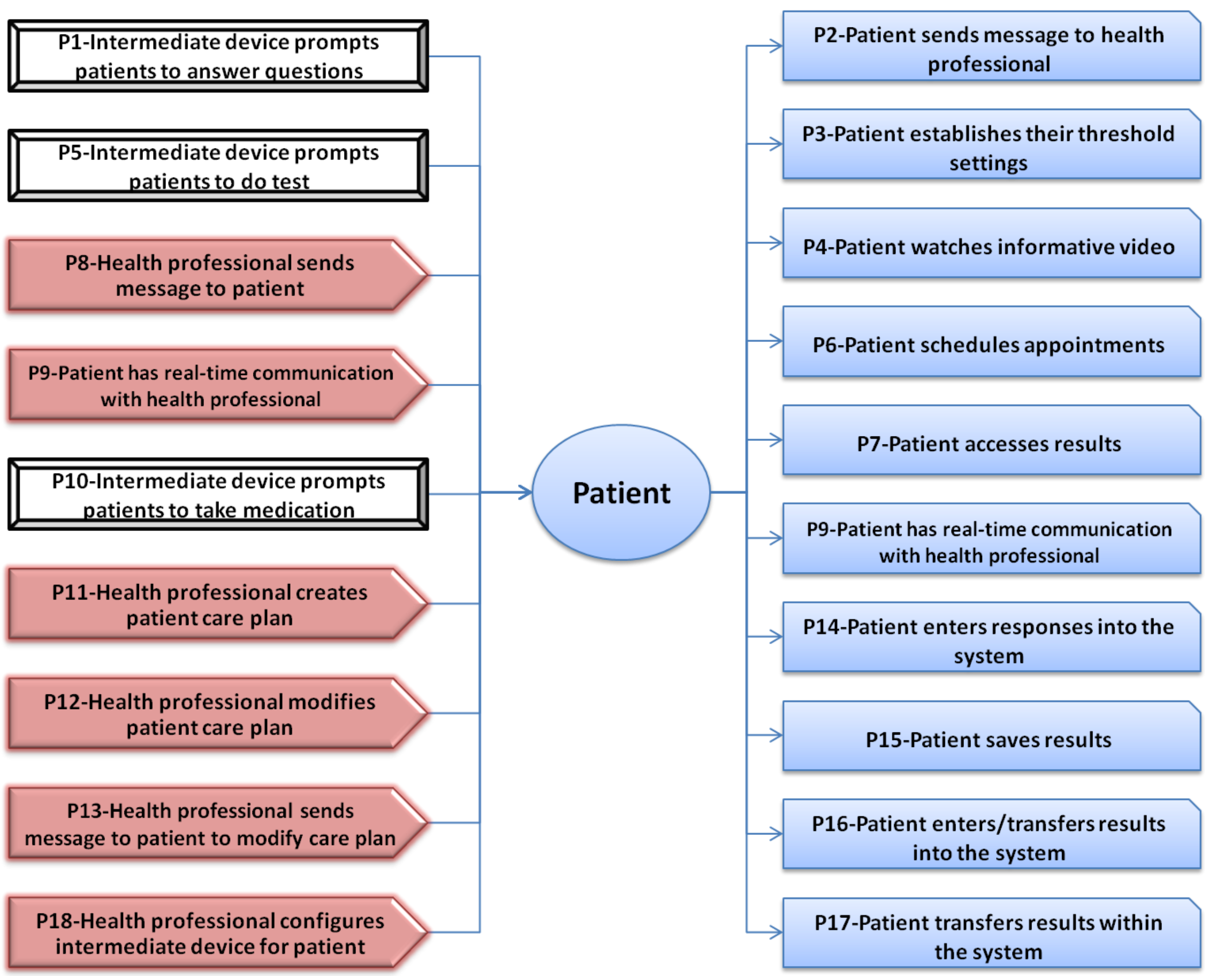


Figure 5-1 – The patient centred view of a telehealth system

5.3.2 Caregiver

2 capabilities are related to the caregiver and were grouped into 2 separate categories (Table B-2). Of these categories, 1 is initiated by the caregiver and 1 has an outcome that affected the caregiver. The other actors: patient and health professional, do not initiate actions that affect the caregiver. Similarly the caregiver does not initiate actions that affect them.

Figure 5-2 shows the categorised capabilities related to the caregiver in pictorial form.

Figure 5-2 – The caregiver centred view of the telehealth system.

5.3.3 Health professional

21 capabilities were related to the health professional and were grouped into 14 categories (Table B-1 and Table B-3).

Figure 5-3 shows the categorised capabilities related to the health professional in pictorial form.

Nine of 14 categories were initiated by the health professional. Three of 14 categories had an outcome that affected the health professional. They were: ‘H5-Intermediate device sends results to health professional’ (in this case, the health professional is just receiving results and has to decide whether to act on them), ‘H6-System alerts health professional’ and ‘P2-Patient sends message to health professional’. These can be placed in two groups: those initiated by other system entities (intermediate device, EPR and web portal); those initiated by the patient.

Two of 14 categories were initiated by the health professional and had an outcome affecting the health professional. They were: ‘H1-Health professional reviews/analyzes results’ (in this case, the results have already been received and the health professional is taking the time to analyse them) and ‘P9-Patient has real-time communication with health professional’.

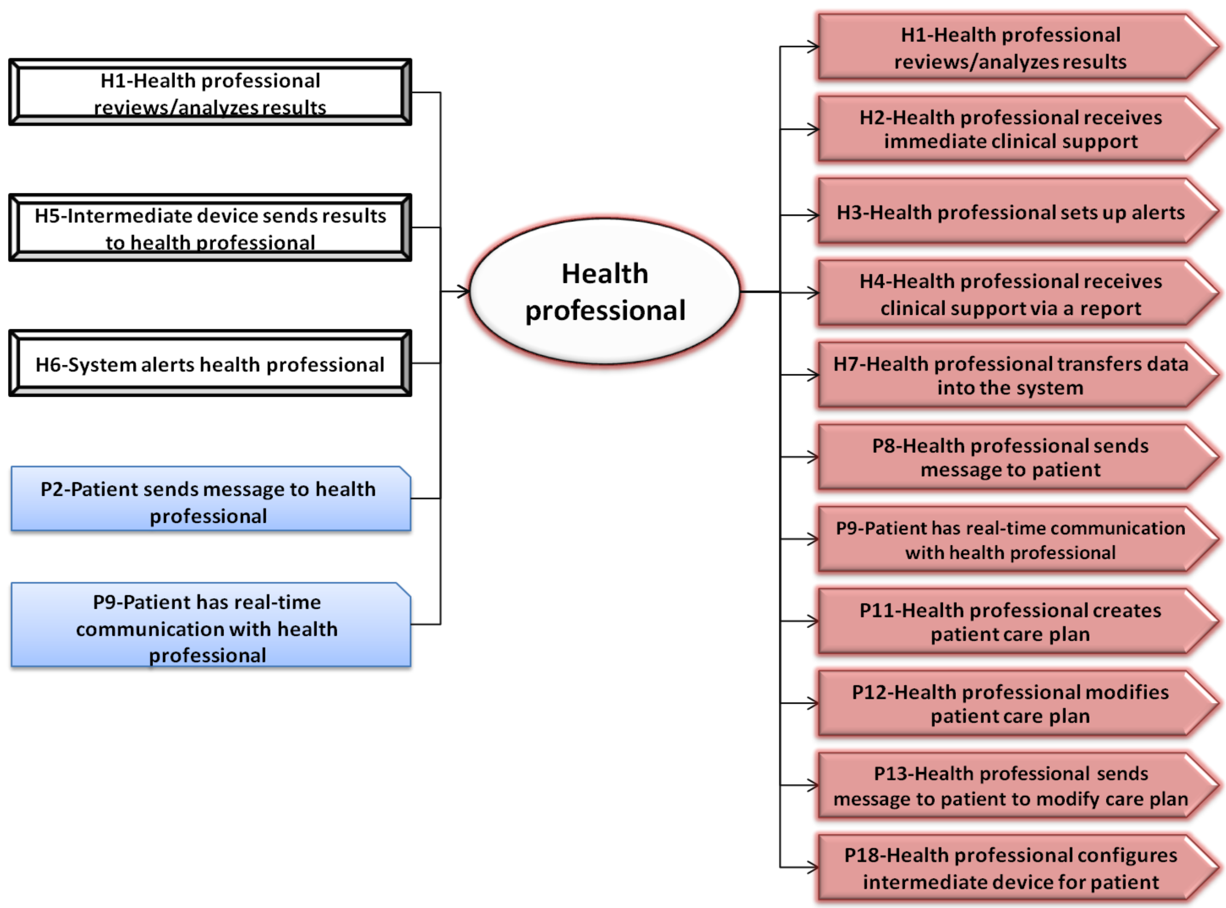


Figure 5-3 – The health professional centred view of the telehealth system

5.3.4 Non-actor entities

14 capabilities were related to non-actor entities and were grouped into 6 categories (Table B-4).

Figure 5-4 (A-B) and Figure 5-5 (C-E) show the categorised capabilities related to the non-actor entities in pictorial form.

Intermediate device (with display) was the most popular 'acting entity' and was used in all six categories of capabilities.

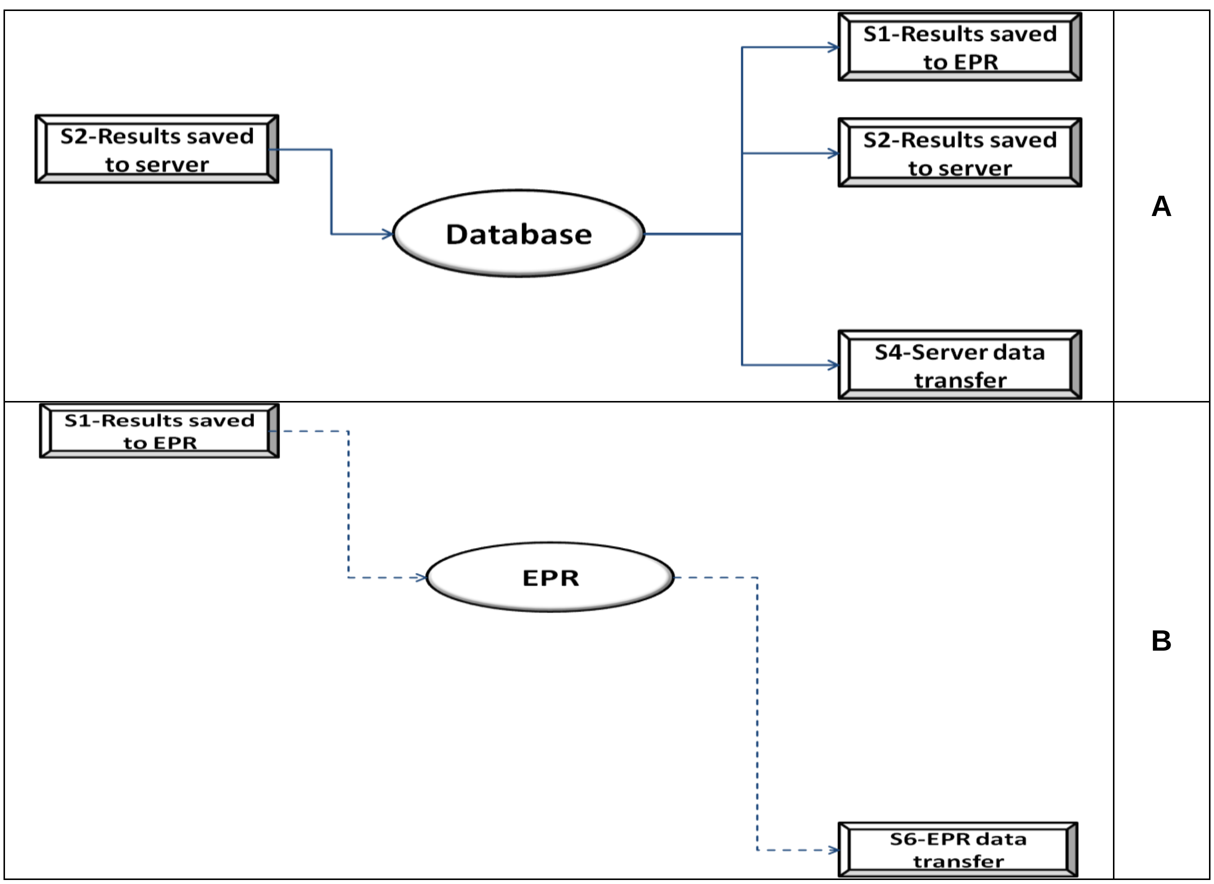


Figure 5-4 – Non-actor capabilities of a telehealth system: A=Database; B=EPR

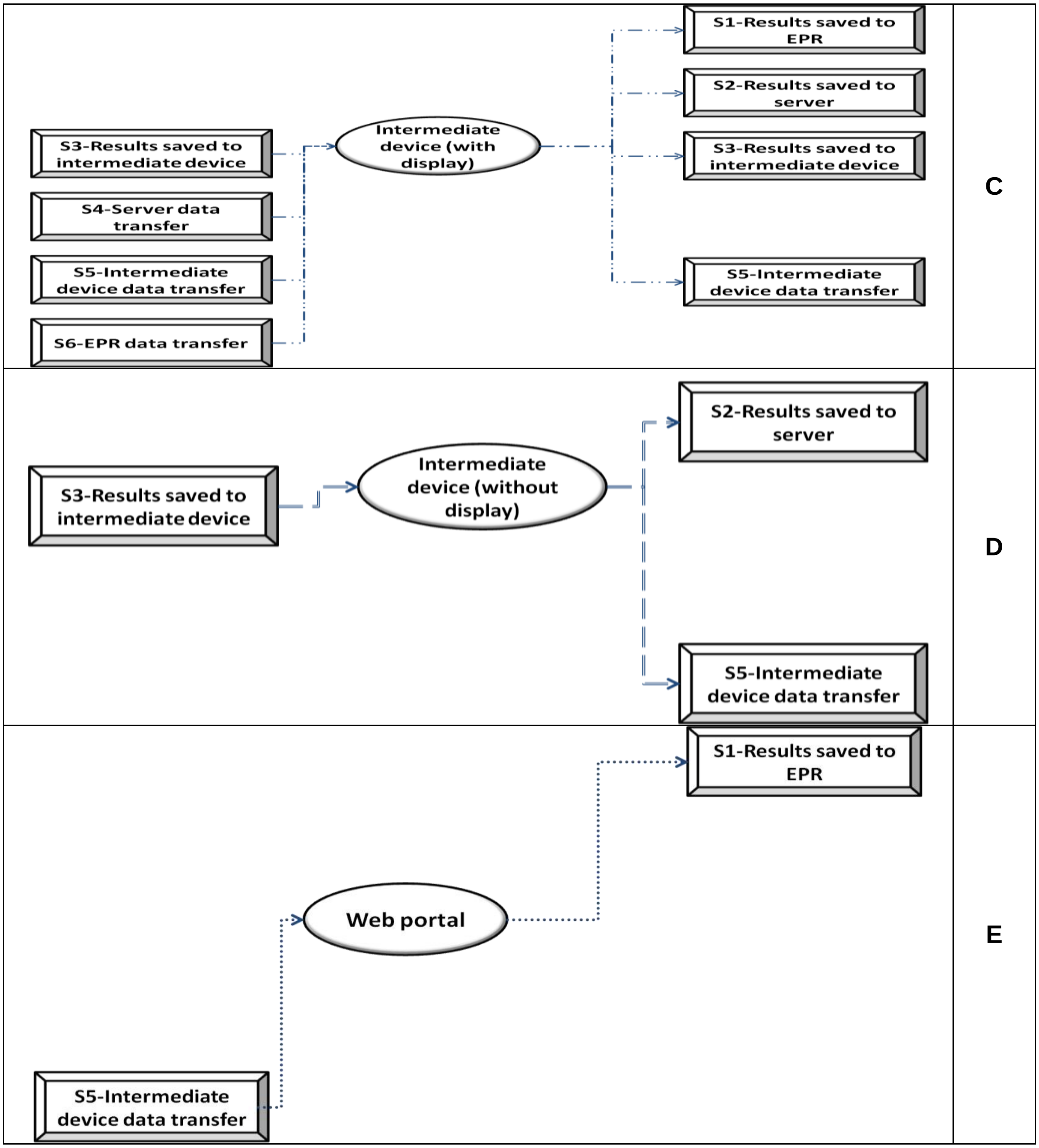


Figure 5-5 – Non-actor capabilities of a telehealth system: C=Intermediate device (with display); D=Intermediate device (without display); E=web portal

5.3.5 Overview of categorised capabilities for actors within the individual telehealth offerings

This section shows the categorised capabilities based on the actors for each of the telehealth offerings.

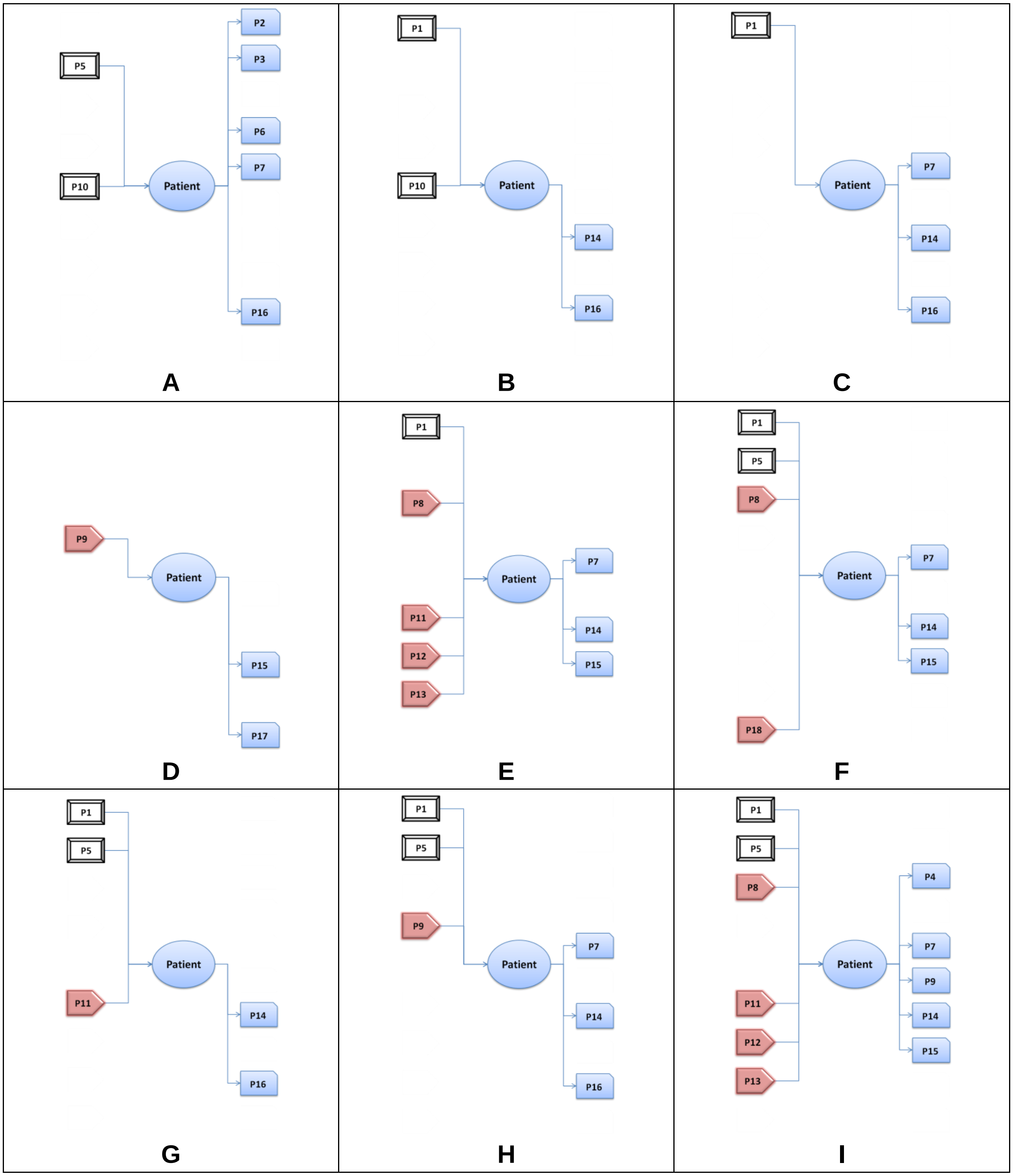
5.3.5.1 Patient centric view of current telehealth offerings

The patient centric view is shown in Figure 5-6.

The variance in the categorised capabilities currently offered to patients is high, with the number of capability categories offered ranging from 1 (offering J) to 11 (offering I). This is out of a total of 18 possible categories (Table B-1 and Figure 5-1). Aside from the example of offering I, all current offerings have less than half the possible patient centric capability categories.

The categorised capabilities seen in more than six of the offerings are ‘P1-Intermediate device prompts patients to answer questions’, ‘P7-Patient accesses results’ and ‘P14-Patient enters responses into the system’.

The following four capability categories are only present in a single telehealth offering: ‘P2- Patient sends message to health professional’ (offering A), ‘P3- Patient establishes their threshold settings’ (offering A), ‘P6- Patient schedules appointments’ (offering A) and ‘P18- Health professional configures intermediate device for patient’ (offering F).


A
P5
P10
Patient
P2
P3
P6
P7
P16
B
P1
P10
Patient
P14
P16
C
P1
Patient
P7
P14
P16
D
P9
Patient
P15
P17
E
P1
P8
P11
P12
P13
Patient
P7
P14
P15
F
P1
P5
P8
P18
Patient
P7
P14
P15
G
P1
P5
P11
Patient
P14
P16
H
P1
P5
P9
Patient
P7
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I
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Patient
P4
P7
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P15

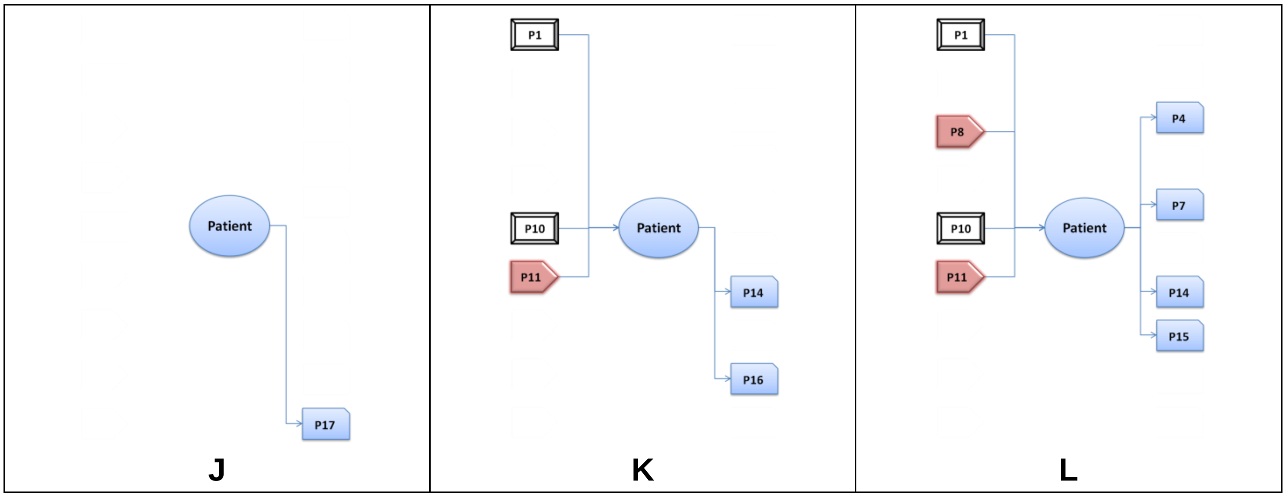


Figure 5-6 – Patient capabilities from current telehealth offerings

5.3.5.2 Caregiver centric view of current telehealth offerings

The caregiver centric view is shown in Figure 5-7. Only four of the offerings have caregivers as actors in the system. The capability category of caregivers accessing results is available in four systems. The category of caregivers receiving alerts is available in two of the offerings.

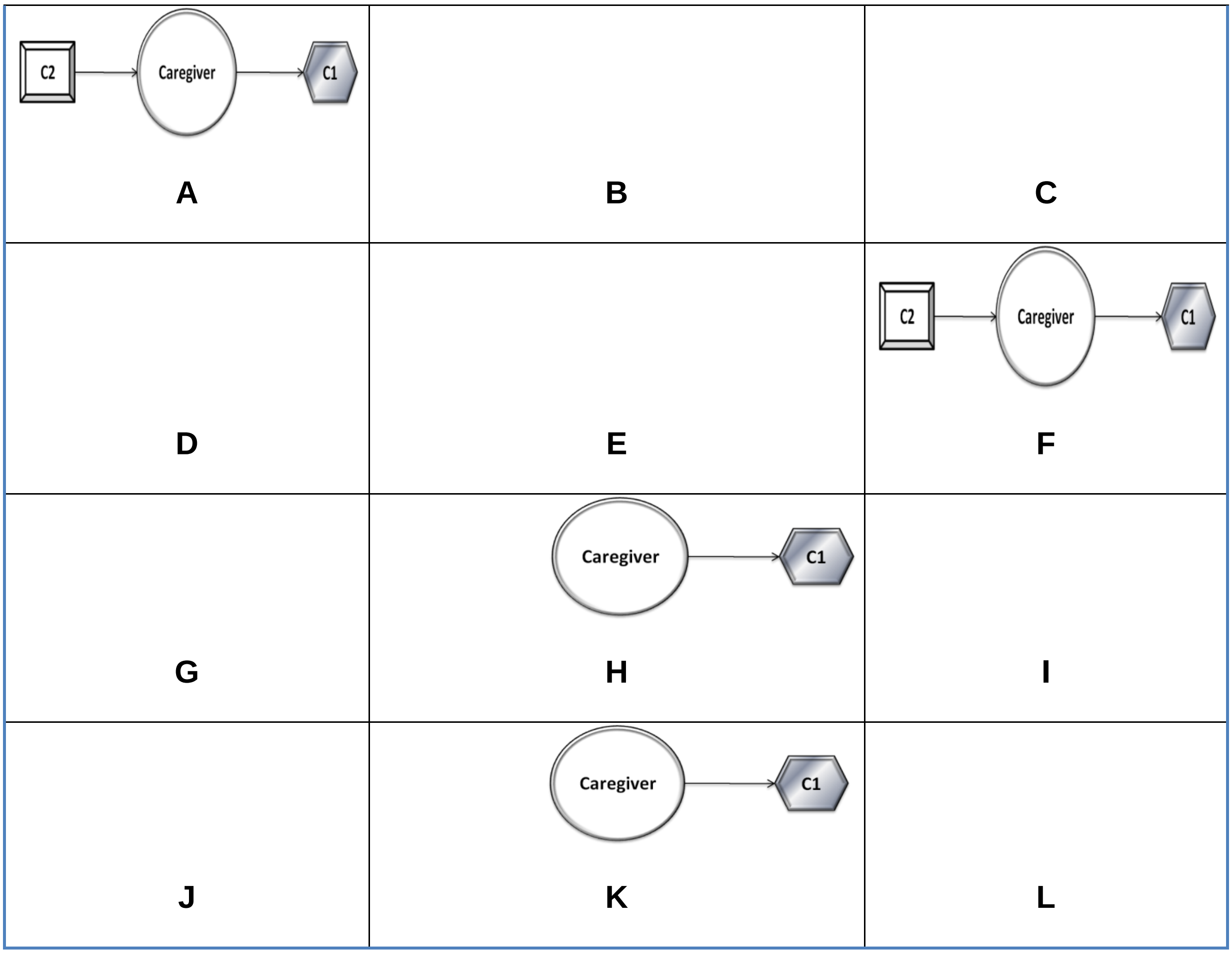


Figure 5-7 – Caregiver capabilities from current telehealth offerings

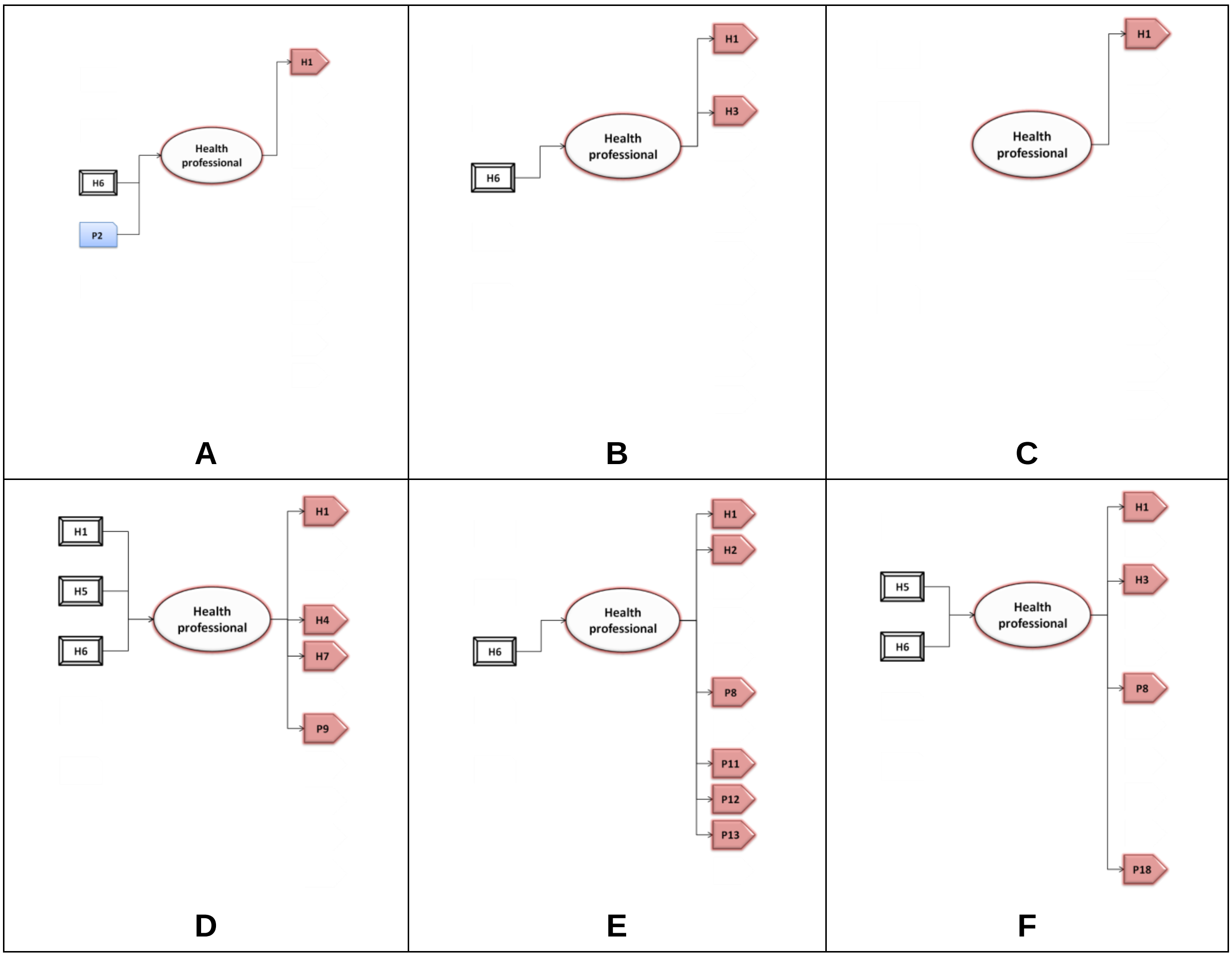
5.3.5.3 Health professional centric view of current telehealth offerings

The health professional centric view is shown in Figure 5-8.

The amount of capability categories offered ranges from 1 (offering C) to 8 (offering I).

The categorised capabilities seen in more than six of the offerings were ‘H1-Health professional reviews/analyzes results’ and ‘H6-System alerts health professional’.

Two capabilities were present in a single telehealth offering: ‘H4-Health professional receives clinical support via a report’ (offering D) and ‘H7-Health professional transfers data into the system’ (offering D).



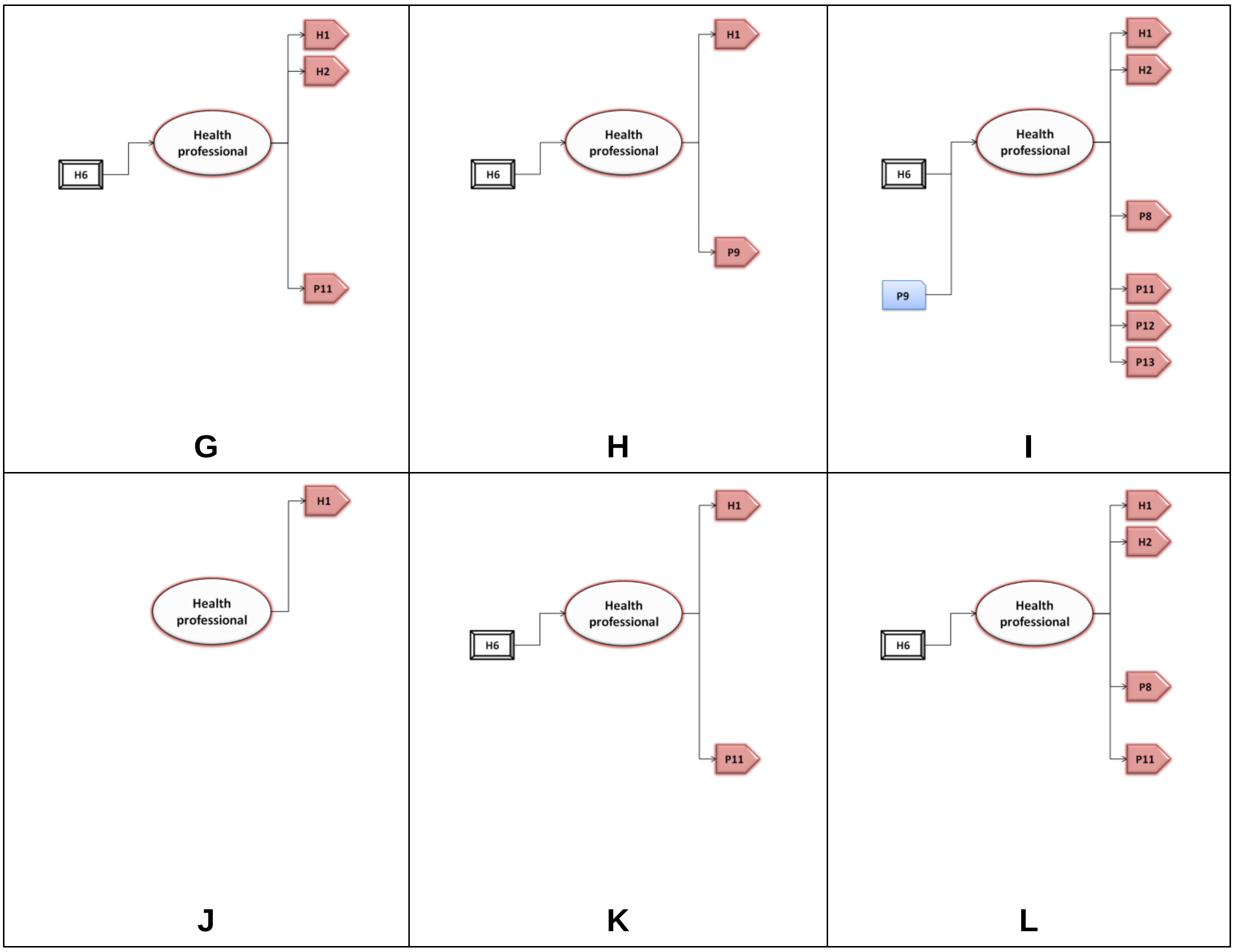


Figure 5-8 – Health professional capabilities from current telehealth offerings

5.4 Discussion

The discussion of the capability categories is presented based on the three actors found in telehealth systems: patient, caregiver and health professional. It considers categories in the following order: actor as initiator, outcome affects actor, actor initiates and is affected by the same outcome. It goes on to consider the variance of capability categories across current telehealth offerings. This is followed by a discussion of categories that did not involve actors.

5.4.1 Overview of capability categories

An overview of telehealth capability categories by actor is given in Table 5-2. The patient capability categories dominate in current telehealth systems forming over half of all the capability categories related to actors (18 of 34). The number of patient as initiator and number of outcome affects patient categories are almost equal at 9 and 8 categories respectively. If there are any underlying reasons for this equality it is difficult to see them in the data set.

Caregivers had the least amount of capabilities. Patients and health professionals initiated the same amount of capabilities, therefore suggesting that they are the most active participating actors in telehealth systems. Patients are also affected by the highest number of categories.

	Patient	**Caregiver**	**Health professional**	**Total**
Categories initiated by actor	9	1	9	
Categories where outcome affects actor	8	1	3	
Categories initiated by and is affected by actor	1		2	
Total categories related to actor	18	2	14	34

Table 5-2 – Distribution of capability categories for actors

5.4.2 Capabilities for patients

5.4.2.1 'Patient as initiator' categories

Two trends can be observed in the patient as initiator categories. One is that of patients as data generators or transmitters: patients provide test results and questionnaire responses that are analysed or used by other system components. The second is that of some degree of active management of their health. Patients can establish their threshold settings (they can set targets that they want to meet); watch information videos (to become more knowledgeable about their health); schedule appointments and access their results (to view trends of data showing their progress). These categories support points raised in government policy that advocate patient empowerment (Department of Health, 2006b) such that they can play an active role in managing their health.

Nearly all system entities are affected by the capabilities initiated by the patient: the patient his or herself, a health professional, web portal, intermediate device (with display), intermediate device (without display), database and call centre. The actors that the patient's action affects are themselves and health professionals.

It is interesting to note that none of the patient's actions directly affect the caregiver, though the caregivers have access to the patient's results.

5.4.2.2 'Outcome affects patient' categories

These are composed of 8 categories. They are dominated by the health professional (5 of 8) with the rest initiated by other system entities.

For those initiated by the health professional, the dominant number of categories (3 of 5) consisted of actions regarding patients' health plans: creation, transmission and modification of the plans respectively. This appears to be the current direct patient-affecting role for health professionals in current telehealth systems.
The system entities are intermediate device (with display), web portal and EPR. In each case the action is of the form of automated prompts to aid patients in compliance with routines.

5.4.2.3 'Patient is initiator and is affected by the same outcome' category

'P9-Patient has real-time communication with health professional' is the only capability category where patients can have real-time communication with another system actor: in this case to receive immediate feedback on their results from health professionals.

5.4.2.4 Variance of patient capability categories across current telehealth offerings

The most popular capability category within telehealth offerings for patient as initiator is ‘P14-Patient enters responses into the system’ appearing in 9 of the 12 offerings. Other popular patient as initiator categories were ‘P7-Patient accesses results’, found in just over half of the telehealth offerings and ‘P16-Patient enters/transfers results into the system’ found in exactly half of telehealth offerings.

The most popular capability category for outcome affects patient is ‘P1-Intermediate device prompts patients to answer questions’, found in 9 of the 12 offerings.

3 of 4 capability categories that are only present in a single telehealth offering were present in offering A, indicating offering A to be an outlier in current telehealth offerings. Since the capability categories (P2, P3, P6) are advocating the patient taking charge of their healthcare, this system may be more suited to patients that are experienced in managing their health (i.e. have suffered from the condition for a long time).

5.4.3 Capabilities for caregivers

5.4.3.1 ‘Caregiver as initiator’ categories

The only category initiated by the caregiver was that of accessing patient’s results. This suggests that currently, the caregivers’ presence within telehealth systems is marginal and limited to support via knowledge of patients’ progress.

Caregivers do not directly affect other actors of the systems and unlike the other two actors, caregivers do not initiate an action that impacts on themselves. There are no obvious reasons in the data for the current minimal role of caregivers, but it raises a clear barrier for the adaptation of such systems for joint telehealth and telecare use.

5.4.3.2 'Outcome affects caregiver' categories

The only category with an outcome affecting the caregiver was 'C2-caregiver receives alerts'. This was initiated by the web portal. Alerting caregivers, is a way of providing reassurance to them of the health status of the patient especially if the caregivers are family members.

There were no actors with an outcome affecting the caregiver.

5.4.3.3 Variance of caregiver capability categories across current telehealth offerings

The caregiver was present in only 4 of the 12 telehealth offerings, which seems to indicate that the majority of service providers do not currently consider the caregiver as having a role in telehealth systems.

5.4.4 Capabilities for health professionals

5.4.4.1 'Health professional as initiator' categories

Categories in which the health professional is initiator show four roles played by them. They are informed of patients' results; they are alerted when there are unusual results entered by patients; they can advise the patient on issues about their health; and they can receive clinical support from other health professionals. As noted above, health professionals are primarily responsible for setting up the care plan of the patients.

These capabilities imply that telehealth systems may help to complement the role of health professionals within healthcare. However, a difference between this and traditional administration of healthcare is the potential increase in the speed of the communication process. A training issue also arises for health professionals in the best-practice use of the required new technology. Six entities are affected by the capabilities initiated by the health professional. These are: patient, health professional, web portal, intermediate device (with display), call centre and EPR.

The actors that the health professional's action affects are themselves and patients. It is interesting that none of the health professional's actions directly affected the caregiver. Hence there is no human back-up in current telehealth systems for situations in which the health professionals are unable to communicate with the patient.

5.4.4.2 'Outcome affects health professional' categories

Categories where the outcome affects the health professional can be conveniently divided into two groups.

The first group is those initiated by the patient (1 of 3). This only contains one category. The benefit of the patient having a capability to do this is they can be advised sooner about their health. The disadvantage of this is that health professionals may receive non urgent enquiries which will result in overburdening them with information.

The second group is those initiated by other system entities (2 of 3): they are intermediate device (with display), intermediate device (without display), web portal and EPR. These relate to providing information to the health professional. The issue of how to avoid overloading the health professional with data and allowing them to prioritise should be a key aspect of telehealth systems, though in current telehealth systems, minimal information was available of the details of algorithms to help achieve this.

It is interesting that there is three times the amount (9 compared with 3) of 'outcome affects health professional' categories compared with 'health professional as initiator' categories. It is unclear from the analysis why this is the case.

Alerts to health professionals in telehealth systems will draw their attention to cases that may otherwise be missed. Alerts to health professionals also prompt them to contact the patient and this may result in either no action or the subsequent change of their care plan at an earlier, rather than later stage.

5.4.4.3 ‘Health professional is initiator and is affected by the same outcome’ categories

These categories (‘H1-Health professional reviews/analyzes results’ and ‘P9-Patient has real-time communication with health professional’) point to telehealth systems allowing health professionals to gain access to test results that patients would have carried out on their own. The benefit this has is if the health professionals notice anything unusual about the results, they can quickly make contact with the patient to for instance modify their care plan.

5.4.4.4 Variance of health professional capability categories across current telehealth offerings

The most popular capability category, found in all current telehealth offerings, is ‘H1-Health professional reviews/analyzes results’. This capability category is both initiated by and affected by the health professionals. This category may form a short summary of what the basic capability of a current telehealth system is.

The most popular capability category for outcome affects health professional is ‘H6-System alerts health professional’ (10 offerings). While, the most popular capability category for health professional as initiator, aside from H1, is ‘P11-Health professional creates patient care plan’ (5 offerings).

Four capability categories are only present in 1 single offering. Two capability categories are only present in offering D. They are: ‘H4-Health professional receives clinical support via a report’ and ‘H7-Health professional transfers data into the system’. The receipt of clinical support via a report is a capability available when specialists are consulted by a General Practitioner (GP). ‘P18-Health professional configures intermediate device for patient' is only found in offering F. While 'P2-Patient sends message to health professional' is only in offering A.

5.4.5 Capabilities by non-actor entities

The non-actor capability categories resulted in two outcomes: results being saved (S1, S2 and S3) and results being transferred to another component of the telehealth system (S4, S5 and S6). This implies that the saving of results and information transfer within telehealth systems are equally important actions.

5.4.5.1 Database

Categories which the database initiates show two roles. They save results to EPR; they transfer results to another component of the telehealth system (intermediate device (with display)).

Only one category is initiated by the database and its outcome affects the database: 'S2-Results saved to server'. The database itself or an intermediate device (with display) can affect the database, causing results to be saved to it.

5.4.5.2 EPR

Only one category is initiated by the EPR: 'S6-EPR data transfer'. This indicates that one the roles of EPR is to transfer data to another component of the telehealth system.

The other role for the EPR was that of saving results. This is demonstrated by only one category: 'S1-Results saved to EPR'. This action was initiated by three system entities (database, intermediate device (with display) and web portal). In all three cases, they are saving results to the EPR.

5.4.5.3 Intermediate device (with display)

Two categories are initiated by the intermediate device (with display): 'S1-Results saved to EPR' and 'S2-Results saved to server'. These categories affected the EPR and database and involved saving results.

Two categories have actions that affect the intermediate device (with display): 'S4-Server data transfer' and 'S6-EPR data transfer'. These categories are initiated by the database and EPR. These results involved the transfer of data therefore supporting the role of intermediate devices being that of a connector used to exchange information in a telehealth system (Adeogun et al. 2011a).

Two categories were initiated by and had an outcome affecting the intermediate device (with display): 'S3-Results saved to intermediate device' and 'S5-Intermediate device data transfer'.

In particular, S3 is only seen in intermediate devices.

5.4.5.4 Intermediate device (without display)

Two categories are initiated by the intermediate device (without display): 'S2-Results saved to server' and 'S5-Intermediate device data transfer'. These categories affected the database and intermediate device (with display).

Only one category had an outcome affecting the intermediate device (without display): 'S3-Results saved to intermediate device'. As noted above, S3 is only seen in intermediate devices.

5.4.5.5 Web portal

'Web portal as initiator' category

Only one category is initiated by the web portal: 'S1-Results saved to EPR'. This shows that the role of web portal is that of transferring data in the system.

'S5-Intermediate device data transfer' is the only category with an action that affects the web portal.

5.4.5.6 Variance of non-actor capability categories across current telehealth offerings

'S2-Results saved to server' was the most commonly represented capability among the telehealth offerings. Three categories: 'S1-Results saved to EPR', 'S4-Server data transfer' and 'S6-EPR data transfer' were represented in four telehealth offerings.

'S3-Results saved to intermediate device' is the only category found in offering J.

These results show that non-actor entities have a place in telehealth systems as they supplement information exchange.

From the data set, it has not been possible to identify reasons why there are more categories for intermediate device (with display) compared with those that don't display data.

5.5 Limitations and further work

The derived capabilities in this paper are limited to telehealth systems for managing chronic diseases.

This paper raises some questions about the current state of the art in telehealth systems that cannot be answered by the current data set of the paper. This is notably the case for caregivers, for example: why there are few capabilities related to the caregiver; why caregivers do not have a direct impact on the other actors; why do caregivers have a limited role currently in systems; and why do the other actors' actions not have a direct impact on caregivers.

5.6 Conclusions

The aim of the paper was to derive capabilities of telehealth systems since limited evidence was available in literature of a systematic review of such. Capability has been defined in this paper as the ability of a system entity to perform an action. The system entities considered are those previously identified in a study (Adeogun et al. 2011a).

The capabilities were based on the perspective of actors though their views were not obtained and were compiled from 12 telehealth offerings for managing chronic diseases.

A hierarchical methodology based on the actors was used to group the capabilities into categories. This methodology considered actors initiating actions over the actor being affected by the capability. Non-actor capabilities were grouped into a separate category.

40 categories of capability were derived from 55 individual capabilities: 18 categories for the patient, 2 categories for the caregiver, 14 categories for the health professional and 6 categories for non-actor entities.

Patient as initiator categories showed their role is to provide data and also have more responsibility in managing their health.

For cases where the outcome affects the patient, these are dominated by actions by health professionals involving the creation/modification of patients care plans.

Although, caregivers have access to patient’s results and are alerted of unusual results entered by patients, they do not have an action with a direct impact on the patient. They also do not impact on the health professionals.

For categories where the health professional is the initiator, telehealth systems helped to complement their role since they are involved in setting up care plans, are alerted when there are unusual results entered by patients, can advise the patient on issues about their health and can receive clinical support from other health professionals.

Where the outcome affects the health professional, the role of health professionals is to increase awareness of the patient’s progress to be able to provide better treatment for them.

The non-actor capabilities result in two outcomes: results being saved and results being transferred to another component of the telehealth system.

6 Evaluation of the state-of-the-art in informatics in glucometers

Abstract

This review evaluated the level of informatics in glucometers through an assessment of the quantity and types of information and advice provided to users. Manufacturer websites were investigated and the characteristics of glucometers were examined. One hundred glucometers from 27 manufacturers were analysed. Many glucometers contained simple informatics features and five also contained on- device graphing features for users to monitor trends. Some manufacturers have extended informatics via external software. A small number of glucometers provided knowledge for the user by, for example, simple embedded decision support protocols. However, it is suggested that glucometers could better serve as primary care devices through the incorporation of more decision support directly on the device.

6.1 Introduction

The change in emphasis from acute to primary care is producing a requirement for a new generation of medical monitoring devices. In addition to the technical challenges that will need to be overcome, informatics challenges must be met, if device users are to obtain full services from such devices. In particular, problems with future point-of-care devices for medical use may result from the inaccuracy, poor transmission, garbled reception or misinterpretation of the information they are designed to provide (Meier and Jones, 2005). Therefore, it is useful to assess the state-of-the-art in informatics for current medical monitoring devices, of which the most sophisticated and widely used example is the blood glucometer. This article represents such an assessment, along with a comparison of the state-of-the-art with medical informatics models.

6.1.1 Background on diabetes

Diabetes mellitus is a chronic condition characterised by elevated blood glucose due to absolute or relative deficiency of insulin. In 2000, it was estimated that there were 171 million people in the world with diabetes (World Health Organization, 2006). The classic symptoms of diabetes include 'increased urinary frequency (polyuria), excessive thirst (polydipsia), excessive hunger (polyphagia) and unexplained weight loss' (World Health Organization, 2008a) and these aid in its diagnosis along with a blood test. The World Health Organization (WHO) describes two main types (2008a).

Type 1 diabetes (insulin-dependent diabetes mellitus) – is commonly found in children and adolescents in whom the pancreas is unable to produce sufficient insulin to metabolise glucose in the blood thus resulting in hyperglycaemia. Type 2 diabetes (non-insulin dependent diabetes mellitus) – usually occurs in adults and is related to obesity and unhealthy diets. There is a third type which only affects pregnant women – gestational diabetes, but this is generally a temporary condition normally resolved 6 weeks after delivery. However, in such women, the risk of developing a subsequent case of type 2 diabetes has been shown to increase.

6.1.2 Monitoring diabetes

Patients with diabetes need to monitor their blood glucose regularly as there are risks associated with high blood glucose in the body including: eye damage, leading to blindness; kidney damage, leading to renal failure; nerve damage, leading to impotence and foot ulcers which may result in amputation (diabetes is the leading cause of non-traumatic amputation); ketoacidosis, a high concentration of ketones in the body occurring when the body is unable to metabolise glucose for the cells, thus finding an alternative by using fat and proteins instead; heart disease; stroke; coma – in extreme cases (World Health Organization, 2008b).

Blood glucose monitoring for patients can be done through regular visits to their health professional, however patients can also monitor their own blood glucose regularly with a glucometer or glucose meter.

6.1.3 Glucometers

Glucometers are designed for monitoring rather than for diagnosing diabetes. Some glucometers require coding, which refers to calibrating the meter to the batch of test strips being used as there is variation between batches of strips. If the glucometer is not calibrated, it will give an incorrect result (Proud and Bayer, 2004).

The blood sample for the test is generally taken from the fingertip as this provides the most accurate result but it also causes the patient the most pain because the fingertips contain many nerve endings. Therefore, some glucometers allow the testing of blood samples from other sites and this is known as alternative site testing (AST). The sites include 'upper-arms, thighs, base of the thumb, stomach areas and forearms' (Cembrowski, 2002; Lucidarme et al. 2005; American Diabetes Services, 2010).

A lancet is needed to obtain the blood sample and it has different settings to determine the depth to which the skin will be pierced, which helps in determining the size of sample obtained. Modern glucometers are able to analyse relatively small amounts of blood (minimum of 0.3 µL).

The test strips for glucometers vary and the latest ones available are designed to allow easier blood application. Some have a confirmation window that will provide assurance to the patient that a sufficient amount of blood has been provided (Diagnostic Devices Inc., 2010). Glucometers provide the blood glucose results in specified units: either mg/dL (which is the standard for USA) or mmol/L (which is the standard in UK, Canada and some

European countries). Some glucometers have the capacity to store the results and some also have averaging features to aid users in gaining an overview of their blood glucose levels over periods of time.

6.1.4 Aim

The aim of this review was to ascertain the state-of-the-art in informatics for glucometers. The level of informatics available on the device was analysed and the quantity and types of information provided to users were investigated. The review describes the methodology used, gives the results obtained from that methodology, discusses the findings and compares them against the state-of-the-art in informatics.

6.2 Methodology

A key word search was carried out to identify different types of commercially available glucometers. An on-line resource, for example (Mendosa/Diabetes Monitor, 2010), and the British National Formulary (BNF) were of particular assistance.

Glucometer manufacturers' websites were investigated to obtain the details of the glucometers they supplied. In total, information on 100 glucometers, available between the years 1998 and 2008, was obtained. This represented 27 manufacturers. The list of glucometers assembled for this review was not exhaustive; however it included popular brands available, for example, Abbott, Bayer, LifeScan and Roche Diagnostics.

The operating manuals of 72% of glucometers were available online or after request from manufacturers. There were no manuals for 28% of devices by 14 manufacturers/distributors thus resulting in incomplete information. However, a short description was normally provided by the manufacturer for those glucometers that did not have online manuals. The manuals contained detailed instructions on how to operate the glucometer as well as its features and specifications.

The manuals were analysed to obtain glucometer specifications and operating details. A categorisation scheme was drawn up to investigate whether glucometers possessed particular informatics features. Where glucometers were supplemented with ‘off-device’ data management software, the capabilities of the software were analysed. The results obtained are presented below in five groups: information before testing, testing, on-device data manipulation after testing, off-device data management software capabilities and “advice” given by the glucometer.

6.3 Results

6.3.1 Information before testing

Sixty-seven per cent of the devices reviewed required coding and 27% did not. Information about coding could not be obtained for 6% of devices. Nineteen per cent of the devices had the option of setting reminders for the patient to test, which shows that many manufacturers have not considered this as an essential feature to incorporate.

Sixty-two per cent of the devices displayed an error message indicating that the glucometer was not operating in the right temperature range. In addition, 37% of devices also displayed a thermometer symbol on their screen to indicate that it was not operating in the right temperature range.

6.3.2 Testing

The time taken to generate results on devices was compared and the range was between 3 and 50s. Some devices provided a time range for the time taken to obtain the result and for the purpose of data analysis this was adjusted to the maximum time given. The shortest time taken to obtain test results was 3s and that was seen in 1 device – 'Evolution' (Infopia). The majority of the devices (30%) generated their result in 5s, followed by 20% of devices generating their result in 10s and 15% of devices generating results in 7s (see Figure 6-1). The maximum time recorded was 50s on 'Prestige IQ' (Home diagnostics).

6.3.3 On-device data manipulation after testing

Twenty per cent of the devices allowed results to be flagged or marked with a symbol in order to associate a particular event to the result.

Five per cent of the devices allowed users to add a comment to annotate the result. The glucometers provided predefined comments for users to select from. Table 6-1 shows examples of the comments available. Normally, the comments were found in a single list. However, the "OneTouch UltraSmart" (LifeScan) glucometer divided them into four categories – food, health, exercise and medication.

Eighty-one per cent of the devices calculated an average of the results recorded. Devices varied in the number of days over which an average could be calculated, and in how many variations of averages were permitted. The maximum number of variations of the average was six types, i.e. 7-, 14-, 21-, 28-, 60- and 90-day averages. Figure 6-2 plots the number of glucometers against the number of types of average which they were able to display.

The majority of devices (21%) calculated three types of averages, with 15% that calculated 7-, 14- and 30-day averages, 2% that calculated 7-, 14- and 28-day averages and 3% that calculated 14-, 30-, 90-day averages. One device, 'Eclipse' (Infopia) allowed the patient to set three unique averages. Twenty per cent of the devices calculated six types of averages and 19% calculated 1 type of average. Glucometers calculating six types of averages were limited to four manufacturers: CardioCom, Diabetic Supply of Suncoast Inc., Diagnostic Devices Inc. and TaiDoc.

Seventy-nine per cent of the devices allowed results to be downloaded to a computer, thus showing that a majority of manufacturers have considered this as a feature to include. Eleven per cent did not allow results to be downloaded. Manufacturer's information for downloading could not be obtained for 10% of glucometers.

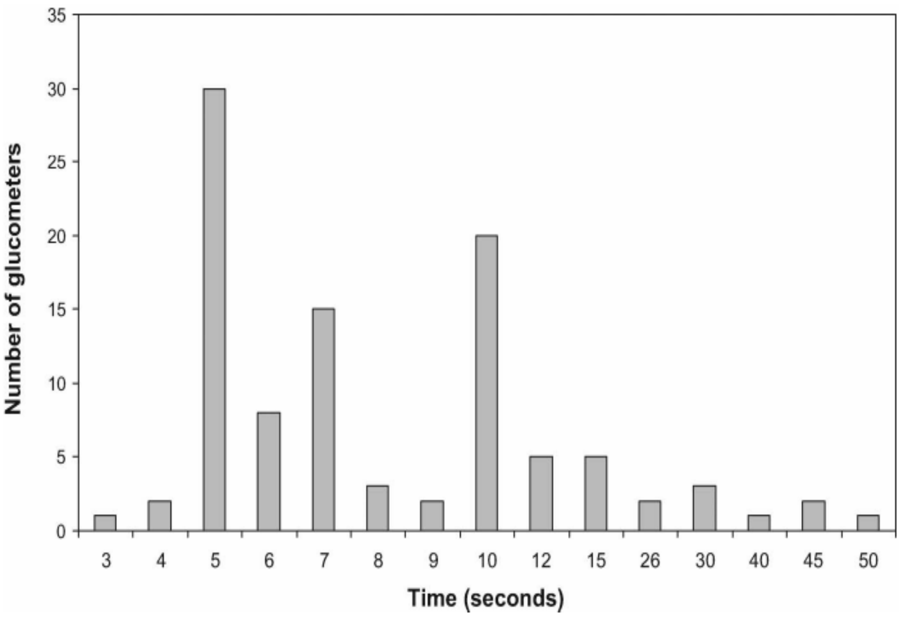


Figure 6-1 – Duration of the test

Glucometer	Available Comments
Accu-Chek Complete (Roche Diagnostics)	Before meal, after meal, fasting, snack, feel hypo, before exercise, after exercise, illness, invalid test, other's result, user defined, stress, L1 control, L2 control, oral medication
OneTouch Profile (LifeScan)	Fasting, pre breakfast, after breakfast, pre noon meal, after noon meal, pre dinner, after dinner, different food, bedtime, during night, pre exercise, after exercise, illness, hypoglycaemia, other
OneTouch UltraLink (LifeScan); OneTouch Ultra2 (LifeScan)	No comment, stress, not enough food, illness, too much food, feel hypo, mild exercise, menses (period), hard exercise, vacation, medication, other
OneTouch UltraSmart (LifeScan)	**Food comments**: before breakfast, after breakfast, before lunch, after lunch, before dinner, after dinner and night **Health comments**: stress, feel hypo, illness, menses, vacation, other

	Exercise comments: before, during, after **Medication**: none

Table 6-1– A summary of comments provided on five glucometers to annotate the results

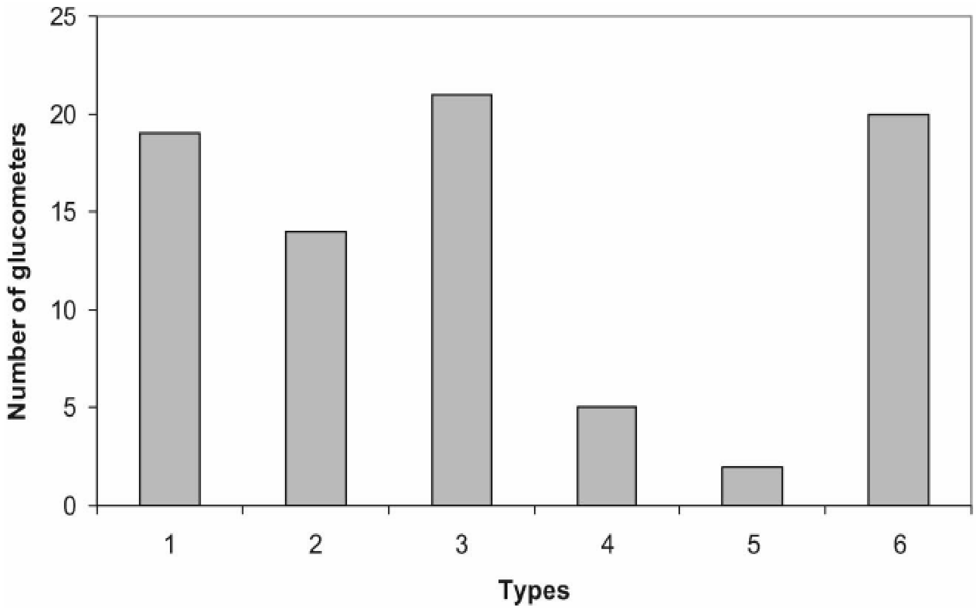


Figure 6-2 – Types of averages calculated on glucometers

6.3.4 Off-device data management software

Fifty-one per cent of glucometers were found to be available with data management software, which extended data analysis ‘off device’. Of these software packages, 90% required data to be transferred via a USB cable; 10% used infra-red connection.

Eighty per cent highlighted outliers in the blood glucose concentration either within a ‘logbook’ or in graphs generated. Ninety per cent allowed the generation of reports, the number of types of reports ranging from 5 to 12. Forty per cent allowed reports to be emailed, however printing or faxing of results were offered as an alternative.

Sixty per cent allowed the importing of extra data in addition to the data downloaded from glucometers. Thirty per cent did not have import facilities. Manufacturer's information could not be obtained for the remaining 10%. Seventy per cent allowed exporting of data to another application whereas 20% did not have export facilities. Manufacturer's information could not be obtained for the remaining 10%.

All the software packages reviewed the calculated averages. Seventy per cent had further statistical analysis capabilities such as standard deviation, minimum and maximum.

6.3.5 On-device and off-device 'advice'

Seventy-seven per cent of the devices displayed a comment, for example 'hi' or 'lo' whenever the blood glucose result was not within the specified measuring range of the device. All manuals included definitions of these comments. The measuring range of 53% of the glucometers was between 20 and 600 mg/dL (or 1.1–33.3 mmol/L). For 23%, manufacturer's information could not be obtained. Within these 77 devices, 73% specified in the manual that users needed to repeat their test to confirm the results, whenever these warning comments were displayed.

Certain glucometers also provided warnings for actual, measured values of blood glucose that were particularly high or low. When a user's blood glucose was lower than a specific range, 'OneTouch Profile' (Life Scan) and 'OneTouch UltraSmart' (LifeScan) glucometers displayed a message: 'Do you need a snack?'

'Danger' or 'Call Dr' was displayed on "OneTouch Profile" (LifeScan) when a user's blood glucose was higher than the specified range. The other glucometers displayed a message related to checking ketones in the blood.

'Accu-Chek Complete' (Roche Diagnostics) displayed a message while the user was carrying out a test, known as the tip of the day, which sometimes provided a reminder or supplied information to the user about managing their diabetes.

Twenty-one per cent of the glucometers displayed messages providing advice on the further action to take based on their blood glucose result. For example, a message to check for ketones was displayed. Fifty-two per cent did not provide further comments. Manufacturer's information could not be obtained for the remaining 27%.

'GlucoTel' (BodyTel Scientific Inc), (not yet commercially available) was specified to incorporate human interaction in terms of the provision of advice. Once results are transmitted and stored in the user's electronic patient health record held on an external database, health professionals could set the option of being alerted (via email, text message or fax) should the user's blood glucose result be extreme. They could then provide the most appropriate advice to the user.

Seventy-four per cent of the glucometers were found to provide information explaining the messages that were displayed on the glucometers. These included error messages. This information was always placed in the manual. Manufacturer's information could not be obtained for the remaining 26%. Twenty-five per cent of the glucometers surveyed had manuals that provided multiple reasons for individual error messages, leaving some interpretation of the message to the user. For error messages, the glucometers provided advice to the user regarding the actions to take and in some cases users were advised to redo their test. Error messages shown on the glucometers included issues relating to the testing process, for example, faulty test strips, the size of the blood sample provided and the temperature at which the test was carried out. Other error messages were related to general problems with the glucometer which would make it unusable. Certain general messages were provided in a pictorial form, e.g. a battery symbol represented low battery on the glucometer and a thermometer symbol indicated that the environmental temperature for the glucometer was not in the right range.

6.4 Discussion

6.4.1 Information provided to users

Coding or calibration of a meter prior to testing is an extra step in blood glucose testing and glucometers that are automatically coded reduce the error that may occur in blood glucose results. Sixty-seven per cent of the glucometers reviewed required a coding step.

Newer glucometer models have been developed with automatic coding features. However, neither set-up provided the user with an estimate of the calibration error.

As testing of glucometers indicates that glucometer inaccuracy is so high that they cannot yet be used as a diagnostic test, this lack of error estimation is a serious limitation on their informatics capabilities (Slingerland and Miedema, 2003).

'Prodigy Eject' (Diagnostic Devices Inc.) and 'Assure Pro' (ARKRAY) reminded users to carry out a control test which enabled patients to check that the glucometer and strips were functioning correctly. This was a necessary step that needed to be carried out occasionally to ensure that the results obtained from the glucometer were accurate and the patient was not misinformed, which may lead to incorrect medication being administered leading to side effects. Control tests were also suggested from the manual when unexpected results were obtained from the glucometer.

The proportion of glucometers reviewed providing an alarm function was 19%. This is particularly important as patient non-compliance with monitoring regimes is an important barrier in the move from acute to primary care. In particular, users with busy or unpredictable lifestyles, reduced memory function or those yet to establish a monitoring routine would benefit from improved alarm functions.

Many of the reviewed glucometers incorporated a feature such that the measurement process started automatically once a sufficient blood sample had been provided; otherwise an error message was displayed by the glucometer.

A general trend was seen in the provision of advice to users, through the manual, of possible post-test actions to take. Seventy-three per cent of the glucometers instructed users to redo their test when unexpected results were obtained. Retests were also suggested whenever there were no factors that could be affiliated to the result obtained by user action, (see below) (for example, the glucometer may have produced a low result, but the user had recently had a meal). Seventeen per cent of the glucometers displayed a message regarding checking for ketones. One glucometer, ‘Precision Xtra’ (Abbott) provided the facility to test for ketones, allowing the user ability to immediately act on the advice.

6.4.2 User interaction with the results

Twenty per cent of the glucometers allowed results to be flagged on the device. The intention of the flags was to highlight particular results so that when data were reviewed, users would be able to discuss with their health professional, possible contributory factors, such as food intake or exercise. However, the flag systems generally consisted of one letter symbols and so could not provide detailed descriptions of factors. Six glucometers had added to the utility of flags by allowing their association with meals, i.e. a result could be flagged as occurring before or after a meal. For these glucometers, flagged results were also not included in the calculation of averages of results. This was a way of excluding outliers and the bias they may have introduced into users’ averages. However, this assumes that the correct course of action would be to exclude these flagged events when calculating a users’ average data.

Averaging of results was a simple and quick way of data manipulation, possessed by 81% of glucometers. This was the most advanced form of data manipulation seen on most glucometers, although ‘OneTouch UltraSmart’ (LifeScan), ‘WaveSense Keynote’ (Agamatrix), ‘WaveSense

Keynote Pro' (Agamatrix), 'Presto' (Agamatrix) and 'Accu-Chek Complete' (Roche Diagnostics) provided on-device functionality to visualise mini graphs to observe trends in the results.

Predefined comments by manufacturers could be added to results to annotate them. Notably, 'Accu-Chek Complete' (Roche Diagnostics) provided software that allowed comments to be modified. Incorporation of this approach into glucometers in general would allow both users and health professionals to monitor and assess how the user's lifestyle was influencing their blood glucose and the advice that could be given to the user on how to improve their health.

In order to improve functionality, 74% of manufacturers have developed off-device software to manipulate results obtained from the glucometer. The off-device software possessed certain common features across manufacturers, such as graphing functionality to visualise trends and an electronic 'logbook'.

All glucometers reviewed had a memory capacity. This functionality reduced the need for users to otherwise manually log their blood glucose data.

6.4.3 Glucometers and informatics

Several informatics models exist which could be applied to glucometers. For example, Georgiou (2002), described a health informatics model comprising data, information and knowledge where data were at the lowest level of the hierarchy and have limited meaning on their own. Information provided context for managing data, whereas knowledge provided guidance for the cause of action to take based on insight and experience. In terms of conformity with such a health informatics model, all glucometers evaluated displayed data. To provide information about the result, 81% of glucometers incorporated an average function that allowed possible trends in the data to be identified, but this was not automatically displayed. Cases where information was provided automatically were when extreme results were displayed (e.g. Hi or Lo), and when tests were carried out in extreme conditions (i.e. a temperature symbol was displayed).

Some glucometers also possessed an aspect of knowledge although this was limited to comments when an extreme result was obtained. To further improve the quality of knowledge provided, glucometers would need to be embedded with decision support which would incorporate results with known facts about diabetes thus aiding users in managing their health. For example, glucometers could include a rule-based decision framework as described by Manjanatha et al. (2007). Manjanatha et al. (2007) noted that current medical devices did not integrate user care information with device-generated data, therefore advice could be provided by the device. Though the authors came to these conclusions for devices offering continuous monitoring, which provided information based on changing conditions of users, the information in this article indicates that this conclusion could be extended to stand-alone devices such as glucometers.

6.5 Conclusion

This article has described the results from an evaluation of commercial glucometers. It has highlighted the main informatics features available. Many glucometers provide information through their manuals. However, limited data processing and real-time decision support were found. It is suggested that glucometers could better serve as primary care devices by incorporating more decision support directly on the device.

7 Intermediate devices in telehealth systems: types available, where they are found and who uses them?

Abstract

'Intermediate devices' are "connectors between point-of-care devices, patients and health professionals" (Adeogun et al. 2011a). Limited evidence is available in literature concerning descriptions of types of intermediate devices and where they can be used within telehealth systems. Therefore the purpose of this paper is to provide details of types of intermediate devices used within telehealth systems, to consider their position between entities of the system and the inputs and outputs they exchange with other entities.

12 telehealth offerings previously evaluated (Adeogun et al. 2011a) for managing chronic diseases were used in the evaluation. Types of intermediate device, their locations of use and the actors using them were identified.

Six types of intermediate devices were found in the evaluation: personal computer, mobile phone, television, landline phone, proprietary device with data display and proprietary device without data display. These were used by three actors: patient, caregiver and health professional.

Five classes of 'informatic location' currently exist for intermediate devices.

Class 1: devices located between the patient and multiple entities.

Class 2: devices located between the caregiver and web portal.

Class 3: devices located between the health professional and multiple entities. Health professionals currently only use generic intermediate devices.

Class 4: devices located between a point-of-care device and multiple entities.

Class 5: devices located between web portal and EPR.

7.1 Introduction

7.1.1 Research Context – What is an Intermediate Device in a Telehealth System?

Generic models of telehealth systems, based on how information is exchanged between components of the system, have recently been developed by the authors (Adeogun et al. 2011a). The models were based on an evaluation of 12 telehealth systems available in the UK (Adeogun et al. 2011a).

Figure 7-1 represents a 'baseline' telehealth model: all evaluated telehealth systems have five entities. These entities are: patient, point-of-care device(s), web portal, personal computer (PC) (highlighted in a bold square) and health professional (Adeogun et al. 2011a).

In this baseline telehealth model the PC plays a particular role: it represents an 'intermediate device', in this case found between the web portal and health professional.

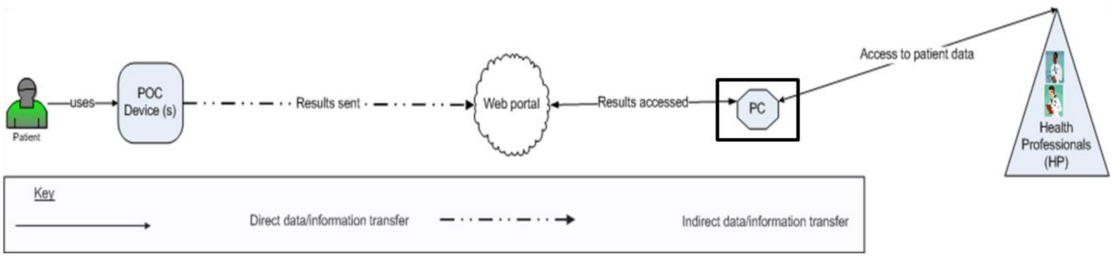


Figure 7-1 – The baseline telehealth model (Adeogun et al. 2011a)

Figure 7-2 represents a 'fully-featured' telehealth model, comprising all the entities, along with their related functionalities, observed in current telehealth systems in the UK (Adeogun et al. 2011a).

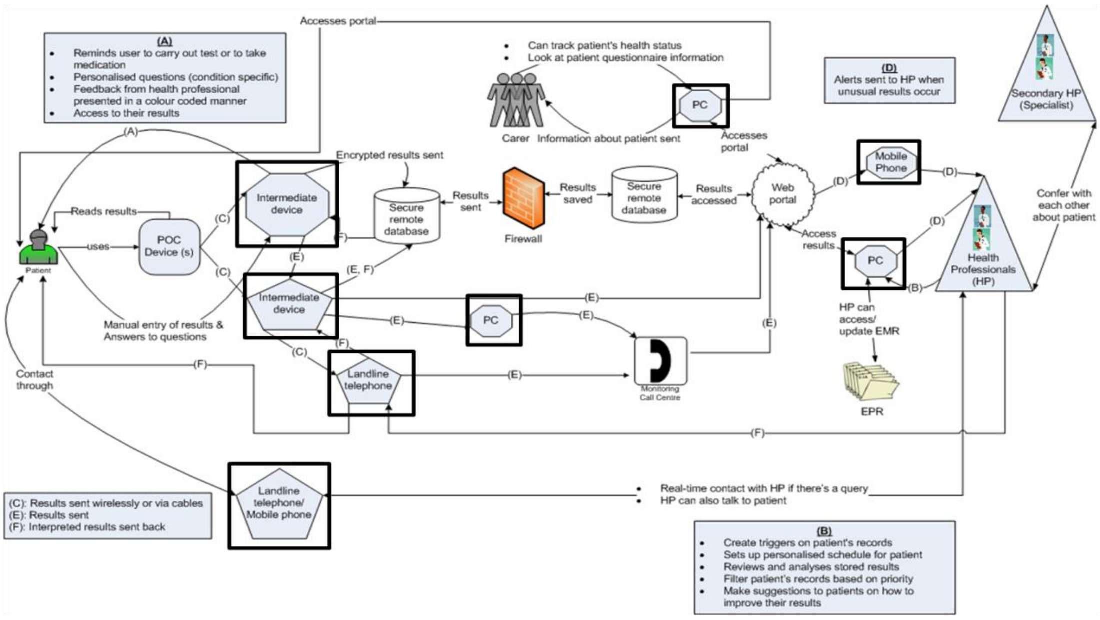


Figure 7-2 – The fully-featured telehealth model highlighting locations of intermediate devices (Adeogun et al. 2011a)

From the above, the authors defined 'intermediate devices' as "connectors between point-of-care devices, patients and health professionals" (Adeogun et al. 2011a). The authors also noted that some devices could be described as 'generic' i.e. designed originally for other purposes but now reused within a telehealth system, for example, mobile phone, PC etc.; while others are 'proprietary', i.e. designed to fulfil a specific role of exchanging data/information between entities of telehealth systems (Adeogun et al. 2011a).

Although clearly 'intermediate devices' play important roles in telehealth systems, there is little other information in the literature on this topic.

Bedini et al. (2006) have described some of the characteristics of, and discussed the classification of, telemedicine systems. However they did not provide details of the criteria chosen to select the categories nor the categories themselves. Shah and Robinson (2008) described two classes of users of medical device technologies based on the purpose of use of the device. They further divide the classes into groups based on the position of the user in the healthcare system. The groups were then divided into types and subtypes based on personal and professional traits.

Turning to the regulators, the Food and Drug Administration (FDA) has a system for classifying medical devices, but this is based on their safety and effectiveness (FDA, 2009). Similarly, according to the Medicines and Healthcare products Regulatory Agency (MHRA), medical devices are classified based on risk to users and the rules of classification are found in Annex IX of the Council Directive 93/42/EEC (2010).

7.1.2 Research questions

As noted above, within the academic literature there is as yet, no formal study of the types of intermediate devices, their 'locations' within telehealth systems, nor how they interact with other components of the system.

This paper, therefore, seeks to address the following research questions:

1. What are the types of intermediate devices that can be used in telehealth systems?
2. Where are intermediate devices located within telehealth systems?
3. Which entities do intermediate devices receive their inputs from and provide their outputs to?
4. Which types of intermediate devices are used by the actors of the system?

The findings from these research questions should allow an initial picture of the place of intermediate devices within telehealth systems to emerge. As such it is hoped that they will be of interest to system providers and to payers who are seeking to understand the properties of telehealth systems.

Further, knowledge of the specific types of devices available would help emerging telehealth service providers in planning whether current 'intermediate devices' can fit into their proposed system.

7.2 Methodology

The methodology for each of the research questions is given below, in sections 7.2.1 – 7.2.4.

7.2.1 What are the types of intermediate devices that can be used in telehealth systems?

Type is defined here as the variant of the intermediate device being used, for example a television or mobile phone. The type was identified directly from the offering. Each type was tabulated and recorded based on the following two features described:

(i) Its availability as a proprietary or generic device.
(ii) Its ability to display data.

7.2.2 Where are intermediate devices located within telehealth systems?

In this context, "where", means the 'informatic location' in the telehealth system. 'informatic location' was assessed as follows:

1. Each device’s ‘informatic location’, with respect to the system entities from which it receives or to which it provides data, was identified. System entities are defined as in (Adeogun et al. 2011a). They are: patient, caregiver, health professional, point-of-care device, database, call centre, web portal and electronic patient record (EPR).
2. The direction of data flow between the entities was noted.
3. For each device, a simple flow path diagram was drawn to represent the information derived from steps 1 to 2.
4. In each flow path diagram, the entities were arranged left to right based on the general order of decreasing informatic proximity to the patient.
    a. Informatic proximity was simply defined as the number of nodes (entities) in the telehealth system between patient and entity).
    b. Two other actors found in telehealth systems (caregiver and health professional) were given a lower priority to patients. The assigned order of precedence was: patient > caregiver > health professional. Patients were chosen as the most important actor since the central goal for healthcare is to benefit them by improving their health and well-being.
    c. For the remaining entities, the order is based on their position within the fully-featured telehealth model (Figure 7-2) by counting the number of nodes between them and the patient.
    d. The order of precedence of the entities is as follows: patient > caregiver > health professional > point-of-care device > database > call centre > web portal > EPR.
5. The flow path diagrams were grouped based on the system entity located to the left of the intermediate device, i.e. in closest informatic proximity to the patient. These were based on the order of precedence of the entities.
6. Following the generation of the flow path diagrams, the frequency of instances of each type of intermediate device in a particular ‘informatic location’ was recorded in a table.
7. The process was as follows:

a. On the x-axis of a table, data was arranged in the following order: the leftmost entity, each type of intermediate device available and the rightmost entity.
b. On the y-axis, the specific arrangement of entities was added and the entity to the left and to the right of the intermediate device were distinguished in separate columns.
c. Every instance of the intermediate device in a particular 'informatic location' position was recorded in a table. A total column is also provided in the table showing the total frequency of occurrences of a intermediate device in an 'informatic location'.

7.2.3 Which entities do intermediate devices receive their inputs and provide their outputs to?

Entities are as defined in section 7.2.2. Type of intermediate device is as defined above in section 7.2.1.

The methodology to derive this was:

1. Each type of intermediate device was noted on the x-axis of a table.
2. The entities of telehealth systems, along with all the types of intermediate devices identified were noted on the y-axis of the same table.
3. Each of the diagrams generated from section 7.2.2, were studied and where the direction of data flow was observed as a direct input or output to an intermediate device, this was recorded.
4. An arrow was added in the table to indicate the direction of information flow i.e. whether it was being received by the intermediate device or whether was being provided by the intermediate device.

7.2.4 Which types of intermediate devices are used by the actors of the system?

An earlier study by the authors showed that three types of actors existed in current telehealth systems: patients, caregivers and health professionals (Adeogun et al. 2011a). Type of intermediate device is as defined above (7.2.1). The types used by actors were assessed by the following steps:

1. The flow path diagrams constructed in 7.2.2 were studied for those involving actors.
2. In a table, the different types of intermediate devices were noted on the x-axis, while the three actors on the y-axis.
3. For each actor type, where a type of intermediate device was identified adjacent to them, this was recorded in the table.

7.3 Results

7.3.1 What are the types of intermediate devices that can be used in telehealth systems?

Six types of intermediate devices were found in the 12 telehealth offerings examined. These are shown in Table 7-1. The table introduces a coding for the device type. This coding is used throughout the rest of this paper, particularly in the diagrams. The table shows whether the devices are proprietary or generic and whether they display data.

Type	Proprietary or Generic	Data display	Diagram Code
Personal computer	Generic	Display	PC
Mobile phone	Generic	Display	MP
Television	Generic	Display	TV
Landline phone	Generic	-	LP
Proprietary device (PD) with data display capabilities	Proprietary	Display	PD-D
Proprietary device (PD) without data display capabilities	Proprietary	-	PD-N

Table 7-1 – Types of intermediate devices found in telehealth systems.

7.3.2 Where are intermediate devices located within telehealth systems?

Table 7-2 represents an overview of the 'informatic location' of intermediate devices within current telehealth systems. They are taken directly from the flow path diagrams constructed. The flow path diagrams can be found in the supplementary material (Appendix C).

19 individual 'informatic location's of intermediate devices exist and these are placed into five groups. The frequencies of each intermediate device located between two entities are shown in the right-hand column of the table.

The most frequent 'informatic location' is between the patient and web portal. The second most popular are jointly: point-of-care device--web portal; and point-of-care--database.

Entity 1	PC	MP	TV	LP	PD-D	PD-N	Entity 2	Total
Patient	3	1			2		Web portal	**6**
		1			1		EPR	**2**
					2		Database	**2**
				1			Call centre	**1**
				1			Health professional	**1**
			1				PD-N - Database	**1**
					1		PC - Health professional	**1**
Caregiver	1	1			1		Web portal	**3**
Health professional				1			Health professional	**1**
	1	2					Web portal	**3**
	1	1					EPR	**2**
Point-of-care device	1	2			2		Web portal	**5**
	1	1			2	1	Database	**5**
				1			Call centre	**1**
					1		PD-D - Web portal	**1**
					1		PD-N - Web portal	**1**
						1	LP - Call centre	**1**
						1	PC - Call centre	**1**
Web portal		1					EPR	**1**
Total	**8**	**10**	**1**	**4**	**13**	**3**	**Total**	**39**

Table 7-2 – Overview of 'informatic location's for different types of intermediate devices.

7.3.3 Which entities do intermediate devices receive their inputs and provide their outputs to?

7.3.3.1 Receiving inputs

Table 7-3 is an overview showing the types of intermediate devices and the entities they receive their inputs from. They are taken directly from the flow path diagrams constructed which can be found in the supplementary material (Appendix C).

Patients and point-of-care devices are the main entities that intermediate devices received their inputs from (5 types of devices; followed by health professional, web portal and EPR and (all with 3 types of devices).

Intermediate devices also receive inputs from themselves with PD-D and PD-N being the most common. Intermediate devices do not receive inputs from call centres.

Entities that intermediate devices received inputs from		PC	MP	TV	LP	PD-D	PD-N
Patient	➔	✓	✓	✓	✓	✓	
Caregiver	➔	✓				✓	
Health professional	➔	✓	✓		✓		
Point-of-care device	➔	✓	✓		✓	✓	✓
Database	➔					✓	✓
Call centre	➔						
Web portal	➔	✓	✓			✓	
EPR	➔	✓	✓			✓	
PC	➔					✓	
MP	➔						
TV	➔						✓
LP	➔						
PD-D	➔	✓				✓	✓
PD-N	➔	✓		✓	✓		

Table 7-3 – Entities that intermediate devices received their inputs from

7.3.3.2 Providing outputs

Table 7-4 is an overview showing the types of intermediate devices and the entities they provide their outputs to.

Patients are the main entity that intermediate devices provide outputs to (5 types of devices); followed by database and web portal (both with 4 types of devices). Intermediate devices do not provide outputs to point-of-care devices.

Intermediate devices also provide outputs to themselves. These are PC, PD-D and PD-N (2 instances); TV and LP (1 instance). Intermediate devices do not provide outputs to MP.

PC	MP	TV	LP	PD-D	PD-N		Entities that intermediate devices provided outputs to
✓	✓	✓	✓	✓		➔	**Patient**
✓	✓			✓		➔	**Caregiver**
✓	✓		✓			➔	**Health professional**
						➔	**Point-of-care device**
✓	✓			✓	✓	➔	**Database**
✓			✓			➔	**Call centre**
✓	✓			✓	✓	➔	**Web portal**
✓						➔	**EPR**
				✓	✓	➔	**PC**
						➔	**MP**
					✓	➔	**TV**
					✓	➔	**LP**
✓				✓		➔	**PD-D**
		✓		✓		➔	**PD-N**

Table 7-4 – Entities that intermediate devices provided outputs to

7.3.4 Which types of intermediate devices are used by the actors of the system?

Table 7-5 shows the range of types of intermediate devices used by the three actors of telehealth systems. They are taken directly from the flow path diagrams constructed which can be found in the supplementary material.

Patients use all the intermediate devices apart from PD-N.

Caregivers use three types of devices: PC, MP and PD-D.

Health professionals also use three types of devices: PC, MP and LP.

Actor	PC	MP	TV	LP	PD-D	PD-N
Patient	✓	✓	✓	✓	✓	
Caregiver	✓	✓			✓	
Health professional	✓	✓		✓		

Table 7-5 – Types of intermediate devices used by actors of telehealth systems

7.4 Discussion

7.4.1 Types of intermediate devices

This paper has shown the types of intermediate devices used within current telehealth offerings. Four types of generic devices and two types of proprietary devices were identified (Table 7-1). Both the generic and proprietary class of devices feature devices with and without display capabilities.

7.4.2 'Informatic' location of devices

Five classes of intermediate devices, classed by their 'informatic location' were found in the telehealth offerings. The details of the classes are shown in Table 7-6.

Class No.	Entity 1		Entity 2
1	Patient	ID	Multiple entities
2	Caregiver	ID	Web portal
3	Health professional	ID	Multiple entities
4	Point-of-care device	ID	Multiple entities
5	Web portal	ID	EPR

Table 7-6 – Summary of classes of intermediate devices based on 'informatic location' (ID is 'intermediate device')

Each of these classes is discussed in more detail below.

Class 1 – Intermediate devices located between the patient and multiple entities.

The first group of intermediate devices are those that link the patient to other entities. All the types of intermediate devices are used. However, more generic devices are used than proprietary devices. In addition, more devices with data display features are used as compared with those without display.

Current systems show no preference in type of device being used: both proprietary and generic are used.

In most cases, a single intermediate device is used between patients and other entities; however there were 2 instances where combinations of devices are used.

(i) TV linked to PD-N to exchange information with a database. This may be because the capabilities of the TV are limited for a telehealth system and a proprietary device is required to make it fully effective.

(ii) PD-D linked to PC to exchange information with the health professional. This may be because a PD-D is primarily designed for use by patients rather than health professionals.

Patients were the only actor interacting with TV since this is usually in a fixed location such as a home environment. With the increasingly internet-connected capabilities of TVs, future systems may utilise these resources more, rather than developing and deploying new devices that may involve training the patient.

Class 2 – Intermediate devices located between the caregiver and web portal.

The second group of intermediate devices are those that connect the caregiver to the web portal. Three types of intermediate devices are used here: PC, MP and PD-D; all of which are able to display data; in current telehealth offerings; caregivers only use intermediate devices with data display features.

This is significant because it suggests that caregivers are able to see the patient's results and any additional information that will enable them to support the patient. They may also be able confirm whether the patient is adhering to the correct routine.

Class 3 – Intermediate devices located between the health professional and multiple entities

The third group of intermediate devices are those that connect the health professional to other entities. The analysis of current telehealth offerings suggests that health professionals only use generic intermediate devices.

It is interesting that in current systems, proprietary devices are used by other actors of the system rather than health professionals. This may be indicative of the features that existing proprietary devices possess, since these are currently tailored to meet the needs of patient (Adeogun et al. 2011b).

Class 4 – Intermediate devices located between a point-of-care device and multiple entities.

The fourth group of intermediate devices are those used to connect point-of-care devices to other entities such as web portals, databases and call centres.

Both generic and proprietary devices are used; however in current telehealth offerings a higher number of instances of proprietary devices are found.

All generic devices are in use in class 4 with the exception of TV, thus highlighting that connectivity between point-of-care devices and TVs may not yet exist. Emerging service providers may therefore need to take this into consideration.

Class 5 – Intermediate devices located between web portal and EPR

The fifth group of intermediate devices are located between the web portal and EPR. MP was the only device used and there was only one instance of its use.

7.4.3 Inputs and outputs for intermediate devices

With respect to entities providing inputs and outputs to intermediate devices, there is no significant difference between the use of proprietary and generic devices.

It was however noted that intermediate devices receive inputs from point-of-care devices but do not provide outputs to them. Furthermore, intermediate devices do not receive inputs from call centres but do provide outputs to them.

Intermediate devices receiving inputs from other intermediate devices reveal that in some cases, a combination of intermediate devices is used to exchange information between entities (Table 7-3). This was true for all the devices except MP, which neither receive inputs nor provide outputs to other intermediate devices.

7.4.4 Are proprietary intermediate devices needed?

Overall, there is a clear preference in current telehealth offerings for intermediate devices which are capable of displaying data (32) to those which cannot (7). There is a less strong preference for devices that are generic (23) in comparison to proprietary (16).

This therefore raises the issue of whether proprietary devices are really needed in telehealth systems, if generic devices are available to play the same role?

Within 3 of 5 classes identified, both proprietary and generic intermediate devices are used to connect entities. While in 2 of 5 classes, only generic devices are used.

However, proprietary devices are only found exclusively within 3 of the 19 different possible ‘informatic locations’. These are: ‘Patient – PD-D - Database’; ‘Point-of-care device - PD-D - PD-D - Web portal’ and ‘Point-of-care device - PD-D - PD-N - Web portal’. These three locations do not appear to share common characteristics, nor have different characteristics from those where both generic and proprietary intermediate devices are found.

In contrast generic devices were found exclusively in 7 of 19 ‘informatic’ locations. Five of these link actors in the system to other entities. For instance, three are in class 3, connecting the health professional to multiple entities; and two are in class 1 connecting the patient to multiple entities.

7.5 Limitations

This paper has highlighted that both generic and proprietary intermediate devices can be used in certain ‘informatic locations’, however it is difficult to say what the rationale is for the choice of particular device type for particular ‘informatic location’.

Further investigation is needed through discussion with existing service providers to ascertain the reasons they have chosen to use generic or proprietary intermediate devices in particular ‘informatic location’s.

7.6 Conclusions

‘Intermediate devices’ in telehealth systems are connectors between point-of-care devices, patients and health professionals.

This paper sought to identify the types available, their location of use within telehealth systems and their users.

Types were assessed based on two features: whether a device was a proprietary or generic device and whether the device had the ability to display data.

Six types of intermediate devices were found in the evaluation. Proprietary devices exist in two types: those with and those without data display. Generic devices exist in four forms: personal computer, mobile phone, television and landline phone, with the first three types capable of displaying data. With respect to the entities that provide inputs to and take outputs from intermediate devices, no significant difference was found between proprietary and generic devices.

‘Informatic’ location was derived by observing how data was exchanged between entities in the telehealth systems. Five classes of ‘informatic’ location currently exist for intermediate devices.

Class 1 represented intermediate devices located between the patient and multiple entities.

Class 2 represented intermediate devices located between the caregiver and web portal.

Class 3 represented intermediate devices located between the health professional and multiple entities. Health professionals currently only use generic intermediate devices.

Class 4 represented intermediate devices located between a point-of-care device and multiple entities.

Class 5 represented intermediate devices located between web portal and EPR.

It was found that currently intermediate devices receive inputs from point-of-care devices but do not provide outputs to them. Furthermore, intermediate devices do not receive inputs from call centres but do provide outputs to them.

There was no evidence found to support a requirement for proprietary intermediate devices being used in telehealth systems in favour of generic devices. Both generic and proprietary intermediate devices are used in 3 of 5 classes identified and in the remaining 2 classes, only generic devices are used. Proprietary devices are found exclusively in 3 of 19 possible ‘informatic location’s: Patient - PD-D - Database; Point-of-care device - PD-D - PD-D - Web portal and Point-of-care device - PD-D - PD-N - Web portal.

It could not be ascertained what the current rationale is amongst telehealth system providers for the choice of a particular device type for a particular ‘informatic location’.

8 Capabilities of Proprietary Intermediate Telehealth Devices

Abstract

Objective

Proprietary intermediate telehealth devices are those which are specifically designed as connectors between the entities of telehealth systems. This paper seeks to understand what are the capabilities of such devices and then to investigate how these are clustered on the current generation of devices.

Materials and Methods

14 current-generation devices available from 12 device providers were selected and analysed. Four categories of questions were composed to evaluate the devices: setup/configuration, available features, inputs and outputs.

Results

Data was collected and synthesised on the following capabilities: availability from suppliers, setup, environments of use, multiple-condition monitoring, multiuser capabilities, prompts, reminders and alerts, interaction with the health professional, access to historical data, device inputs and their transfer technology.

Conclusions

There are three main roles for proprietary intermediate devices in telehealth systems: displaying information to the patient; receiving data manually/automatically; forwarding results and questionnaire responses to another entity.

Provider perspective: Intermediate devices are usually part of closed proprietary systems. Providers produce disease-customisable devices. Connectivity is considerably ahead of the current generation of point-of-care devices. However, little data is available on connection to rest of the proprietary system.

Patient perspective: Clear benefit that one intermediate device can potentially be used with several chronic conditions. Simple setup, authentication procedures and automatic data transfer are key design aspects.

Health Professional perspective: Little direct interaction with the health professional.

Payer perspective: Details of costs of devices are generally unavailable; system providers indicate cost variability is based on “user requirements”.

8.1 Introduction

Intermediate telehealth devices can be defined as connectors between entities of telehealth systems (Adeogun et al. 2011a).

They fall into two classes. The first class is adapted devices which are those originally designed for other uses and have been adapted for telehealth systems, usually via integrating software into the device. These include mobile phones and personal computers (PC). The second class is proprietary devices, which, in contrast are those specifically designed for use in a telehealth system (Adeogun et al. 2011a).

From a systems perspective, there is evidence that intermediate devices are the key invariant component in a telehealth system. A particular telehealth offering can be used for multiple diseases and contain varied types of actors, but its intermediate device or devices are usually fixed: possessing particular sets of capabilities (Adeogun et al. 2011a). For this reason their capabilities form an important area of study.

8.1.1 Previous case studies

Some descriptions of the use of individual intermediate devices already exist in the literature. For example, Luptak et al. (2010) describe a study in which patient feedback was obtained on intermediate device used in daily chronic care.

Case-study evidence is also emerging that such devices can form part of systems that have tangible medical impact. Several PCTs (Primary Care Trusts) within the UK, have implemented telehealth systems incorporating intermediate devices. Examples include systems for patients with heart failure, and devices in systems to monitor chronic obstructive pulmonary disease (COPD) (Marshall, 2009). Device use in the latter has helped community nurses to prioritise their work, resulting in a decrease by 80% of home visits (Marshall, 2009).

8.1.2 The perspective of healthcare providers

However, there has been no systematic study of the capabilities of current intermediate devices, nor of how those capabilities are clustered on current devices.

From the perspective of those considering implementing telehealth systems for chronic care, this means that it is difficult to know whether their expectations could be met with current systems. For example, the answer to a question such as, can current telehealth systems monitor multiple diseases and if so what range of diseases can be covered, is dependent on whether the intermediate device of a system will connect with and process data from multiple point-of-care devices. Questions on how patients are monitored, prompted and advised are also dependant on the capabilities of intermediate devices. The same is true for questions of data security and confidentiality, key information capture and system usability.

8.1.3 Research questions

This paper assesses currently available intermediate devices in telehealth systems.

It initially seeks to do two things. Firstly, to understand the capabilities of such devices. Secondly, to show how such capabilities are clustered on the current generation of devices.

Using this information it then seeks to summarise the capabilities of the devices as seen from an actor-centric viewpoint, i.e. the viewpoint of a potential patient, caregiver, health professional or payer.

8.2 Method

8.2.1 Criteria for selecting devices

As little information is currently available on adapted devices, this study was limited to proprietary devices. It was also limited to devices which met the following criteria:

1. Devices that have a degree of certification i.e. FDA 510(k) or CE mark.
2. Devices that have been designed primarily for a patient rather than a health professional.
3. Devices that can be used outside the hospital environment.

Using these criteria, a total of 14 intermediate devices were analysed. Table 8-1 lists the devices evaluated, the organisation using or distributing them, the type of certification and appropriate references.

8.2.2 Data capture

Proprietary devices available between November 2009 and April 2010 were analysed. Company websites and brochures were assessed to obtain information about the proprietary devices. Where there were insufficient details, the organisations were contacted requesting additional information and where necessary, a visit to the organisation was made.

Organisation	Device name	Certifications	References
AxSys Technology Ltd	Exceliview (no longer supported)	Could not be obtained	AxSys (2005)
Bosch/Health Hero Network	Health Buddy	CE compliant; TUV US & C medical approved; FDA 510(k)	Health Hero Network (2008); FDA (2010e)
Cardiocom	Commander Home monitor	FDA 510(k)	FDA (2010d)
CareFusion	TeleAM	CE Mark; FDA	Personal communication, Jürgen Behringer (2010)
Docobo	HealthHUB	ISO 9002/EN46002 and European Class IIa Medical Device standards	Carson et al. (2005); Docobo (2008b)
$DigiO_2$	Care Pal	FDA 510(k)	$DigiO_2$ (2010a, 2010b); FDA (2010a)
Honeywell International Inc/ Home Telehealth Ltd	Honeywell HomMed Genesis DM	FDA 510(k)	Honeywell (2010), Home Telehealth Ltd (2010), Advantage HomeHealth Services (2007); FDA (2010c);
Intel	Health Guide	FDA 510(k)	Intel (2008, 2010b)
MedApps	HealthPAL	FDA 510(k)	FDA (2010f)
Telehealth solutions	Home pod	Could not be obtained	Telehealth Solutions (2009, 2010b)
Tunstall	mymedic Telehealth Monitor	CE Marked; Medical Device directive	Tunstall (2008, 2009, 2010a, 2010b)
	mymedic plus Telehealth Monitor	FDA 510(k)	Tunstall (2008, 2009, 2010b); FDA (2010b)
Tynetec	Telehealth interface unit	Could not be obtained	Tynetec (2010b)
	SayPhone 21	Could not be obtained	

Table 8-1 – Proprietary intermediate devices with data display capabilities

8.2.3 Evaluation questions

A set of questions were developed to evaluate proprietary intermediate devices.

The questions correspond to four categories.

Setup/configuration: what is the required process to setup the intermediate device? (Table 8-2).

Available features: what are the features available on the intermediate device? (Table 8-3).

Inputs: how does the intermediate device receive its inputs? (Table 8-4).

Outputs: what are the outputs produced by the intermediate device? (Table 8-5).

1 – Setup/configuration	
1.1	Are you the only suppliers of the device or can it be purchased from somewhere else?
1.2	Is the device provided to the patient as fully-functional i.e. plug-and-play or is specific software required to make the device fully operational in the system?
1.3	Does the user need to create an online account to establish process?
1.4	Do users need to explicitly configure the device?
1.5	Which environment can the device be used (home only, anywhere)?
1.6	How much does the device cost?

Table 8-2 – Criteria used to assess proprietary intermediate devices (Setup/configuration)

2 – Available features	
2.1	What condition is the device designed to monitor?
2.2	Can the device be customised to several health conditions?
2.3	Is the device for single/multiple users?
2.4	Does the device have voice prompts?
2.5	Does the device have video capabilities?
2.6	Does the device provide reminders?
2.7	Does the device provide instructions of how to carry out the test?
2.8	Is the connection between the point-of-care device and intermediate device a wired or wireless connection?
2.9	List the type of connections in operation: Bluetooth, Infrared, Wi-Fi etc?
2.10	Is there a progress bar (or something similar) displayed on the device to show that the user has sent their test results or they are in the process of being received by the health professional?
2.11	Can the patient send a message to the health professional through the device?
2.12	Can the patient access historical data through the device?
2.13	Can the patient receive a message from the health professional through the device?
2.14	Are there authentication requirements before users can proceed with test?

Table 8-3 – Criteria used to assess proprietary intermediate devices (Available features)

3 – Inputs	
3.1	What are the types of point-of-care devices that can be connected?
3.2	Is data transfer automatic from the point-of-care device to the intermediate device or does the user have to manually enter the data?
3.3	Does the device ask user symptomatic questions?
3.4	What is the mode of interaction between patient and device (touch screen, button press etc)?
3.5	Does the device confirm the user selection/entry?

Table 8-4 – Criteria used to assess proprietary intermediate devices (Inputs)

4 – Outputs	
4.1	Where is the data from the device transferred to?
4.2	Are alerts provided to the patient on their result before they are sent to a data repository?
4.3	Do other users within the system receive an alert?
4.4	What is the mode of delivering alerts?

Table 8-5 – Criteria used to assess proprietary intermediate devices (Outputs)

8.2.4 Clustering

In order to be able to see how capabilities are clustered in currently available intermediate devices, the clusters have been presented in the paper in tabulated form (Tables 8-6 to 8-19).

For each cluster table, the horizontal axis shows the device number in the study. The vertical axis shows the capabilities. Where a capability is present, a tick has been shown in the table; if absent, it has been shaded in black so that the clustering can easily be seen visually. Where the data were unobtainable, the corresponding position in the table has been left blank. Where additional coding of the data were required, this coding has been shown in a key below the table.

8.3 Results

This section describes the findings of the analysis of proprietary intermediate devices based on the questions detailed in Tables 8-2 to 8-5. For each data set, where the data percentages do not add up to 100%, the remaining data were unobtainable in this study.

Within each section of the results, there are two parts. The first part concerns individual capabilities of the devices: how often they are present and what is their nature. The second concerns how these individual capabilities are clustered on current devices.

8.3.1 Availability

93% of intermediate devices are purchasable from a single provider while 7% (device 5) are available from multiple providers (3 suppliers in total).

As shown in Table 8-6, much less information was available from manufacturers on devices provided within a system with 79% of data being unavailable. 21% of devices are sold for use within a system package. Within this group, one device (device 8) can also be bought off the shelf. Device 5, available from multiple suppliers, is only sold for use within a system package.

Cost information was generally unavailable from the manufacturers. Manufacturers indicated that costs varied with quantity and with user requirements.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Single supplier	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Multiple suppliers					✓									
Device sold as part of a system package	✓				✓			✓						
Device can be bought off the shelf								✓						
Cost of device (£)	V				V			1000					V	V

Table 8-6 – Availability of proprietary intermediate devices (Key: V=Variable, depending on request)

8.3.2 Setup

Devices neither require explicit configuration by the patient, nor establishment of any on-line account (though information was unavailable in 21% and 29% of cases respectively).

8.3.3 Environments

14% of intermediate devices can be used in both home and hospital, 50% are exclusively for home use and 36% can be used in any location.

Table 8-7 shows the clustering of intended device environments. All devices that were usable outside the home and hospital environment were also designed for use in that environment.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Home	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Hospital	✓		✓	✓		✓	✓	✓					✓	
Other				✓		✓	✓	✓					✓	

Table 8-7 – Environments in which proprietary intermediate devices can be used

8.3.4 Multiple conditions and point-of-care connection options

All of the intermediate devices evaluated can be customised to manage several health conditions including: asthma, COPD, diabetes, heart disease and hypertension. 21% of devices were said to be used for managing unspecified "chronic conditions".

Table 8-8 shows the clustering of conditions by device. The majority of devices are used for a cluster of four diseases, COPD, diabetes, heart disease and hypertension. In contrast, asthma is much less well served.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Can be customised to several health conditions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asthma	✓	✓				✓		✓					✓	
COPD		✓		✓	✓	✓		✓	✓	✓	✓		✓	
Diabetes		✓		✓			✓	✓	✓	✓	✓		✓	
Heart disease		✓		✓		✓		✓	✓	✓	✓		✓	
Hypertension	✓	✓		✓		✓	✓	✓	✓	✓	✓		✓	
Unspecified chronic condition			✓									✓		✓

Table 8-8 – Chronic conditions managed by proprietary intermediate devices. (Where the chronic condition is shown as unspecified, this means that the organisation did not describe the condition)

93% of intermediate devices evaluated allow multiple point-of-care devices to be connected to them. The remaining 7% of intermediate devices obtain their data from another intermediate device. Point-of-care devices include: glucometers, weighing scales, blood pressure (BP) monitors, pulse oximeters, spirometers and peak flow meters.

Table 8-9 shows the different types of point-of-care devices providing inputs to intermediate devices. The most popular were BP monitor, weighing scale, glucometer and pulse oximeter. The less popular ones were peak flow meter and spirometer. The coagulometer and urine analyser were least represented.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
BP monitor	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Weighing scale		✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓
Glucometer	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓			
Pulse oximeter		✓			✓	✓	✓	✓	✓	✓	✓		✓	✓
Peak flow meter	✓	✓		✓	✓				✓					
Spirometer						✓				✓	✓			
Coagulometer								✓						
Urine analyser								✓						

Table 8-9 – Types of point-of-care devices providing inputs for proprietary intermediate devices

8.3.5 Multiple Users

36% of intermediate devices are designed for the use of multiple users; and 64% by only a single user (Table 8-10).

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Device is for multiple users	✓					✓			✓			✓		✓

Table 8-10 – Proprietary intermediate devices designed for multiple users

8.3.6 Prompts, Reminders and Confirmations

Voice prompts are available on 64% of devices, 29% do not have this feature.

86% of intermediate devices provide reminders to users, 7% do not.

In cases where users enter data or select an option on the intermediate device, 36% display a confirmation to the user of the selected option, 21% do not.

64% of intermediate devices ask the user symptomatic questions, whereas 29% do not.

50% of intermediate devices display a confirmation to the user that their results have been transferred to the health professional, 21% do not. This confirmation took the form of a progress bar or a message displayed to the user.

Table 8-11 shows the clustering of the prompts capabilities of intermediate devices.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Has voice prompts	■	✓	✓	■	✓		✓	✓	✓	✓	✓	✓	■	■
Provides reminders	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	■
Asks questions	■	✓		✓	✓	✓	■	✓	✓	✓	✓	■	✓	■
Confirmation of the user selection/ entry				✓	■		■	✓		✓	✓	■		✓
Confirmation of transmission of results	✓			✓	✓		✓	■		✓	✓	■	✓	■

Table 8-11 – Prompts available on proprietary intermediate devices

8.3.7 Alerts

Alerts are provided directly to patients in 29% of intermediate devices (Table 8-12); while 64% of devices do not provide alerts to patients. In each case this is in the form of messages displayed on the intermediate device informing the user that their result is not within the expected target range.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Alerts on results to patient before they are sent to a data repository				✓						✓	✓		✓	

Table 8-12 – Alerts to patients on proprietary intermediate devices

8.3.8 Advice and Communication with the Health professional

57% of intermediate devices provide instructions to the user as to how to carry out a particular test, 21% do not. In one device (device 5), training videos are provided for the user.

No device was found to have the capability for patients to send additional messages to their doctor (though information was unavailable for 29% of cases).

One device (device 12) allows an alarm call to be made to the doctor.

Health professionals are alerted when the patients' results are outside specified thresholds. (However, none of these alerts are through the intermediate device.)

29% of intermediate devices enable patients to receive messages from the health professionals compared with 42% that do not have this feature. In one of the devices (device 5), a 2-way video call can be organised by the health professional to discuss issues with the patients. Table 8-13 shows the device capabilities for advice and communication.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Provides instructions of how to carry out test				✓	✓			✓	✓	✓	✓	✓		✓
Has video capabilities					✓			✓						
Patient can send a message to the health professional														
Patient can receive a message from the health professional					✓	✓		✓					✓	

Table 8-13 – Advice provided to users on proprietary intermediate devices

8.3.9 Historical data

Patients can access historical data on the device in 36% of intermediate devices (devices 1, 5, 6, 8, 13) compared with 43% that do not provide this feature.

8.3.10 Authentication

29% of intermediate devices (devices 1, 5, 8, 13) require authentication by the users, although this feature requires activation; 50% do not require this.

8.3.11 Automatic or manual results input

Results of point-of-care tests are automatically transferred from the point-of-care device to the intermediate devices in 50% of cases. Results are manually entered in 7% of devices. In 29% of devices, results transfer is both automatic and manual.

Table 8-14 shows the clustering of results transfer based on mode of input.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Manual data entry into the device	✓			✓	✓	✓			✓					
Automated data entry into the device				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 8-14 – Automatic or manual results input for proprietary intermediate devices

8.3.12 Device Inputs

The inputs for the intermediate devices are either data from point-of-care devices and/or responses to questionnaires to help assess the symptoms of the patient. 79% of intermediate devices allow patients to interact with them through buttons, 14% had a touch screen interface.

Table 8-15 shows the availability of these features.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Buttons available for patient to interact with the device	✓	✓		✓		✓	✓		✓	✓	✓	✓	✓	✓
Touch screen available for patient to interact with the device					✓			✓						

Table 8-15 – Proprietary intermediate device inputs

8.3.13 Information transfer technology

To transfer results to the intermediate device from a point-of-care device, 64% of devices provide both wired and wireless connections, 21% provide only a wireless connection. The wireless connections include: Bluetooth, GPRS (General Packet Radio Service), infrared, radio, GSM (Global System for Mobile Communications), M2M (Mobile to mobile) Cellular GPS and Wi-Fi. The wired connections are through USB or serial cables.

Table 8-16 shows the details of the wired connections from the point-of-care device to intermediate device with the serial port being the most popular.

Table 8-17 shows the details of the wireless connections from the point-of-care device to the intermediate device, with Bluetooth being the most widely used.

Table 8-18 shows the information transfer technology in operation between the devices and other components of telehealth systems. As can be seen, few providers made this information available. There is no pattern in the types of information transfer technology used, although GPRS was used by three devices (2, 8 and 9).

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Wired connection to point-of-care device	✓			✓	✓		✓	✓	✓	✓	✓		✓	
Serial Port connections	✓			✓			✓	✓	✓	✓	✓		✓	
USB	✓				✓			✓					✓	

Table 8-16 – Wired information transfer technology between point-of-care devices and proprietary intermediate devices

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Wireless connection to point-of-care device	✓			✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Bluetooth	✓			✓	✓		✓	✓		✓	✓		✓	
Infra red				✓						✓	✓			
Radio												✓		✓

Table 8-17 – Wireless information transfer technology between point-of-care devices and proprietary intermediate devices

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
GPRS		✓						✓	✓					
GPS							✓							
GSM							✓							
M2M Cellular							✓							
POTS		✓							✓					
Wi-Fi								✓						
3G								✓						
Broadband								✓						
Dialup Modem								✓						

Table 8-18 – Information transfer technology between proprietary intermediate devices and other components of telehealth systems

8.3.14 Data transfer destination

Results and responses to the questions are transferred to: a software application (29%) a secure server (57%) or another intermediate device (7%).

Table 8-19 shows the breakdown by device.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Data is transferred to a data server	✓	✓		✓	✓	✓	✓	✓					✓	
Data is transferred to a software application									✓	✓	✓	✓		
Data is transferred to an intermediate device														✓

Table 8-19 – Data transfer destination for intermediate devices

8.4 Discussion

In this section, the key capabilities and their variance on current proprietary intermediate devices are summarised. Capabilities of proprietary devices are then considered based on actor-centric perspectives, i.e. those of the patient, health professional and payer and system provider. It should be noted that a caregiver perspective is not given, as no interactions of the devices with caregivers were found.

8.4.1 Key capabilities of current proprietary intermediate devices

Three main types of capability were identified from the current analysis.

Firstly: to display information to patients. These are reminders, instructions of how to conduct tests, symptomatic questions and confirmation of their entry or the successful transmission of results to another entity. Most proprietary devices provided reminders and asked the patient questions. Just over half of proprietary devices showed users how to do their test. Half of proprietary devices showed a confirmation of results transmission, while few confirmed the user entry.

Secondly: to act as a channel which receives results, automatically from point-of-care devices or manually via data entry by the patient. Half of devices allowed automatic input of results, while few allowed manual results entry.

Thirdly: to act as a channel for the forwarding of results and questionnaire responses to another entity. This may be another intermediate device, external server or software application. Most proprietary devices transferred results to an external server.

8.4.2 Provider perspective

By definition all the devices evaluated in this study were for use in the home. In a study by Hopp et al. (2007), showing the management of diabetes, the devices were only used within the home environment, however, providers consider multiple environments to be a market, as more than one third of devices were also suitable for hospital use.

Devices are clearly provider-specific, with only a single device being available from multiple suppliers. From the limited information available, providers appear keen on selling a whole system package; only one device is available off the shelf. The state-of-the-art is therefore that intermediate devices are usually part of closed proprietary systems.

All of the intermediate devices evaluated can be customised to manage several health conditions with the majority of devices usable for a cluster of four diseases: COPD, diabetes, heart disease and hypertension. Hence, nearly all intermediate devices are designed for connection to more than one point-of-care device. Point-of-care devices that can be connected include: glucometers, weighing scales, blood pressure (BP) monitors, pulse oximeters, spirometers and peak flow meters.

This requirement for point-of-care device connectivity leads to information being widely available from suppliers on information technology for data transfer from point-of-care device to intermediate device. Nearly all intermediate devices allow transfer using both wired and wireless media. In contrast little data is available as to how the intermediate device connects to rest of the proprietary system.

Interestingly, the multiple connectivity features of intermediate devices, for use to connect with point-of-care devices, contrast with current point-of-care devices. Results from a recent study focussing on glucometers showed that only 79% allowed the data to be transferred. Of these, the majority (90%) used a USB cable, while 10% used infra-red connection (Ajai et al. 2009). None used any other wireless technology.

Providers seem divided as to whether single-user or multiple-user intermediate devices will gain them market share, with only a third of devices being multi-user capable. Aside from the opportunity to sell more devices, if each device is only for a single user, providers may consider that this device limitation reduces requirements for setup and authentication and helps with data security for the patient.

Providers also appear to be currently divided as to the necessity of either voice or video technology. Voice prompts were present on over half the intermediate devices, but video technology was available on only one. The case for the utility of video technology in intermediate devices seems yet to be made.

In contrast, providers are essentially unanimous in device designs which exclude the initiation of direct communication with a health professional by the patient.

8.4.3 Patient perspective

Providers appear keen to minimise the information technology knowledge required of the patient. For the patient this translates to simple setup and authentication procedures (few devices had any authentication) and automatic data transfer from the point-of-care device to the intermediate device. Perhaps this is also a reason why only a third of devices allow patients access to historical data.

Less than a third of devices enable patients to receive messages from the health professionals with one device allowing a two-way video call initiated by the health professional.

With regards to device interaction with patients, nearly all devices provide reminders to patients; over two thirds are capable of quizzing patients about their symptoms. The majority of devices also provided test instructions. In contrast, the figure for point-of-care devices (glucometers) for reminders is 19% (Ajai et al. 2009). This difference indicates where intermediate devices can bring benefits in patient independence and compliance above those available from the current generation of point of care devices.

In contrast, few intermediate devices are designed to provide alerts, for example following an unexpected result. An anecdotal reason, given by some suppliers, is to avoid raising false alarms. However, this compares with, again taking glucometers as examples of point of care devices, to 77% percent that do provide alerts (Ajai et al. 2009).

Certain chronic diseases are risk factors for others, for example, diabetes for cardiovascular disease, cerebrovascular disease and renal disease (Adler et al. 2000). Therefore, it is a clear benefit from the patient perspective that one intermediate device can potentially be used with several chronic conditions.

8.4.4 Health professional perspective

Unlike for the case of the patient, intermediate devices have little direct contact with the health professional: the health professional sees aspects of the system rather than the intermediate device.

The main role of health professionals in relation to the intermediate device is that of selecting the types of questionnaires that will be used to regularly assess the patient's health. This role of health professionals is echoed by Hopp et al. (2007), where questions are specifically configured for patients. Hopp et al. (2007) added that health professionals trained patients in how to use the device to collate their responses. The aspect of training patients was not investigated in this paper.

8.4.5 Payer perspective

The detail of cost of devices was generally unavailable and system providers indicated the variability of the cost of systems is based on user requirements. Since devices are provided as part of a telehealth solution it is usually the cost of the system that the payer sees.

Whilst providers see multiple chronic disease capabilities as a selling point, anecdotal evidence from one provider indicates that payers are initially interested in buying provision for a single chronic disease.

8.5 Limitations

In order to predict the directions of future development of proprietary devices, an extensive survey would need to be carried out to ascertain the expectations of the actors as to the additional features they need.

There is very limited data and analysis available in the literature on proprietary intermediate devices. Hence it is difficult to compare and contrast the data and analysis of this paper with the work of other researchers.

8.6 Conclusions

Proprietary intermediate telehealth devices are those which are specifically designed as connectors between the entities of telehealth systems.

In this paper their capabilities have been analysed in current telehealth systems for the management of chronic diseases.

From the perspective of the different actors concerned with telehealth systems the following can be concluded:

Provider perspective: Intermediate devices are usually part of closed proprietary systems, i.e. they are provider-specific and normally sold as part of a whole system package. Providers produce disease-customisable devices, capable of connection to more than one point-of-care device via wired and multiple wireless media; their connectivity is considerably ahead of the current generation of point-of-care devices. In contrast little data is available from providers on how the intermediate device connects to rest of the proprietary system. Providers currently design the majority of devices for a single-user.

Patient perspective: Simple setup and authentication procedures (few devices had any authentication) and automatic data transfer from the point-of-care device to the intermediate device seem key aspects of device design for patients. The majority of devices provide reminders to patients, quiz patients about their symptoms and provide test instructions; this contrasts with current point-of-care devices. However, few intermediate devices are designed to provide alerts, again in contrast to point-of-care devices. For the patient there is a clear benefit that one intermediate device can potentially be used with several chronic conditions.

Health Professional perspective: Proprietary intermediate devices have little direct interaction with the health professional: their current main role is restricted to selecting the types of questionnaires that will be used to assess the patient’s health.

Payer perspective: The details of costs of devices were generally unavailable and system providers indicated the variability of the cost of systems is based on user requirements. Since devices are provided as part of a telehealth solution it is usually the cost of the system that the payer sees.

9 Applying capabilities of telehealth systems to a healthcare policy

Abstract

Telehealth systems allow the administration of healthcare to patients separated by a distance from their health professional. This paper aimed to identify government objectives that could be delivered through telehealth systems and its capabilities.

A six-step methodology was developed and applied to a UK policy. The steps involved: identifying government objectives, assessing whether a telehealth system could be used to deliver it and the possible capabilities needed to meet the objective. Questionnaires were used to validate the steps developed with a response rate of 43%.

12 objectives were identified from the policy. One third of these objectives were evaluated as unsuitable for delivery by telehealth systems mainly because of the lack of detail given in the policy report. Telehealth systems were particularly suited to objectives related to long term conditions. Respondents to the questionnaires had differing opinions in some cases (issues related to the NHS constitution, management of cancer and screening).

Where an objective was evaluated to be possible for delivery by a telehealth solution, the most common types of capabilities applicable were: patients receiving information from health professionals and patients being prompted to do an action.

Although, there were differing opinions given by respondents, there was a consensus of opinion that telehealth systems would help to educate the patient and empower them by increasing their role in managing their health.

9.1 Introduction

9.1.1 Motivation

Although, telehealth has been available for some time and its benefits are becoming known, limited evidence is found within literature of its wide application to an entire government policy. This paper considers such an application.

It takes as an example UK health policy in 2010. It considers telehealth systems as a way of delivering the proposed healthcare services that particular health policy required. Although it is based on the UK's National Health Service (NHS), it should have wider applicability to other environments as many of the challenges facing the UK are not unique to it but are global.

These global challenges are:

1. An ageing population (World Health Organization (WHO, 2004, 2008); Saranummi et al. 2006; Wakefield 2003).
2. Change in people's lifestyle (Saranummi et al. 2006).
3. Information accessibility: The internet has eased accessibility to information (Department of Health, 2008). The challenge however relates to providing patients with accurate evidence-based knowledge rather than general (anecdotal/untested) knowledge available from unsolicited and unapproved websites.

9.1.2 Research Questions

This paper addresses two research questions.

1. What government healthcare objectives can be delivered by telehealth systems?
    a. For healthcare objectives where delivery by telehealth is not possible, an explanation has been provided.

   b. For the healthcare objectives where telehealth is possible, the role that telehealth can play is stated.
2. What are the capabilities from current telehealth systems that can be used to deliver the healthcare objectives?

The answers to these research questions would be relevant to the departments of health within government, health professionals and telehealth service providers. For the government, the answers would be guidelines which could act as a starting point for implementing telehealth systems. Health professionals would be given a clear explanation of the role of telehealth systems and could adapt their current practices accordingly. For telehealth service providers, an overview of the required capabilities resulting from this approach would mean that they could tailor their future services to incorporate these.

Before progressing, a brief description is provided of telehealth systems.

9.1.3 What are telehealth systems?

Telehealth is an aspect of telemedicine which covers “health promotion and disease prevention” (Koch, 2006). Telemedicine is defined as “the use of telecommunications to transmit information and data relevant to the diagnosis and treatment of medical conditions, or to provide health services or aid healthcare personnel at distant sites” (Maheu and Allen, 2010). Wyatt and Liu, (2002) defined telemedicine as the use of electronic media “to mediate or augment clinical consultations”. Anecdotal evidence suggests that telemedicine refers to only clinical services, while telehealth includes both clinical and/or non-clinical services (Global Media, 2010). With this in mind, this paper considers telehealth systems from both the clinical and non-clinical perspective with the focus being on administering healthcare to patients irrespective of the distance that separates them and their health professional.

A previous study by the authors has shown that telehealth systems are composed of entities that aid data and information exchange with the goal of supporting patient management (Adeogun et al. 2011a).

9.1.4 Focus of this paper

This paper's focus is identifying how government objectives may be met through telehealth systems and its capabilities. It uses a top-down approach by considering objectives proposed by the government for delivering healthcare and then deriving the required capability categories from telehealth systems to meet them. These capability categories are then compared with the known capability categories of telehealth systems derived from an earlier study (Adeogun et al. 2011c).

9.2 Methodology

This section shows the steps involved in identifying the details of the government objectives and applying current telehealth systems capabilities to them.

9.2.1 What are the key government objectives proposed for the future of healthcare administration?

The data for use in this methodology were taken from chapter 2 of the NHS 2010-2015 report: '*The deal for patients and the public*'.

The first three steps of the method are to move from government healthcare objectives to detailed statements about how this objective could be achieved (Figure 9-1).

These steps for the method are shown in Figure 9-1. Each step within the diagram is numbered to aid identification. The three steps are taken from the data in the report; some are direct quotes, while others are a paraphrase of the statements.

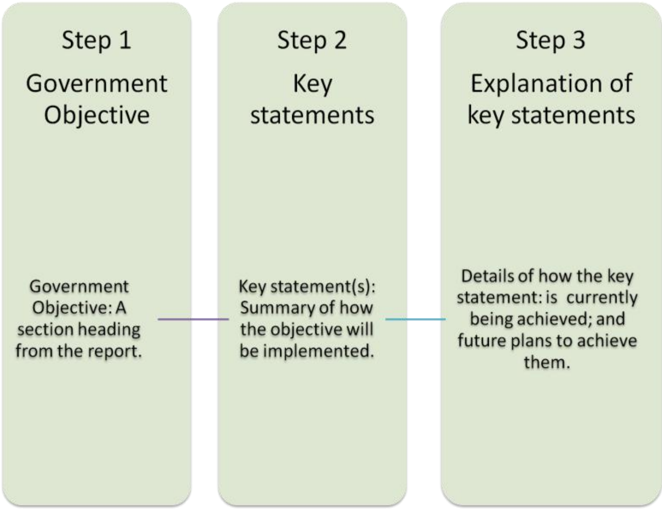


Figure 9-1 – Generic steps 1-3 showing how to develop a government healthcare objective into detailed explanations of plans for implementation

Step 1. What the government plans to do: The government healthcare objective is a section heading from the report.

Step 2. Key statements: The key statements summarised at an intermediate level how this objective could be reached. This data was in the form of several paragraphs following each objective which provided details of how the objective will be implemented.

Step 3. Explanation of what the key statement entails: This step explains the current and prospective actions by the government. The data is taken from details of how each key statement would be developed.

9.2.2 Are telehealth system solutions possible for delivering particular government healthcare objectives?

Step 4. Assessment of whether a telehealth system is possible to deliver the objective: This step relates to examining the explanations of the key statements (step 3) to see whether they include the description of the actors of telehealth systems: the patient, caregiver and health professional.

If they do, a telehealth system is considered as a possibility for delivering that particular aspect. If they do not, a telehealth system is considered as unsuitable. (A worked example of this initial analysis is shown in Table 9-1).

If a telehealth system is a possibility, a statement will be provided explaining the role of a telehealth system in achieving the explanation of the key statement. This is essentially a reframing of the key statement within a telehealth context. For plans where telehealth is unsuitable, an explanation is given.

9.2.3 What are the possible actions needed to meet the government objectives?

Step 5. Possible actions: This step considers the explanations from step 3 and derives the required actions of actors in telehealth systems to meet them (Table 9-2 shows a worked example). This was achieved through the following process.

1. Only the explanations of the key statements where telehealth was considered to be a possible solution (step 4) were considered.
2. The possible actions that may be performed by each actor (patient, caregiver and health professional) were then noted.

9.2.4 What are the equivalent capability categories from current telehealth systems that can be used to deliver the government objectives?

Step 6. Equivalent capability categories: This step uses the capability categories of telehealth systems derived by the authors from a recent study (Adeogun et al. 2011c) as a foundation. Capabilities are defined as “the ability of an entity to perform an action” (Adeogun et al. 2011c).

In step 6, the required actions from step 5 are compared with capability categories from existing telehealth systems to identify whether there is an equivalent capability category (Table 9-2 shows a worked example). Some of the possible actions that would be required in telehealth systems matched exactly with those of existing systems. Some of the possible actions had a one-to-one mapping with current capability categories, while others had a one-to-many mapping, i.e. some possible actions could be achieved by more than one capability category.

9.2.5 Additional Capabilities

For some of the possible actions in step 5, there was no exact match available in the current list of derived capability categories, therefore capability categories are proposed. In some cases, this was a simple modification of existing categories, while in other cases; new categories were proposed. The method for assigning new capability categories involved considering the possible action (from step 5) and considering what the outcome of that action might be.

9.2.6 Worked example

As this methodology is quite complex, a worked example is given here. The example illustrates steps 1 to 6 of the method. Objective three of chapter 2 entitled: '*The deal for patients and the public*' is used here for the worked example.

9.2.6.1 Steps 1 – 3 of the method illustrated by the healthcare objective "A preventative, people-centred, productive NHS".

Objective three: "a preventative, people-centred, productive NHS".

Figure 9-2 represents the first three steps of the methodology. It shows the objective with three key statements followed by the details of how this objective could be achieved.

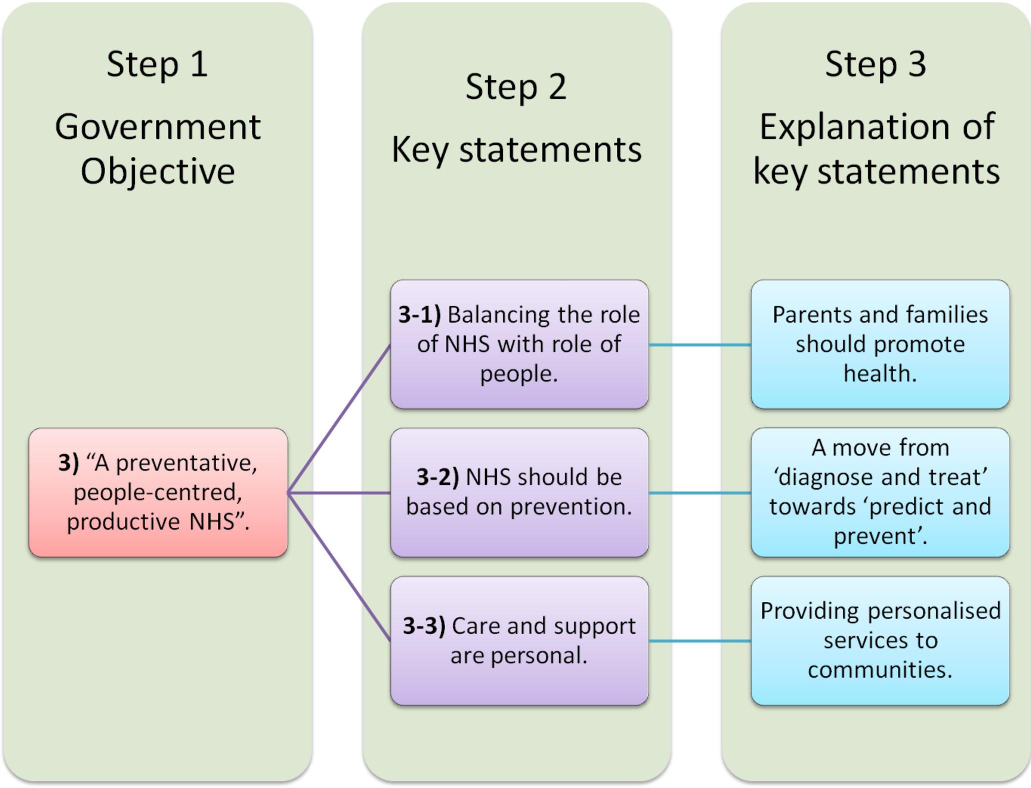


Figure 9-2 – Worked example showing methodological steps 1 to 3 in developing the government objective "a preventative, people-centred, productive NHS" into detailed explanations

9.2.6.2 Is a telehealth system possible for "a preventative, people-centred, productive NHS"?

Step 4 of the worked example is represented by Table 9-1 which shows three columns. The first is the objective number and the key statement number, the second shows whether a telehealth system is possible and the third is the explanation.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
3-1	Yes	To help parents and families in promoting health.
3-2	No	An elaboration of this statement is required to be able to expand this into a telehealth system.
3-3	Yes	To provide personalised services to communities.

Table 9-1 – Worked example showing methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 3

9.2.6.3 Matching possible actions to existing capability categories of telehealth systems

Steps 5-6 of the worked example are illustrated in Table 9-2 and Table 9-3.

Each table represents one of the two key statements that have been analyzed as suitable for a telehealth system (3-1 and 3-3). The explanations of the key statements are restated in the first column; the possible actions are listed in the second column; the equivalent capabilities they can be compared with, are shown in the third column. The fourth column provides additional clarification particularly in cases where there isn't an accurate match of possible actions to capabilities.

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
Parents and families should promote health.	Health professionals send information to people early to raise awareness about certain conditions.	P11-Health professional creates patient care plan.	
	Patients receive information about conditions.	P8-Health professional sends message to patient.	
	Family members should support each other.		There isn't a capability that meets this action. A suggestion is made: Caregiver receives messages.

Table 9-2 – Worked example showing methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 3-1

9.2.6.4 Matching possible actions to existing capability categories of telehealth systems (3-3)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Providing personalised services to communities.	Health professional raises awareness of the appropriate programmes to suit the needs of families.	P11-Health professional creates patient care plan.
	People are aware of the programmes.	P8-Health professional sends message to patient.

Table 9-3 – Worked example showing methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 3-3

9.2.7 Validation of results

A questionnaire was constructed to obtain expert opinion about using telehealth systems to deliver government objectives. Experts were health professionals, telehealth service providers and telehealth researchers. The questionnaire showed steps 1-3 of each government objective and then asked respondents to decide whether a telehealth system is possible as in step 4. The experts were also asked to provide reasons for their answers. An abridged version of the questionnaire can be found in Appendix D.13.

9.3 Results

This section details the outcomes of deriving telehealth systems as a possible way of implementing some of the government objectives.

Chapter 2 of the NHS 2010-2015 report: '*The deal for patients and the public*' contains twelve top-level government objectives. These are:

1. "Rights for patients".
2. "Responsibilities of patients".
3. "A preventative, people-centred, productive NHS".
4. "Supporting people to get and stay healthy".
5. "Delivering through partnerships".
6. "Reaching out to people".
7. "Diagnosing early".
8. "Providing high quality services – treating patients well".
9. "Safer care".
10. "Improving patient satisfaction – increasing choice and control".
11. "Effective care – transforming the lives of patients with long-term conditions".
12. "Social care".

The results below are derived by following steps 1-6 for each of these government objectives. The main body of the results consists of tables with the details of the results from step 4, those concerning which part of the government objectives could be delivered by telehealth systems.

Supplementary results of diagrams showing steps 1-3 of the methodology applied to each objective and the tables showing the details of step 5 and 6 can be found in Appendix D.

9.3.1 Is a telehealth system possible for Objective 1 – "rights for patients"?

Step 4 is represented by Table 9-4.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
1-1	No	One of the aims of the NHS constitution is to empower patients. Although a telehealth system can do this, its role must be specifically defined.

Table 9-4 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 1

9.3.2 Is a telehealth system possible for Objective 2 – "responsibilities of patients"?

Step 4 is represented by Table 9-5.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
2-1	No	The explanation of this plan talks about the ownership of the NHS and a telehealth system is not possible for demonstrating this.

Table 9-5 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 2

9.3.3 Is a telehealth system possible for Objective 3 – "a preventative, people-centred, productive NHS"?

Step 4 is represented by Table 9-1, which is the worked example.

9.3.4 Is a telehealth system possible for Objective 4 – "supporting people to get and stay healthy"?

Step 4 is represented by Table 9-6.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
4-1	No	A telehealth system cannot play a role in establishing partnerships between organisations. Neither can it be used to develop prevention programmes, although once these prevention programmes are developed, telehealth can be used to disseminate the information.
4-2	Yes	To educate families in preventing unhealthy conditions at an early stage.
4-3	Yes	To provide personalised advice.

Table 9-6 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 4

9.3.5 Is a telehealth system possible for Objective 5 – "delivering through partnerships"?

Step 4 is represented by Table 9-7.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
5-1	No	The details of services are required to be able to identify whether a telehealth system can be used to deliver them.
5-2	No	The role a telehealth system will play depends on the specific 'big issue' being tackled.
5-3	Yes	To educate young people and help reduce conception rate in under 18s.
5-4	No	This point raises the issue of promoting the role of pharmacies in society.
5-5	Yes	To create environments that support health.

Table 9-7 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 5

9.3.6 Is a telehealth system possible for Objective 6 – "reaching out to people"?

Step 4 is represented by Table 9-8.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
6-1	Yes	To improve support of vulnerable young first time mothers and their families.
6-2	Yes	To reduce the risk of developing diseases through health checks.
6-3	Yes	To help prevent disease through screening.
6-4	Yes	To provide information to older people about the services available.

Table 9-8 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 6

9.3.7 Is a telehealth system possible for Objective 7 – "diagnosing early"?

Step 4 is represented by Table 9-9.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
7-1	No	A telehealth system cannot be used to reorganise pathology services, without details of existing services.
7-2	No	A telehealth system may not reduce inequalities in regions as this is based on multiple factors.
7-3	Yes	To increase speed of access to specialists.
7-4	Yes	To increase awareness and reach earlier diagnosis.

Table 9-9 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 7

9.3.8 Is a telehealth system possible for Objective 8 – "providing high quality services – treating patients well"?

Step 4 is represented by Table 9-10.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
8-1	No	A telehealth system cannot be used to reduce healthcare infections since this process is primarily based on maintaining high standards of hygiene.
8-2	No	A telehealth system cannot be used to reduce waiting times.
8-3	No	A telehealth system cannot be used to speed up the rate of diagnosing cancer or reduce inequalities in care. Rather, this is dependent on facilities available.
8-4	Yes	To improve the care for people who have suffered a stroke.
8-5	No	A telehealth system cannot be used to reduce waiting times for heart surgery or provide access to rehabilitation.
8-6	Yes	To provide information during pregnancy.

Table 9-10 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 8

9.3.9 Is a telehealth system possible for Objective 9 – “safer care”?

Step 4 is represented by Table 9-11.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
9-1	No	A telehealth system cannot be used to regulate care.
9-2	No	A telehealth system cannot be used to work in collaboration with the National Patient Safety Agency.
9-3	No	A telehealth system cannot be used to report serious incidents affecting patients.
9-4	No	A telehealth system cannot be used to reduce inequalities across organisations.
9-5	No	A telehealth system cannot be used to assess patients at risk of developing VTE (venous thromboembolism).
9-6	No	A telehealth system cannot be used to carry out a risk assessment of patients or implement pressure-relieving measures.
9-7	No	A telehealth system cannot be used to make people accountable.

Table 9-11 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 9

9.3.10 Is a telehealth system possible for Objective 10 – “improving patient satisfaction – increasing choice and control”?

Step 4 is represented by Table 9-12.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
10-1	No	A telehealth system cannot be used to make carers recognised or to ensure patient satisfaction.
10-2	Yes	To disseminate details of a patient survey.
10-3	Yes	To disseminate information about services.
10-4	Yes	To provide alternative ways of supplying information for patients.
10-5	No	A telehealth system cannot be used to determine the income of providers.
10-6	No	A telehealth system cannot be used to increase options available to patients.

Table 9-12 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 10

9.3.11 Is a telehealth system possible for Objective 11 – "effective care – transforming the lives of patients with long-term conditions"?

Step 4 is represented by Table 9-13.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
11-1	Yes	To provide better management of COPD and asthma.
11-2	Yes	To provide better management of heart failure.
11-3	Yes	To provide better management of diabetes.
11-4	Yes	To provide better management of cancer.
11-5	Yes	To provide better management of dementia.

Table 9-13 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 11

9.3.12 Is a telehealth system possible for Objective 12 – "social care"?

Step 4 is represented by Table 9-14.

(Objective #-Key statement #)	Is a telehealth system possible?	Explanation
12-1	No	A telehealth system cannot be used to reform social care services since this is based on specific plans locally.

Table 9-14 – Methodological step 4 of whether a telehealth system is possible for the details of key statements for objective 12

9.4 Discussion

The discussion is divided into five parts.

Part 1 is a discussion of entire government objectives for which a telehealth system was not possible. Part 2 discusses key statements within the remaining government objectives for which a telehealth system was not possible and reasons why this was the case. This is followed by part 3 which is a discussion of entire government objectives that a telehealth system was suitable for. The fourth part covers capability categories from telehealth systems that were applied to key statements.

The fifth part of this discussion covers capabilities that are not currently in existence in telehealth systems but would need to be added to meet the aims of the key statements stated in the government objective. The sixth part discusses results obtained from the questionnaire used for validation.

9.4.1 Objectives where a telehealth system was not possible

A telehealth system was not possible for all the aspects of objective 1, 2, 9 and 12. For objective 1 and 2, the key statements were focused on the NHS Constitution, which concentrates on expectations from the health professionals, patients and public that must be met by the NHS. In addition, the explanations noted that the ownership of the NHS was not for a target population but for everyone. Without specific details given in the report, it was not possible to suggest a telehealth system to meet these objectives.

Objective 9 was about ‘safer care’. A telehealth system was not considered as a possibility because the key statements raised were related to the safety of patients within hospitals and preventing/reducing infections.

Objective 12 was about ‘social care’ specifically related to adult care. The explanations of the key statement noted how social care could be reformed through investment and integration with healthcare. Since these plans depend on local councils, which were not given, telehealth was not seen as a solution.

9.4.2 Key statements where a telehealth system was not possible

A telehealth system is not possible for some aspects of certain government objectives. Table 9-15 shows the objectives and the relevant key statements. Beside them is a value representing the proportion of the statements within a particular objective that could not be delivered by a telehealth system.

Objective Number	Key statement number	Proportion of key statements that could not be delivered by a telehealth system (%)
3	2	1 of 3 (33%)
4	1	1of 3 (33%)
5	1,2,4	3 of 5 (60%)
7	1,2	2 of 4 (50%)
8	1,2,3,5	4 of 6 (67%)
10	1,5,6	3 of 6 (50%)

Table 9-15 – Objectives and key statements where a telehealth system was not a possibility

For the case of key statement 3-2, more details would need to be specified on how diseases could be prevented in order to propose a telehealth system for them.

Key statement 4-1 was about establishing partnerships and developing prevention programmes. These could not be met by a telehealth system because information provided was from an organisational perspective.

For key statement 5-1, the specific details of the types of prevention services were not given. For key statement 5-2, information was given about local areas working together, however, the issues affecting specific geographic areas will differ and hence a telehealth system was not considered as a possibility. For key statement 5-

4, Portsmouth PCT was given the task of developing a framework for pharmacies and as such a telehealth system could not be proposed.

Key statement 7-1 was concerned about the reorganisation of pathology services to aid in early diagnosis but again details of the current services are needed in order to identify telehealth as a possible solution. Key statement 7-2 was focussed on reducing inequalities in regions and was therefore not considered as deliverable by telehealth.

For key statement 8-1, the explanation of the key statement was related to reducing infections nationally. This was unsuitable for a telehealth system because it depends on standards of hygiene in healthcare environments. Key statement 8-2 and 8-5 were about reducing waiting times and telehealth systems cannot be used to do this. Key statement 8-3 was about speeding up the rate of diagnosing cancer and this is more reliant on the healthcare facilities available.

Key statement 10-1 was based on satisfaction of patients and carers. It also promoted the importance of carers and a telehealth system cannot be used to do this. Key statement 10-5 was about providing an incentive for providers and therefore unsuitable for a telehealth system. Key statement 10-6 was about increasing choice for patients in terms of where they can receive hospital treatment or which GP they can register with, for which a telehealth system is not suitable.

9.4.3 Objectives where a telehealth system was possible

There were two government objectives where all the key statements could be delivered completely through telehealth systems. They were Objective 6 and 11. Objective 6 focused on targeting many members in society by reaching a wide range of people (young people, older people and people at risk of developing certain conditions). Objective 11 focused on targeting people specifically with long term conditions (COPD, heart failure, diabetes, cancer and dementia).

9.4.4 Capability categories applied to key statements

Table 9-16 shows the distribution of existing capability categories of telehealth systems (Adeogun et al. 2011c) that could be applied to key statements. For display purposes, the capabilities that were not applied to the objectives were not shown in the table.

From Table 9-16, the most frequently used capability was ‘P8-Health professional sends message to patient’. Other frequently used capabilities used were P11-Health professional creates patient care plan followed closely by P9-Patient contacts health professional.

Table 9-17 shows a summary of the capability categories applied to government objectives along with their frequencies.

Interestingly, none of the current capabilities related to caregivers could be applied to the government objectives.

	Objective	3		4		5		6				7		8		10			11				
	Key statement	**1**	**3**	**2**	**3**	**3**	**5**	**1**	**2**	**3**	**4**	**3**	**4**	**4**	**6**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**5**
Category Name	**P1-Intermediate device prompts patients to answer questions**			✓												✓							
	P2-Patient sends message to health professional			✓		✓		✓							✓								
	P7-Patient accesses results						✓																
	P8-Health professional sends message to patient	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓			✓	✓
	P9-Patient has real-time communication with health professional			✓		✓		✓	✓	✓		✓	✓		✓					✓	✓	✓	
	P10-Intermediate device prompts patients to take medication																			✓			
	P11-Health professional creates patient care plan	✓	✓	✓	✓	✓		✓	✓				✓	✓	✓	✓			✓			✓	
	P12-Health professional modifies patient care plan			✓					✓												✓		
	P14-Patient enters responses into the system			✓												✓		✓					
	P16-Patient enters/transfers results into the system			✓					✓												✓		
	H1-Health professional reviews/ analyzes results								✓			✓	✓										
	H3-Health professional sets up alerts											✓	✓								✓		
	H4-Health professional receives clinical support via a report												✓										
	H5-Intermediate device sends results to health professional			✓					✓			✓	✓										
	H6-Health professional receives alerts											✓	✓								✓		
	H7-Health professional transfers data into the system																✓			✓			
	S4-Server data transfer																✓						

Table 9-16 – Distribution of capabilities of telehealth systems applied to key statements within government objectives

Capability category name	Frequency
P1-Intermediate device prompts patients to answer questions	2
P2-Patient sends message to health professional	4
P7-Patient accesses results	1
P8-Health professional sends message to patient	18
P9-Patient has real-time communication with health professional	11
P10-Intermediate device prompts patients to take medication	1
P11-Health professional creates patient care plan	13
P12-Health professional modifies patient care plan	3
P14-Patient enters responses into the system	3
P16-Patient enters/transfers results into the system	3
H1-Health professional reviews/ analyzes results	3
H3-Health professional sets up alerts	3
H4-Health professional receives clinical support via a report	1
H5-Intermediate device sends results to health professional	4
H6-System alerts health professional	3
H7-Health professional transfers data into the system	2
S4-Server data transfer	1

Table 9-17 – Summary of capability categories applied to government objectives

9.4.5 Additional capability categories required for future telehealth systems

This section discusses additional capability categories not currently available in telehealth systems which are needed to meet the government objectives. They are presented in Table 9-18, where the objective numbers and key statements are shown in the first column. The possible actions (step 5 of the methodology) are shown in the second column and the equivalent capability categories are shown in the third column.

These capabilities were placed into four groups which were the same as those derived by the authors in the previous study on capabilities (Adeogun et al.

2011c): patient, caregiver, health professionals and non-actor centric capabilities.

9.4.5.1 Patient-centric capabilities

Additional capability categories for patients were prompts to establish routine or reminding patients of appointments. Patients could also enter additional details about their lifestyle into the telehealth system and receive information. Finally, patients could contact other patients via a forum in order to share and learn from experiences.

9.4.5.2 Caregiver-centric capabilities

Additional capability categories for caregivers were related to receiving information about available services (which patients may also receive) and to help provide support to the patients.

9.4.5.3 Health professional-centric capabilities

Additional capability categories for health professionals involved the searching of patient records to identify most appropriate patients to receive certain information, therefore providing a personalised service. They are also involved in training patients.

9.4.5.4 Non-actor-centric capabilities

Additional capability categories for non-actors were based on having up to date information available in the telehealth system to keep all the actors informed.

Objective #-Key statement #	Possible action	Additional capability
6-3	Patients are notified of screening appointments.	Patient is reminded of appointment.
11-2	Patients are prompted to establish rehabilitation routines.	Patient is prompted to establish a routine.
5-5	People enter details of types of food consumed.	Patient enters additional details into the system.
5-5	People check and receive information about local places for exercise	People make enquiries from the system; People receive information from the system.
7-3; 11-4; 11-5	Patients should be able to ask questions and receive advice about their condition.	Patient contacts other patients via forum. (In this case, the patient receives approved information via a forum from others who may be going through a similar experience).
10-4	Parents can access the information provided by other parents.	Patients access feedback provided by other patients.
4-2	Family members should support each other.	Family members/Caregivers receive messages to help improve patient care.
11-5	Patients and caregivers should be aware of available services.	Caregiver receives information.
8-4; 11-5	Caregivers may also receive this information depending on the severity of the stroke.	Caregiver receives messages to help improve patient care.
6-2; 6-3; 6-4; 11-1; 11-4	Health professionals search patient records to determine if they are within the appropriate age range.	Health professional searches patient records.
6-3	Health professionals can set up triggers for when new patients fit into target population.	Health professional sets up alerts on patient records.
11-3	Patients are trained in self management by health professionals.	Health professional trains patient.
7-4; 11-2; 11-4	GPs may discuss patient symptoms with colleagues.	Health professional receives clinical support verbally.
7-4	GPs can search medical software application to help reach a conclusion about a patient.	Health professional searches medical application for information.
10-3	Telehealth system is incorporated with information of local services.	Information about local services is added to the system.

Table 9-18 – List of additional capability categories required in proposed telehealth systems

9.5 Validation outcome

6 of 14 people (43%) responded to the questionnaire.

The results of this section are presented as follows: section 9.5.1 discusses the entire government objectives which cannot be delivered by a telehealth system following the authors' evaluation. Section 9.5.2 discusses the objectives which the authors evaluated can be partly delivered by a telehealth system. Section 9.5.3 then discusses the remaining objectives which the authors evaluated to be completely deliverable by a telehealth system.

9.5.1 Government objectives evaluated as entirely not deliverable by a telehealth system (Objectives 1, 2, 9 and 12)

Table 9-19 shows the results from the questionnaire analysis for each objective's key statement. The figures shown for the responses are percentages based on those that responded. For key statements, 1-1, 2-1 and 9-1 more than 50% of the respondents disagreed with the original hypothesis of the authors.

	Can a telehealth system contribute to meeting this objective's key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
1-1	83	17	
2-1	67	33	
9-1	67	33	
9-2	33	33	33
9-3	17	50	33
9-4	33	67	
9-5	17	83	
9-6	17	83	
9-7		83	17
12-1		33	67

Table 9-19 – Questionnaire responses for objectives 1, 2, 9 and 12

Objective 1

Respondents noted in their comments that a telehealth system is suitable for delivering the NHS Constitution (related to the "rights for patients") because it would:

- Be "user-friendly".
- Be "robust".
- Be "portable".
- Incorporate point of care testing and devices to inform patients of relevant health services in order to empower the patients.
- Increase awareness and responsibilities of the patients, allowing them to take ownership of their health.

In the authors' initial analysis, it was decided that a telehealth system was unsuitable because specific details needed to be provided.

Objective 2

The reasons given by respondents for the suitability of a telehealth system for the NHS constitution (related to the “responsibilities of patients”) are:

- Providing information about resources and funding of NHS.
- It is “user-friendly”.

The reasons given by respondents for the unsuitability of telehealth are:

- People may prefer to receive advice from a person than from a PC.
- There was uncertainty on how the constitution could be channelled into telehealth.

One would have expected respondents to give key statement 2-1 the same answers as those of key statement 1-1 because they both referred to the NHS constitution however there were differing views (as noted above).

Objective 9

Respondents noted that a telehealth system is suitable for safer care because: it would be achievable through “information and education”.

The authors felt that telehealth could not be used to deliver safer care since this was specifically targeted at reducing hospital infections, while the focus of telehealth systems in this research has been targeted at home environments.

Objective 12

Some respondents did not think that telehealth could be used to deliver social care. They felt that social care needed to be administered at a personal level or it wasn't specifically a telehealth issue. This was similar to the reasons given by the authors in section 9.3.12 (Table 9-14). It is suggested that delivery of social care can be achieved through telecare. A large proportion responded "don't know".

9.5.2 Government objectives evaluated as partially deliverable by a telehealth system (Objectives 3, 4, 5, 7, 8 and 10)

Objective 3

Table 9-20 shows the results from the questionnaire analysis for each key statement in objective 3. For key statement 3-2 (NHS should be based on prevention), the authors evaluated this as 'no' because of the lack of details provided in the policy report. However, respondents held a contrary view stating that telehealth was a possible solution for the following reasons:

- It would educate the patient.
- It is valuable in preventing complications for chronic conditions.
- It would encourage a healthy lifestyle.

	Can a telehealth system contribute to meeting this objective's key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
3-1	67	16.5	16.5
3-2	83	17	
3-3	67	33	

Table 9-20 – Questionnaire responses for objective 3

Objective 4

Table 9-21 shows the results from the questionnaire analysis for each key statement in objective 4. For key statement 4-1 (investment in “prevention and early intervention”), the authors evaluated this as ‘no’ because telehealth systems cannot be used for investing and establishing partnerships between organisations. In contrast, respondents said telehealth was suitable for the following reasons:

- It would provide education.
- Through provision of funding.

	Can a telehealth system contribute to meeting this objective’s key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
4-1	83	17	
4-2	83	17	
4-3	83	17	

Table 9-21 – Questionnaire responses for objective 4

Objective 5

Table 9-22 shows the results from the questionnaire analysis for each key statement in objective 5. For key statement 5-2 (NHS will work at a local level), the authors evaluated this as ‘no’, because issues being tackled locally vary between regions and specific details needed to be provided by the report. On the contrary, respondents said telehealth was suitable for the following reasons:

- It “brings healthcare to the patient”.
- Through “information and education”.

	Can a telehealth system contribute to meeting this objective's key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
5-1	33	50	17
5-2	67	33	
5-3	67	33	
5-4		33	67
5-5	83		17

Table 9-22 – Questionnaire responses for objective 5

Objective 7

Table 9-23 shows the results from the questionnaire analysis for each key statement in objective 7. For key statement 7-3 (earlier diagnosis of cancer), the authors evaluated this as ‘yes’, because telehealth can be used to speed up the access to specialists. In contrast, respondents said a telehealth system is unsuitable for this key statement for the following reasons:

- Cancer is quite a specific issue.
- They were unsure about the role of telehealth and noted that diagnosis of cancer can still be achieved in a conventional manner.
- The diagnosis and communication of cancer should be preferably done face to face “not by distance”.
- Patients will need to see the healthcare personnel.

These views by respondents highlight the need for selectivity in health conditions that telehealth systems may be used to deliver.

	Can a telehealth system contribute to meeting this objective's key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
7-1	16.5	67	16.5
7-2		83	17
7-3		67	33
7-4	50	17	33

Table 9-23 – Questionnaire responses for objective 7

Objective 8

Table 9-24 shows the results from the questionnaire analysis for each key statement in objective 8. The responses were evenly shared for key statements 8-4, 8-5 and 8-6.

For key statement 8-4 (improve care for people who have suffered a stroke), the authors evaluated this as 'yes', because telehealth could be used to improve their care. Respondents that said 'yes' gave the reason that telehealth could be used to manage associated risk factors of stroke. Those that said 'no' noted that contact was needed with the health professional.

For key statement 8-5 (improve care for people with a high risk of developing heart disease) the authors evaluated this as 'no', because the issue focussed on is about locating the healthcare facility nearer to patients so that they have better access to such a facility. Respondents that said 'no' noted the following: they couldn't see how telehealth could improve this option; patients need to be where the facility is. Those that said 'yes' said it was clearly linked to telehealth. Although the respondents didn't say how this may be implemented.

For key statement 8-6 (improve care for pregnant women) the authors evaluated this as 'yes', because telehealth can be used to disseminate information during pregnancy. Respondents that said 'yes' noted: "telehealth may be a solution but may not be cost effective". They suggested the use of mobile phone messaging. Those that said 'no' noted:

- "investment in health professionals is needed".
- "Information is already on internet".

	Can a telehealth system contribute to meeting this objective's key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
8-1		83	17
8-2	33	50	17
8-3	17	50	33
8-4	50	50	
8-5	50	50	
8-6	50	50	

Table 9-24 – Questionnaire responses for objective 8

Objective 10

Table 9-25 shows the results from the questionnaire analysis for each key statement in objective 10. For key statement 10-1 (nationwide patient survey), the authors evaluated this as 'no' because a telehealth system cannot advocate the importance of certain human actors within the system. Its primary role is to administer healthcare to patients. In contrast, respondents said telehealth was suitable because the questionnaire can be administered online.

For key statement 10-6 (increase choice and control for patients), the authors evaluated this as 'no' because the choice for patients was based on location of where to receive treatment. In contrast, respondents said 'yes' for the following reasons:

- It would provide information.
- "Information dissemination will only target those who have access to telehealth".

	Can a telehealth system contribute to meeting this objective’s key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
10-1	67	33	
10-2	67	33	
10-3	83	17	
10-4	83	17	
10-5	33.3	33.3	33.3
10-6	67	16.5	16.5

Table 9-25 – Questionnaire responses for objectives 10

9.5.3 Government objectives evaluated as completely deliverable by a telehealth system (Objectives 6 and 11)

Objective 6

Table 9-26 shows the results from the questionnaire analysis for each key statement in objective 6. For key statement 6-3 (screening), the authors evaluated this as ‘yes’ because a telehealth system can help prevent diseases through receiving information. In contrast, respondents said ‘no’ for the following reasons: the workplace/school visit will be more useful; a physical presence is needed to examine the patient and to obtain samples; occasional services may not require telehealth and services within the community should suffice.

	Can a telehealth system contribute to meeting this objective’s key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
6-1	50	33	17
6-2	50	50	
6-3	17	83	
6-4	83		17

Table 9-26 – Questionnaire responses for objective 6

Objective 11

Table 9-27 shows the results from the questionnaire analysis for each key statement in objective 11. For key statement 11-5 (better management of dementia), the authors evaluated this as ‘yes’ because a telehealth system can help to improve the management of dementia. In contrast, respondents said ‘no’ for the following reasons: they can’t see a place for telehealth, maybe telecare; personal touch required.

	Can a telehealth system contribute to meeting this objective’s key statement?		
Objective # - Key Statement #	**Yes (%)**	**No (%)**	**Don't Know (%)**
11-1	83		17
11-2	83		17
11-3	83		17
11-4	67	33	
11-5	17	50	33

Table 9-27 – Questionnaire responses for objective 11

9.6 Limitations

This paper has two main limitations.

The first is that the capabilities are based on a specific healthcare policy derived for a particular country. Therefore all the results may not be applicable to another country. However, the results of this paper may still be interesting to other developed countries since many healthcare challenges are global.

The second is that capabilities for proposed telehealth systems were based on systems for managing long term conditions.

9.7 Conclusions

This paper has evaluated a health policy with the view to identify the objectives for which a telehealth system was possible for and the current telehealth capabilities that may be applicable to them.

A six-step methodology has been described and applied to this health policy. 12 objectives were identified in the health policy report. 4 of 12 were evaluated by the authors as not suitable to be delivered by a telehealth system (1, 2, 9 and 12). 2 of 12 were evaluated as fully deliverable with a telehealth system (6 and 11). The remaining 6 objectives could be partly delivered with a telehealth system.

The objectives for which all six steps were not applicable to were ones where there was either insufficient details provided in the policy or ones where the environments described in the policy did not involve patients being separated by a distance from the health professionals (e.g. hospital).

For objectives fully deliverable with a telehealth system, these were linked to: supporting vulnerable people in the society (young first time mothers and older people); helping to prevent or detect cancer; and other long term conditions (i.e. COPD, heart failure, diabetes, cancer and dementia). Long term conditions are specific areas of health which are suited to being delivered by telehealth.

Where a telehealth system is possible, the most common types of capabilities applied to objectives were patients receiving information from health professionals and patients being prompted to do an action.

From the validation, respondents gave different opinions to those of the authors on issues related to the NHS constitution, management of cancer and screening. They agreed that telehealth systems would help to educate the patient and empower them by increasing their role in managing their health.

10 Discussion of Results

The discussion of this thesis is organised based on findings in chapters 2-9. For each chapter, the major results are highlighted. They are then discussed within the context of the overall aim of the research and their contribution to knowledge.

10.1 Chapter 2 – a review of informatics for decision support in point-of-care devices for long term conditions care

10.1.1 Major findings

Literature was organised into a simple hierarchical health informatics model consisting of data, information and knowledge. These are the basic steps in informatics. For data, important issues identified were: the efficiency of generating data, the availability of structured data storage, timely access to data and data security.

Information had to be sufficient for the user. To generate adequate information, data transfer off a point-of-care device is of key importance because of the lack of on-device information generating capability. Decision Support Systems (DSS) aimed at patients barely exist and more evidence was found of DSS for health professionals.

10.1.2 Contribution

Although the review showed that limited information is available on current point-of-care devices, it was noted that data transfer is important since information is generated away from devices.

The implication of this is that future designs of devices should have efficient ways of transferring data to minimise the errors that may be introduced through manual data entry/transfer. In addition, the issue of interoperability should be investigated to ensure that both the point-of-care device and the component the data is being transferred to can be connected without the need of additional equipment.

The issue of limited information on point-of-care devices has been tackled through the evaluation of telehealth systems (chapter 4). Perhaps this has been one of the reasons that manufacturers and designers have decided not to incorporate additional knowledge onto existing point-of-care devices.

Also, allowing decision making for the patient raises an ethical issue if there was a mistake in the results generated on the point-of-care device.

10.2 Chapter 3 – informatics-based product-service systems for point-of-care devices

10.2.1 Major findings

Using glucometers as a case study, the current level of servitization for point-of-care testing (POCT) devices was considered. From the three sub-classes of product-service systems (PSS), it was ascertained that glucometers are currently supplied as products with some additional functionalities such as the ability to carry out other measurements for blood pressure, ketone and uric acid concentration. It was established that the services affiliated to POCT devices relate to the level of information that the device provides to its users. A result-oriented PSS was proposed and its suitability discussed within the context of POCT devices. In a result-oriented PSS, a result or capability is sold to the customer. This is the most appropriate model applicable to improve the level of servitization for POCT devices such as glucometers.

10.2.2 Contribution

Within the context of the overall research, the full impact of a result-oriented PSS for point-of-care devices will be possible within a telehealth system. This is because capabilities of interpreting data for the patient will be sold as a service. The synthesis and exchange of information will be viewed as delivering a service. This could be likened to the information service provided by NHS Direct where members of the public can receive immediate advice about their symptoms. In the same way, a telehealth system could be used to deliver advice to patients with chronic diseases following their testing.

Since there are many components involved in exchanging information between patients and health professionals (which include both actors and non actors), a systematic way of administering such a service must be thoroughly worked out. This will involve collaboration between multiple organisations. Linking this to results of chapter 8 (capabilities of proprietary intermediate devices), which showed that intermediate devices were part of closed proprietary systems, indicates that the information service for patients must be fully integrated to allow clarity for payers of the system.

10.3 Chapter 4 – models of information exchange for UK telehealth systems

10.3.1 Major findings

This study explicitly defined 11 entities used within current telehealth offerings. The paths of information were then traced in the telehealth offerings to understand information generation and exchange. Following this, three generic models were outlined from the evaluation. The difference between each type of model is the number of entities and the types of information exchange and therefore the number of services that could be provided to actors. The baseline model is based on entities that appeared in all of the existing offerings. The dominant model represents entities present in more than half of the existing offerings. The fully-featured model represents all possible arrangements of all the entities in telehealth offerings. Five forms of information transfer were identified within the telehealth offerings. The leading forms of information transfer are ‘patient-push’ and ‘health professional-pull’.

10.3.2 Contribution

In the context of the research, it is possible to deduce that components of telehealth systems are important in supporting informatics and decision making for the actors of the system. This is because at certain points in the system, data were analysed through predefined algorithms to ascertain whether health professionals need to make contact with the patient regarding their results.

Telehealth systems also help facilitate the exchange of data to help decision making to be faster for all actors concerned. Patients will be able to receive important messages from their health professional on their progress. Caregivers and health professionals will be better informed about patient’s adherence to protocols. In addition, health professionals will be able to ascertain whether a patient is on the most appropriate care plan and make necessary changes.

10.4 Chapter 5 – capabilities of telehealth systems

10.4.1 Major findings

This study derived capabilities of telehealth systems and grouped them into categories based on the perspective of actors. Capability has been defined in this paper as the ability of a system entity to perform an action.

55 individual capabilities were compiled, resulting in 18 categories for the patient, two categories for the caregiver, 14 categories for the health professional and six categories for non-actor entities. The categories were differentiated by those ‘initiated by an entity’ and those ‘whose actions affected an entity’.

10.4.2 Contribution

Within the overall context of this research, a large number of capability categories for the patients and health professionals supported the leading forms of information exchange identified in chapter 4. There was only one category that supported a real-time exchange of information between patients and health professionals. This will help speed up the decision making process about the course of action the patient should take.

Two roles for patients were identified when they initiated an action in telehealth systems: one is to generate/transmit data; the second is to have more responsibility in managing their health. Empowering patients has been one of the key headlines in recent UK government policy (Department of Health, 2006a).

Categories affecting the patient were divided into two groups: health professionals creating/updating care plans; and system entities prompting patients to comply with routines.

Within these patient related categories, this research has shown that current capabilities of telehealth systems will promote better management of patient’s health.

There were no capabilities related to the caregiver that had a direct impact on the patient and health professional. This was not surprising since the frequency of caregivers in current telehealth systems was low. Current capabilities related to caregivers show their passive involvement in the system as they could only access or be alerted about the patient's results.

Four roles of health professionals were identified when they initiated an action: they are informed of patients' results; they are alerted when there are unusual results entered by patients, they can advise the patient on issues about their health; and they can receive clinical support from other health professionals.

These capabilities imply that telehealth systems are likely to complement the role of health professionals within healthcare. Although the difference between this and traditional administration of healthcare is the potential increase in the speed of the communication process. The non-actor capabilities were grouped into two outcomes: results being saved and results being transferred to another component of the telehealth system. This implies that the saving of results and information transfer within telehealth systems are equally important actions for the system.

10.5 Chapter 6 – evaluation of the state-of-the-art in informatics in glucometers.

10.5.1 Major findings

The results from this section are presented in five parts:

1. Information before testing
    - Some glucometers have the option of setting reminders for the patient to test. Most glucometers display an error message indicating that it is not operating in the right temperature range.
2. Testing
    - The time taken to generate results on devices is between 3 and 50 s.
3. On-device data manipulation after testing

- Results can be annotated in some glucometers.
- Most glucometers allow results to be averaged – different types of averages can be calculated (over different day ranges).
- Most of the glucometers allow results to be downloaded to a computer.

4. Off-device data management software capabilities
   - More than half of glucometers evaluated have data management software to allow further analysis of data. Data could be transferred via USB cables in most cases and also via infra-red.
5. Advice given by the glucometer.
   - Short comments are displayed when results are not within the specified measuring range of the device (for instance, some glucometers specified a measuring range of between 1.1 – 33.3mmol/L or 20-600mg/dL). Only a few glucometers provided warnings for measured values of blood glucose that were particularly high or low.

10.5.2 Contribution

A reminder to test is an aspect that helps to promote patient compliance because it can help in cultivating a positive attitude to carrying out the test at regular intervals. Within the context of the research, if tests are carried out regularly, results obtained can be fed into the telehealth system at specific times to speed up the decision making process regarding the subsequent steps that the patient needs to take. The alternative side to this is if patients do not do their tests at scheduled times, caregivers or health professionals might be alerted about this.

Short testing times aid the whole decision making process since patients do not need to wait a long time for their results.

The ability to annotate results directly on testing devices may help promote the transmission of other contextual information about the patient's current circumstance that may aid health professionals in interpreting results. Within the context of the research, intermediate devices also play a similar role when they pose questions to the patient; however intermediate devices do not allow patients to enter free text, thus showing the need for such a feature on point-of-care devices.

Averaging of results would only be useful for patients who have knowledge of how to interpret the results. Therefore, it is suggested that a capability be available for patients to consult health professionals about the averages of their results. Alternatively, there could be a library of information available for patients to consult.

The transfer of data to external software supported the concept that point-of-care devices are part of a larger system of interconnected components. However, the issue of interoperability arises because of the differences in devices. Designers and manufacturers need to take this into consideration for future devices.

Advice from glucometers was limited and this is understandable if they are used within the context of a system, since the needed advice would be provided from other components of the system. Receiving advice from a device raises an ethical issue, as devices may sometimes malfunction. The advice from the device needs to be accurate all the time.

10.6 Chapter 7 – intermediate devices in telehealth systems: types available, where they are found and who uses them?

10.6.1 Major findings

Six types of intermediate devices were found in the evaluation of existing telehealth offerings: personal computer, mobile phone, television, landline phone, proprietary device with data display, proprietary device without data display. These are used by three actors: patient, caregiver and health professional.

Five classes of 'informatic location' currently exist for intermediate devices: Class 1 – devices located between the patient and multiple entities. Class 2 – devices located between the caregiver and web portal. Class 3 – devices located between the health professional and multiple entities. Class 4 – devices located between a point-of-care device and multiple entities. Class 5 – devices located between web portal and EPR[8].

10.6.2 Contribution

Patients use both generic and proprietary devices to exchange information with other entities. Caregivers also use both generic and proprietary devices to exchange information but only with web portals. Health professionals only use generic devices to exchange information with other entities.

After considering the role of intermediate devices in this chapter, the question was raised of whether the proprietary type was needed in telehealth systems since they play the same role as the generic type. Although it was not possible to answer this question, (since organisations were not surveyed on factors influencing their choice of type of intermediate device), what can be said is that currently more systems use generic rather than proprietary devices.

[8] EPR: Electronic Patient Record

10.7 Chapter 8 – capabilities of proprietary intermediate devices

10.7.1 Major findings

Three main capabilities were observed from the analysis. These were firstly: to display information to patients; secondly: to receive data manually/automatically; and thirdly: to forward results and questionnaire responses to another entity. The capabilities were then considered from the perspective of different actors within the system.

10.7.2 Contribution

Within the context of the overall research, the capabilities identified, support the issue that intermediate devices are key components of telehealth systems which support information exchange between patients and other entities. Since proprietary devices are used mainly in the home environment by patients, the features they possess ought to support patients better to promote their independence in managing their chronic conditions. This is highlighted through a simple setup process and automatic data transfer from the point-of-care device to the intermediate device. Reminders are provided in almost all devices. In addition, the capability of a single device being able to manage several conditions is a bonus if the patient suffers from multiple conditions.

10.8 Chapter 9 – applying capabilities of telehealth systems to a healthcare policy

10.8.1 Major findings

This study developed a six-step methodology which worked from government objectives to appropriate telehealth capability categories. This helped to determine objectives for which a telehealth system is suitable or unsuitable.

On the whole, telehealth was considered as a feasible solution for objectives where there are descriptions of actors and possible actions could be proposed for these actors. Also objectives that related to the treatment of patients within a hospital environment were excluded from being delivered by a telehealth system. This is because the focus of the research is on management of conditions within the home environment.

10.8.2 Contribution

Within the context of the overall research, telehealth systems have a role to play in meeting certain government objectives. The telehealth capabilities suited for delivering these objectives centred on health professionals communicating with patients.

This indicates that telehealth systems for the future may help supplement existing modes of communication between patients and other actors. This implies that patients may be better supported in the management of their chronic condition.

10.9 Limitations of studies

The limitations of each study are detailed below.

Chapter 2: There should have been a greater focus on point-of-care devices specifically used by patients within the home environment rather than generic types of point-of-care device.

Chapter 3: Only one example of a point-of-care device (i.e. glucometer) was studied and other point-of-care devices could have been evaluated.

Chapter 4: The telehealth offerings evaluated concentrate on those for the management of chronic diseases and may not be generally applicable to other types of conditions. Also, the effectiveness of telehealth offerings was not evaluated.

Chapter 5: The capabilities derived in this paper are limited to telehealth systems for managing chronic diseases. The study was unable to provide answers for issues related to caregivers such as: why there are few capabilities related to the caregiver; why caregivers do not have a direct impact on the other actors; why do caregivers have a limited role currently in systems; and why do the other actors' actions not have a direct impact on caregivers.

Chapter 7: The study did not investigate the rationale, for factors influencing the choice of type of intermediate device, by existing telehealth service providers

Chapter 8: An extensive survey would need to be carried out to ascertain the expectations of users of proprietary intermediate devices. This would establish the deficiencies of current devices and the additional features required.

Chapter 9: The capability categories of telehealth systems were applied to a specific healthcare policy derived for a particular country. Therefore results may not be applicable to another country. Also, the capability categories for proposed telehealth systems were based on systems for managing long term conditions.

10.10 Future work

This research could be further extended by considering the management of other chronic diseases and extending the evaluation to consider more point-of-care devices. Most of the studies carried out were focussed on medical practice within the UK. Therefore, studies could be carried out on other developed economies to compare similarities and differences in the results.

Feedback of the actors within telehealth systems may also be needed to ascertain their perceptions of how healthcare may be delivered in the future.

10.11 Conclusions

This research aimed to model and analyse information generation and exchange in telehealth systems and to identify and analyse the capabilities of these systems in managing chronic diseases which utilise point-of-care devices.

The aim has been met through extensive literature review carried out systematically. Literature showed that informatics on point-of-care devices was limited to data generation. The studies carried out during this research showed that information is generated through several components of telehealth systems. This research has evaluated and highlighted the role of several components of telehealth systems (devices) involved in information generation and exchange to support decision making for patients.

The conclusions of this work outlined below show how each of the objectives stated at the beginning of this thesis has been met:

- Point-of-care devices are a key component of telehealth systems which provide data for managing chronic diseases.

- It is possible to increase the level of servitization in point-of-care devices through a result-oriented PSS, which offers information as a service to users. This is available through a telehealth system.
- Components of telehealth systems are key to help facilitate the exchange of information which in turn supports users in making decisions about their health. These have been highlighted through generic models of information generation and exchange.
- A majority of capability categories in current telehealth systems are for patients and health professionals, therefore showing that they are key actors in telehealth systems. Caregivers currently have a passive role in the systems.
- Point-of-care devices must have efficient ways of data transfer in order to minimise errors that may be incurred through manual data entry. Point-of-care devices for home use have basic data processing and allow only simple annotation of results.
- Intermediate devices are key components of telehealth systems that allow the exchange of information. Two types were identified: generic and proprietary. Patients and caregivers use both types, although there were larger instances of the proprietary type being used by patients. Health professionals only use the generic type. A study of capabilities of proprietary intermediate devices showed that they have a simple setup process for users and allowed automatic data transfer. They are also able to manage several conditions.
- Telehealth systems have a role to play in meeting certain government objectives, thus they may help to supplement existing modes of communication between patients and other system actors. This implies that patients may be better supported in the management of their chronic diseases through the use of telehealth systems.

The research has captured the model of information generation and exchange for telehealth systems. The capabilities of such systems have been identified and a systematic approach has been used to apply these capabilities to healthcare policy. These are the contributions of the research to knowledge.

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APPENDICES

Appendix A (For Chapter 4) – Supplementary material showing the details of each telehealth offering

A.1 Offering A

Offering A (Figure A-1) represents a system developed for managing diabetes. The process is initiated by the patient who carries out a blood test using a glucometer developed by the company. The glucometer has both USB and Bluetooth capabilities thus allowing results to be transferred to a PC or wirelessly to a mobile phone before being forwarded to a web portal. After results arrive at a portal, real-time access to them is available via a PC to patients, health professionals and caregivers. Alerts are sent to health professionals notifying them of unexpected results. Health professionals are also able to update the patient's EPR. Patients are able to monitor their results alongside other information which health professionals provided. Patients can send messages to their health professional or "schedule" appointments via the portal.

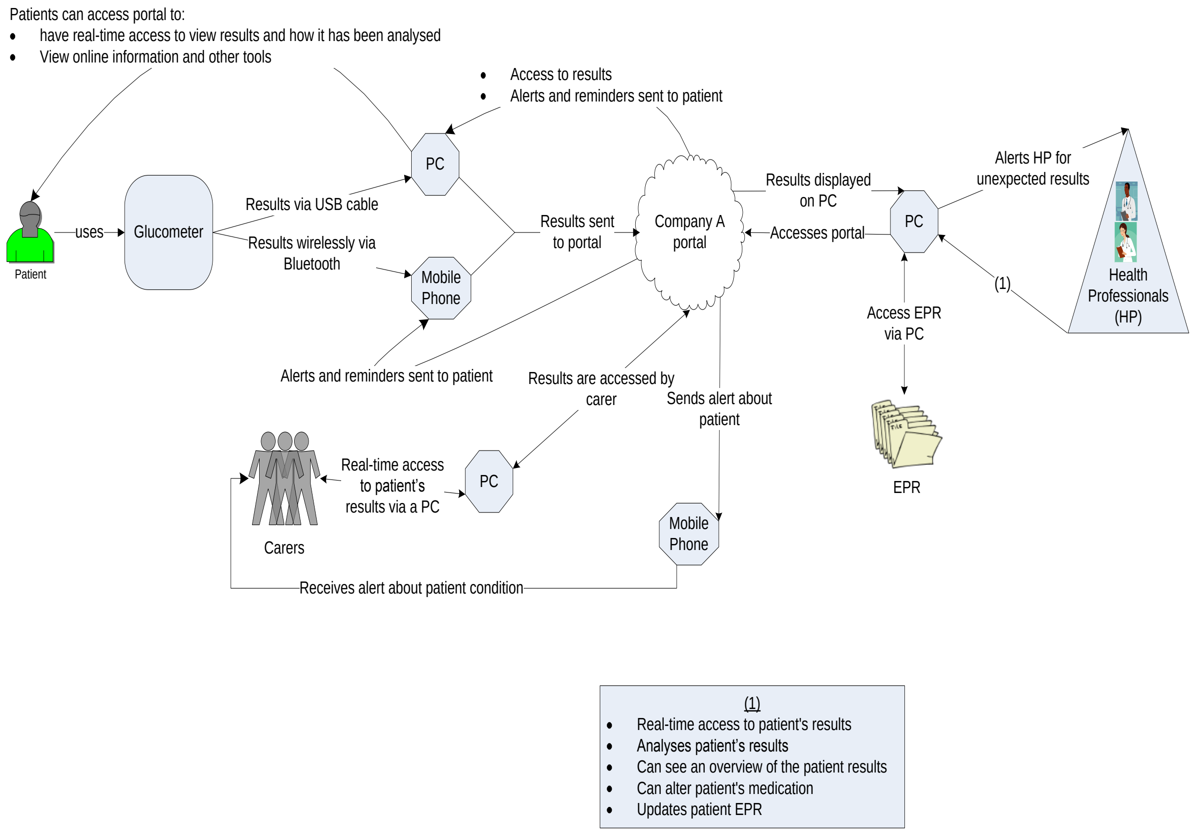

Figure A-1 – Offering A representing a telehealth system for diabetes management

A.2 Offering B

Offering B (Figure A-2) represents a system for monitoring chronic conditions such as diabetes, CHF, COPD and hypertension/high blood pressure. The system provides the capability of using six types of point-of-care devices.

The process is initiated by the patient who can use any of the following point-of-care devices: blood pressure (BP) monitor, weighing scale, coagulation meter (which measures the clotting ability of the blood), pulse oximeter, ECG (electrocardiogram) monitor and glucometer.

After testing, results are sent to four different types of intermediate devices, one generic type and three proprietary types. The generic type is a mobile phone or

BlackBerry which is linked to point-of-care devices through Bluetooth. Of the three proprietary types, two of them are supplied by the same manufacturer Type 1A and 1B. Type 1A of the telehealth monitors transmits data through a telephone landline, while Type 1B transmits data through a GSM (Global System for Mobile Connections) mobile network. The third proprietary device is known as Type 2 and is linked for data transmission from the POC devices through a telephone landline or via Wi-Fi.

The connection types to download results from point-of-care devices include Bluetooth, infrared or an RS232 port. After passing through the intermediate devices, results are transferred securely via web services before being added to the EPR which is programmed to send alerts to health professionals based on predefined triggers. Health professionals are alerted either via a PC (email) or a mobile phone (SMS). The telehealth monitors can be equipped with scripts, which ask patients questions regarding their condition and also reminds them of medications to take.

All the types of telehealth monitors used have EU Medical Device Directive EN60601 certification (British Standards Online, 2006). In addition, the telehealth monitors (type 1A and 1B) also had US Food and Drug Administration (FDA) approval 510(k) (British Standards Online, 2003) while the FDA approval was still pending for telehealth monitor (type 2).

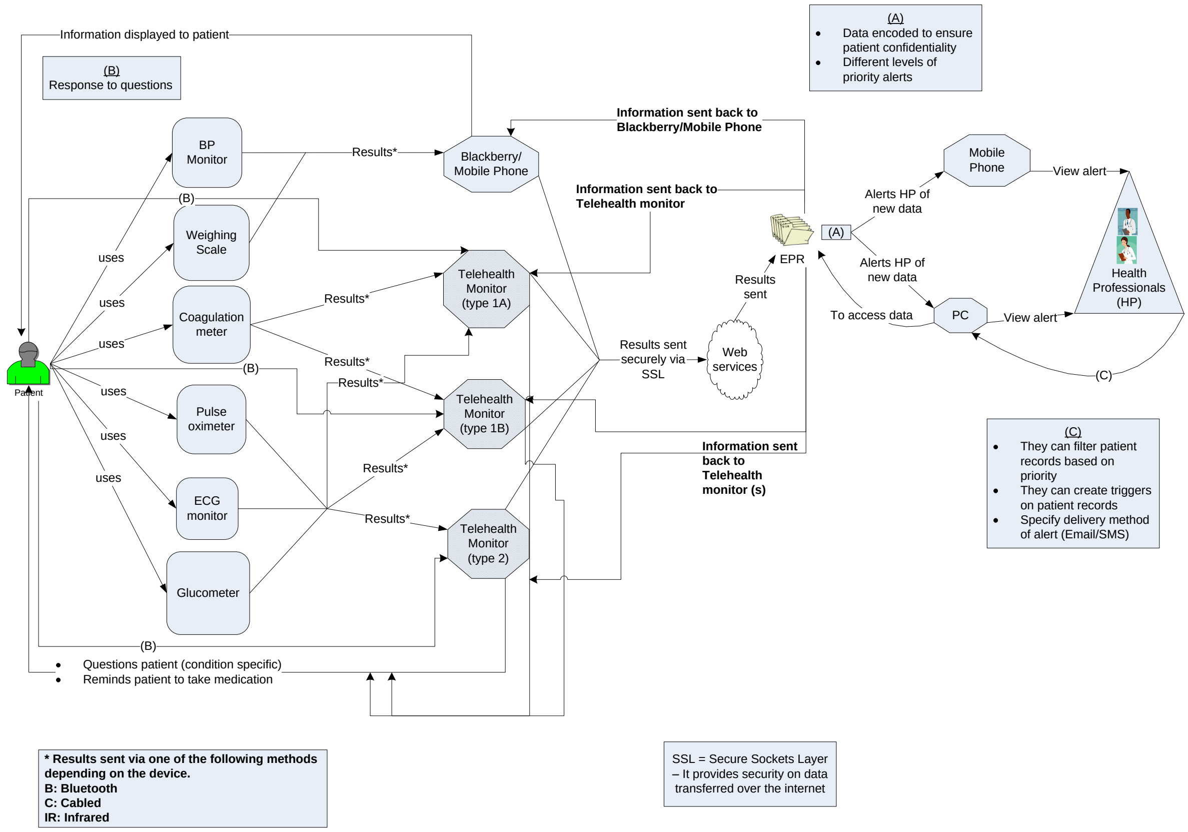

Figure A-2 – Offering B representing a telehealth system for monitoring several chronic conditions

A.3 Offering C

Offering C (Figure A-3) represents a system comprising health management tools for four different conditions, namely diabetes, high blood pressure, asthma and COPD. The following point-of-care devices can be used in the system: glucometer, BP monitor, peak flow meter and pulse oximeter.

The process begins with patients carrying out their test and manually entering results from their point-of-care device into a mobile phone preinstalled with the unique software for this task. Other parameters required to accompany the results are information relating to diet or medication and these are displayed on the mobile phone. Data are transmitted to a secure web page which is accessible to health professionals (specialist nurses and GPs). They review and analyse the data before its interpretation is sent back to the patient via their phone. The results on the phone are colour coded to ease interpretation of the information. The web page is also available to patients. The products used in offering C were certified to the following standards, ISO 13485 (British Standards Online, 2003) and ISO 9001 (British Standards Online, 2008).

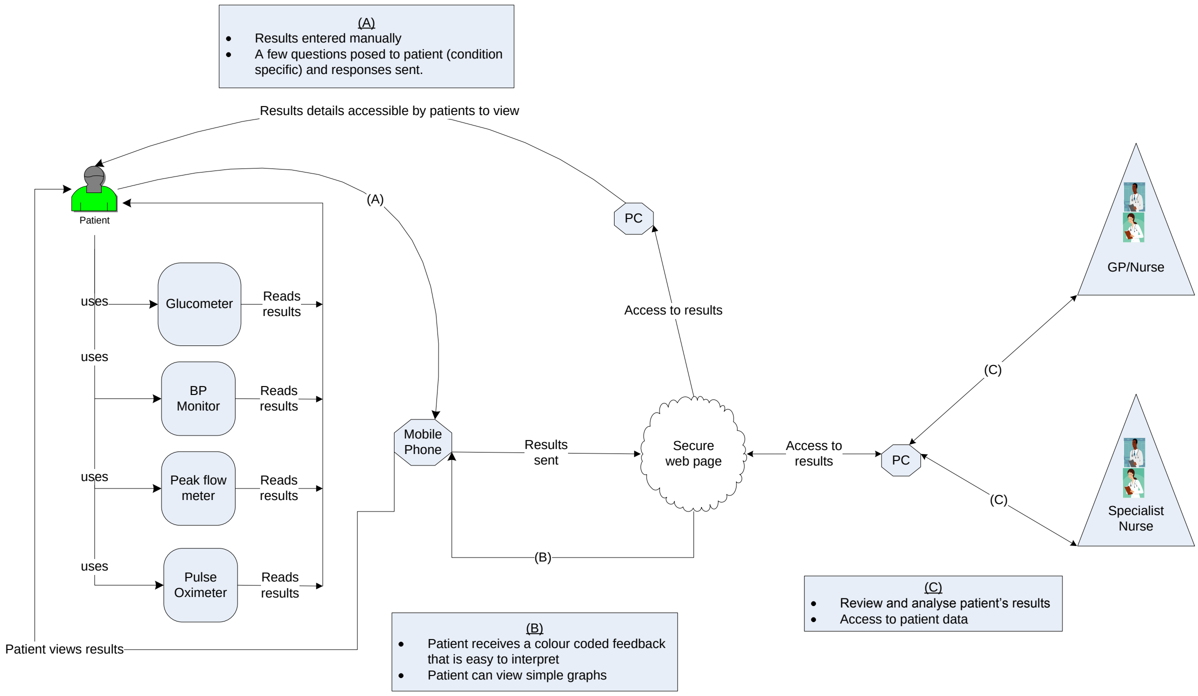

Figure A-3 – Offering C representing a telehealth system for monitoring several chronic conditions

A.4 Offering D

Offering D (Figure A-4) represents a system providing a remote monitoring service for patients with cardiac and respiratory conditions such as CHF, COPD and other chronic respiratory diseases. The offering consists of three sub-sections classified based on the physical location of the entities.

Section 1 describes the service provided to patients when they are at home. The process is initiated by the patient, who can use five different types of point-of-care devices: 12 lead personal ECG monitor, weighing scale, BP monitor, all-in-one monitor (which measured pulse, blood pressure, breathing rate, temperature, heart rate, heart rhythm, ECG and blood oxygen level) and a "MiniClinic" (which helps to detect irregular/abnormal heartbeat). Results from all the devices apart from the personal ECG monitor are sent via a gateway, an intermediate device that transfers results via a telephone line to the monitoring call centre. The monitoring call centre is staffed by dedicated experts (cardiac nurses, cardiology registrars) who evaluate the results and provide its interpretation via the phone to the patient.

Section 2 describes how patients can transmit their results to the monitoring call centre if they are not at home. Only results from the "MiniClinic" can be transferred because it has storage facilities for five readings thus allowing data to be transferred via a USB MiniGate connected to a PC.

Section 3 describes the service provided to GPs who use the professional version of the ECG device. The process here is initiated by the GP carrying out the test on the patient. The device then transmits data through a landline telephone to the monitoring call centre, where experts evaluate the results and provide an initial explanation verbally. A detailed report is sent later by email or fax to the GP.

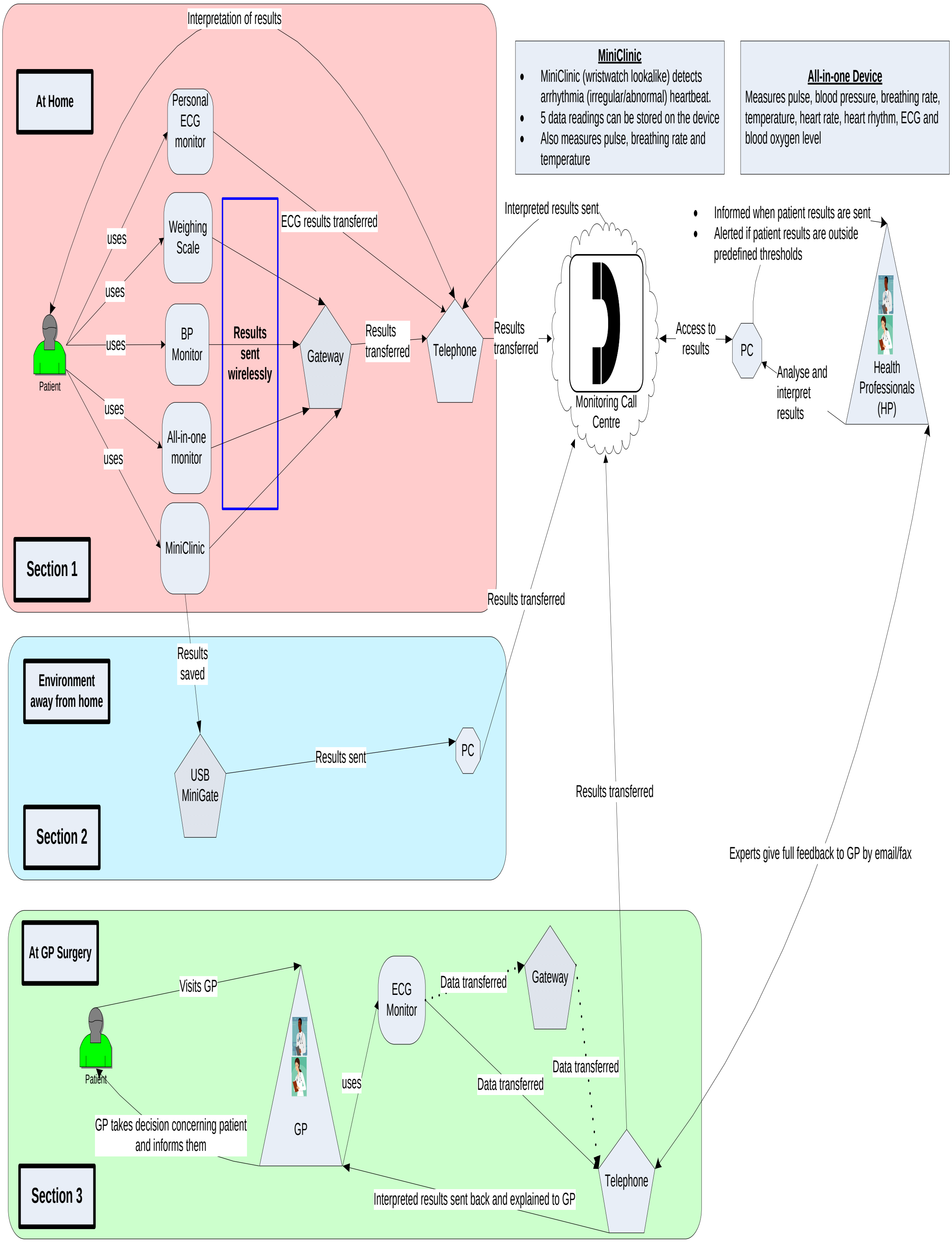

Figure A-4 – Offering D representing a telehealth system for monitoring cardiac and respiratory conditions

A.5 Offering E

Offering E (Figure A-5) represents a telehealth system for managing and preventing long term conditions such as CHF, COPD and asthma.

The process begins with the patient using a vital signs monitor. The results are entered into any of the following three intermediate devices: PC, personal telehealth hub (similar to a personal digital assistant) or mobile phone. The personal telehealth hub is linked to the server through a telephone line. It has the capability to be personalised for each condition that is being monitored by asking the patient symptomatic questions. It also retrieves messages sent by the health professional. The results are transferred into a secure server which is accessible through a web browser to health professionals who analyse results and monitor trends before sending a message to the patient via the personal telehealth hub. Patients have access to the results. Alerts are sent to health professionals if the patient's results are unusual. This is either through an email or via SMS. GPs (primary) and specialists (secondary) health professionals can consult each other through the telehealth system to discuss the patient's progress.

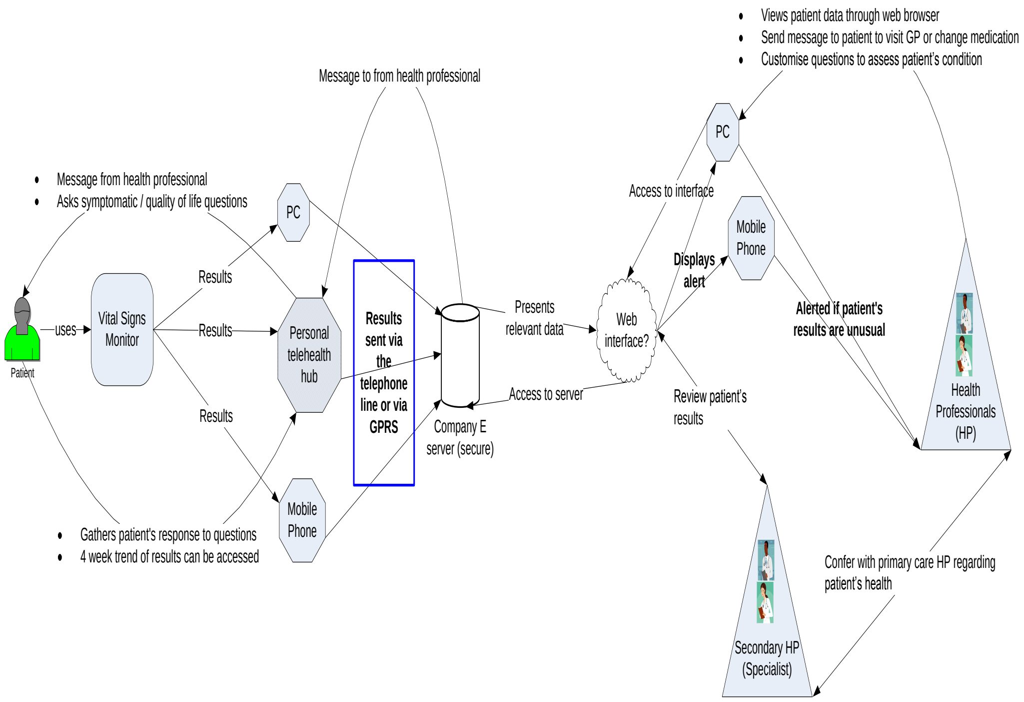

Figure A-5 – Offering E representing a telehealth system for managing and preventing long term conditions

A.6 Offering F

Offering F (Figure A-6) represents a system for monitoring patients with the following chronic conditions: asthma, CHF, COPD, diabetes and hypertension. The system can also monitor patients who have depression, drug and alcohol addiction, are obese, are stopping smoking and have had a stroke. The process begins with the patient using either of five different types of point-of-care devices which included weighing scale, BP monitor, glucometer, peak flow meter and pulse oximeter. Results are sent to a telehealth hub before being sent on to a server. Results are accessible to health professionals in order to assess the patient's health and compliance with current medication regimes etc. They are also accessible to caregivers. Health professionals can set up alerts to be triggered by unusual results entered by patients. They can also configure the hub with personalised questionnaires. The hub records the patient's response as well as delivering other messages which the health professional may have sent. The patient's results are updated on an EPR located at the GP surgery.

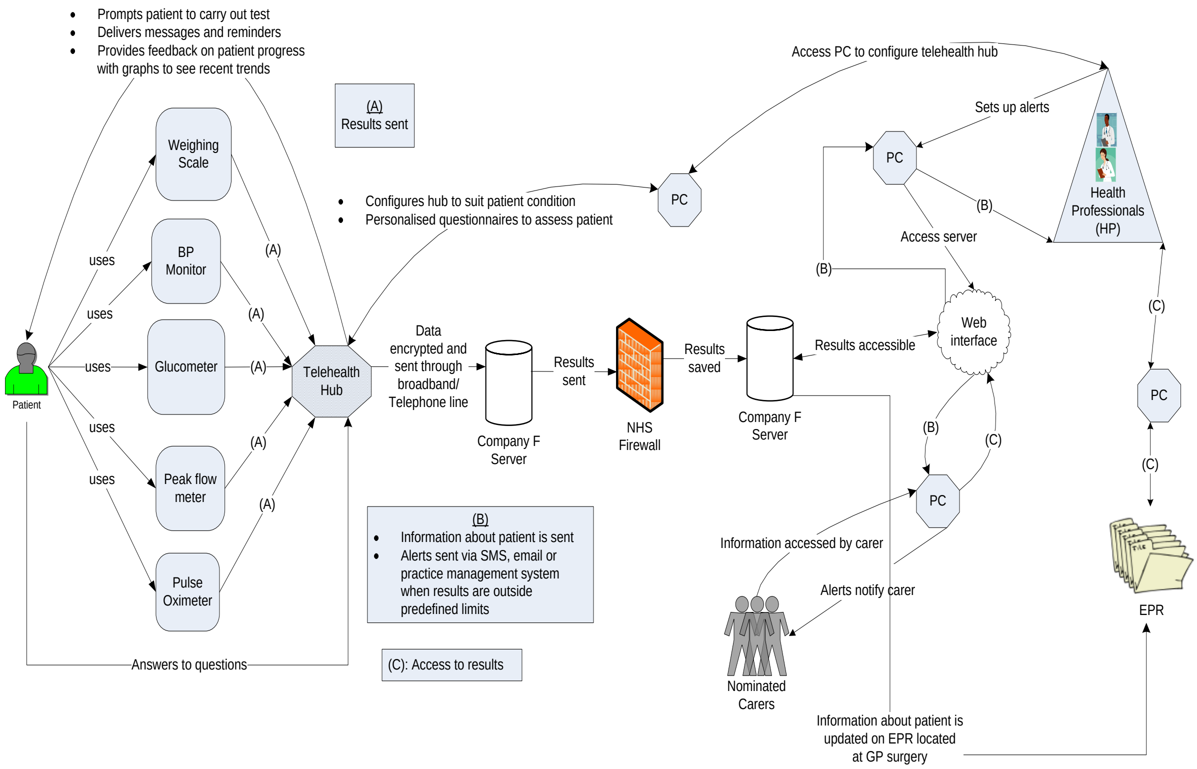

Figure A-6 – Offering F representing a telehealth system for monitoring several chronic conditions

A.7 Offering G

Offering G (Figure A-7) represents a system for managing several chronic conditions namely chronic heart failure, COPD, diabetes hypertension and stroke.

The process is initiated by the device prompting the patient to perform their test. The patient can use eight different types of point-of-care devices including BP monitor, coagulation meter, glucometer, ECG monitor, peak flow meter, weighing scale, pulse oximeter and temperature probe. The results are sent via a serial port, infrared or Bluetooth to two types of telehealth monitors where type 1 is linked into the system via a telephone line and type 2 has GPRS (General Packet Radio Service) capabilities to a GSM network. The telehealth monitors also pose personalised questions to the patient based on their results. These data are transferred automatically to a telehealth software and displayed in a colour coded format thus allowing high priority issues to be quickly identified by health professionals who review and analyse the data to assess the patient's well-being. Health professionals are alerted via SMS or email if the patient's results are extreme or if the patient did not send any results.

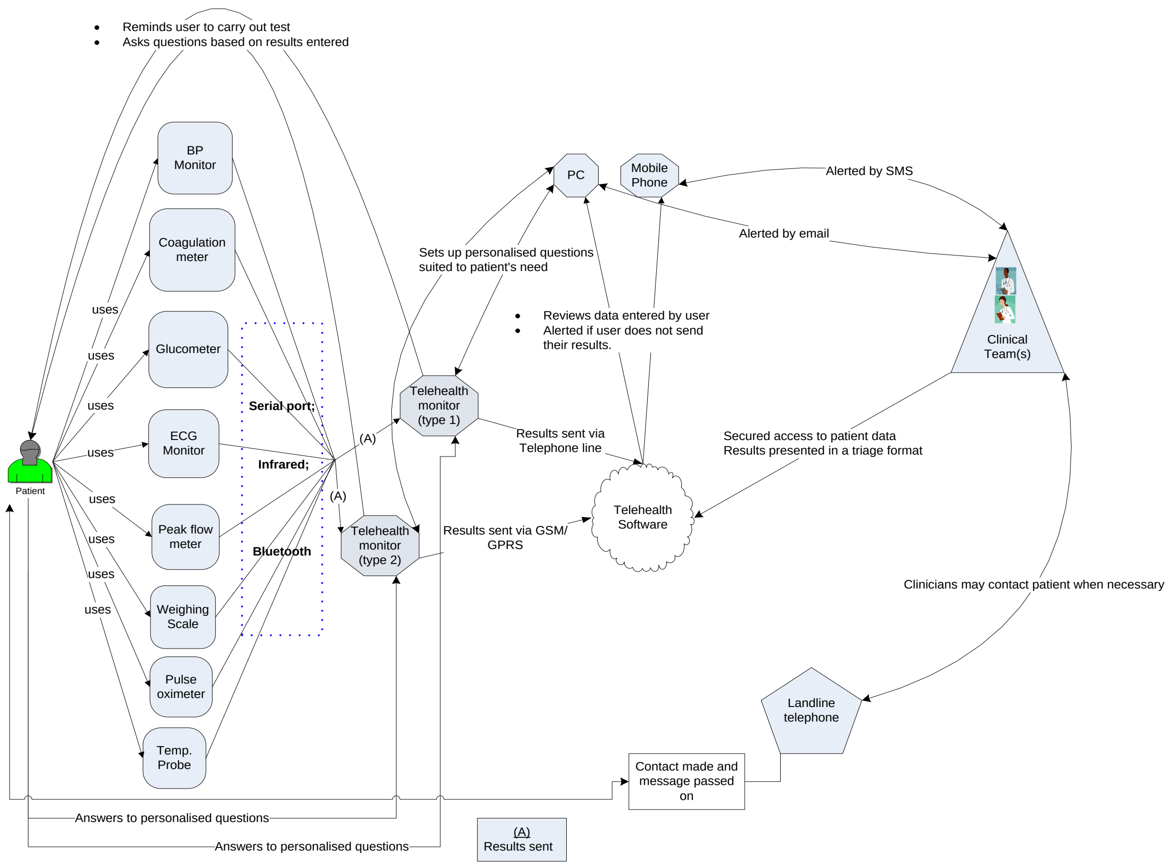

Figure A-7 – Offering G representing a telehealth system for monitoring several chronic conditions

A.8 Offering H

Offering H (Figure A-8) represents a system for monitoring several chronic conditions namely COPD, CHF, diabetes and hypertension.

The process is initiated by the device prompting the patient to perform their test. The patient can use six different types of point-of-care devices namely BP monitor, glucometer, pulse oximeter, peak flow meter, weighing scale and ECG monitor. While taking measurements, patients can speak to the health professional on the phone to obtain additional advice and support. Results and responses from questionnaires are sent to the telehealth monitor via a telephone line or via wireless GPRS (if a telephone line was not available). The telehealth monitor has the added advantage that it could be used in a multi-user environment such as a nursing home. Results are encrypted before being stored in two remote databases to increase data security. A web portal is available which provides access to the results. Access to data are provided to health professionals, patients and their caregivers.

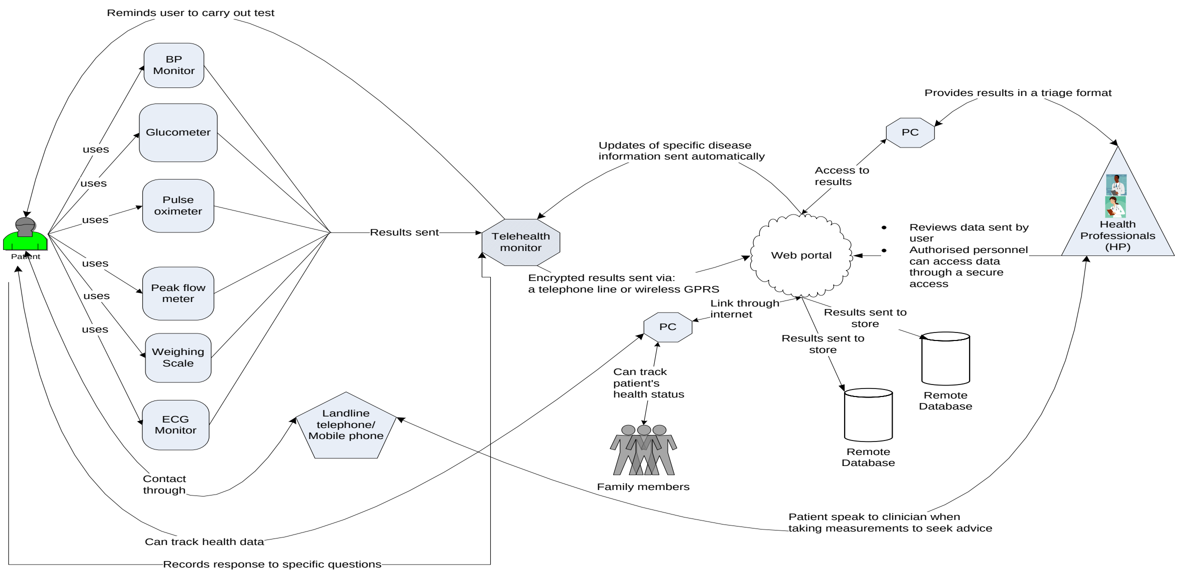

Figure A-8 – Offering H representing a telehealth system for monitoring several chronic conditions

A.9 Offering I

Offering I (Figure A-9) represents a system for monitoring several chronic conditions namely COPD, chronic heart failure and diabetes.

The process is initiated by the intermediate device prompting the patient to carry out a test known as a ‘health session’. During the health session, the patient can watch informative videos about their condition. The patient can use five different types of point-of-care devices which included BP monitor, glucometer, pulse oximeter, peak flow meter and weighing scale. The sessions allow patients to measure vital signs, respond to questions to help assess their health, receive useful information and complete surveys. The intermediate device has audio and video capabilities to enable visual interaction with the health professional. Results from the point-of-care devices are sent to the intermediate device initially before they are encrypted and sent to a remote database. At the end of the health session, data are accessed by authorised health professionals from the database via a health care management suite (a web interface). The health care management suite enables health professionals to modify the patient’s medication or health routine. It also sends alerts, presented in a triage format, to health professionals when the patient’s results are extreme. Health professionals can confer with each other based on information obtained during health sessions. Messages can be sent to the patient via the intermediate device. The intermediate device has the CE mark showing conformation to the EU Medical Device Directive and it also has FDA (2010) approval 510(k).

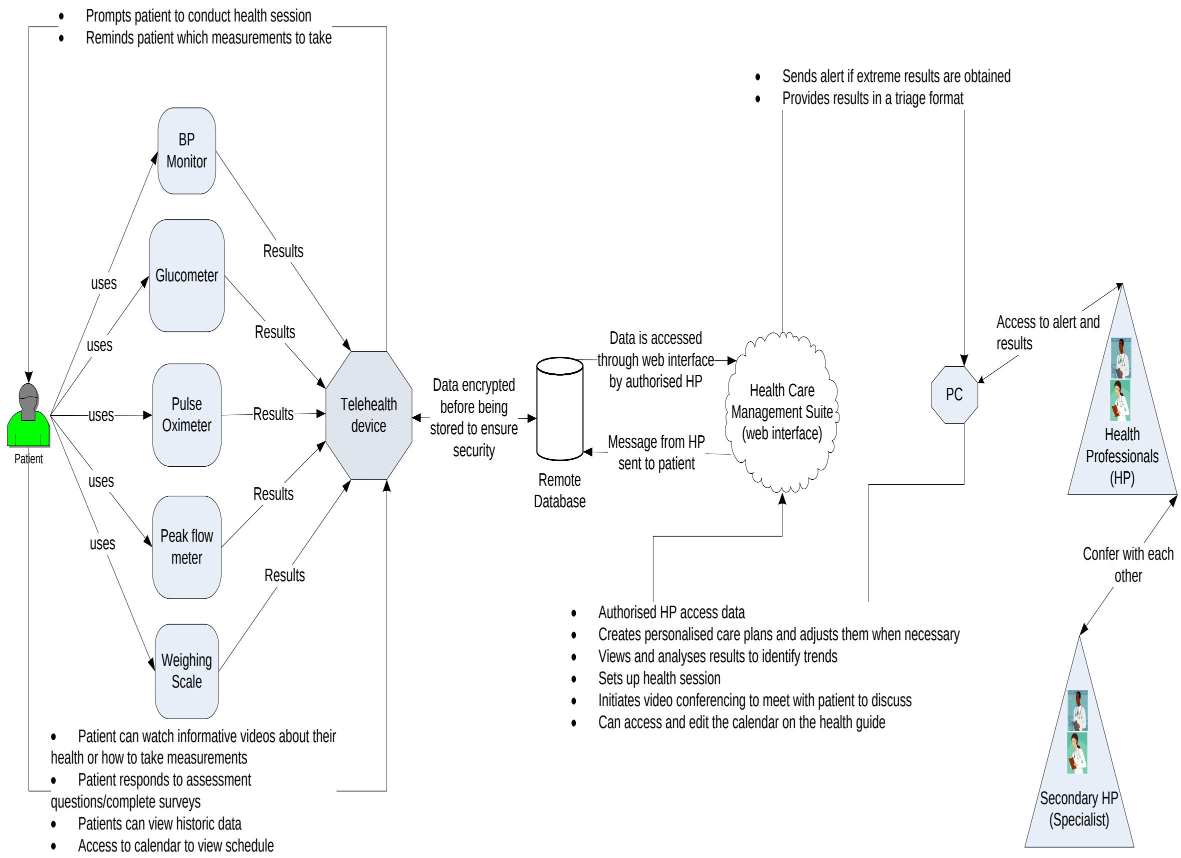

Figure A-9 – Offering I representing a telehealth system for monitoring several chronic conditions

A.10 Offering J

Offering J (Figure A-10) represents a system for monitoring several chronic conditions.

The process begins with patients or caregivers assisting patients, in using three different types of point-of-care devices which are: weighing scale, BP monitor and pulse oximeter. The results are sent to a telehealth monitor which transmits data to either of the two following intermediate devices. Device A uses an ADSL broadband connection for data transfer while device B can store the data on a removable memory card before using a telephone line to transfer the data to the health care software. Data are downloaded to a PC preinstalled with the software. They are analysed and graphs can be viewed, saved and exported from the software by health care professionals. Access to data is secured through passwords.

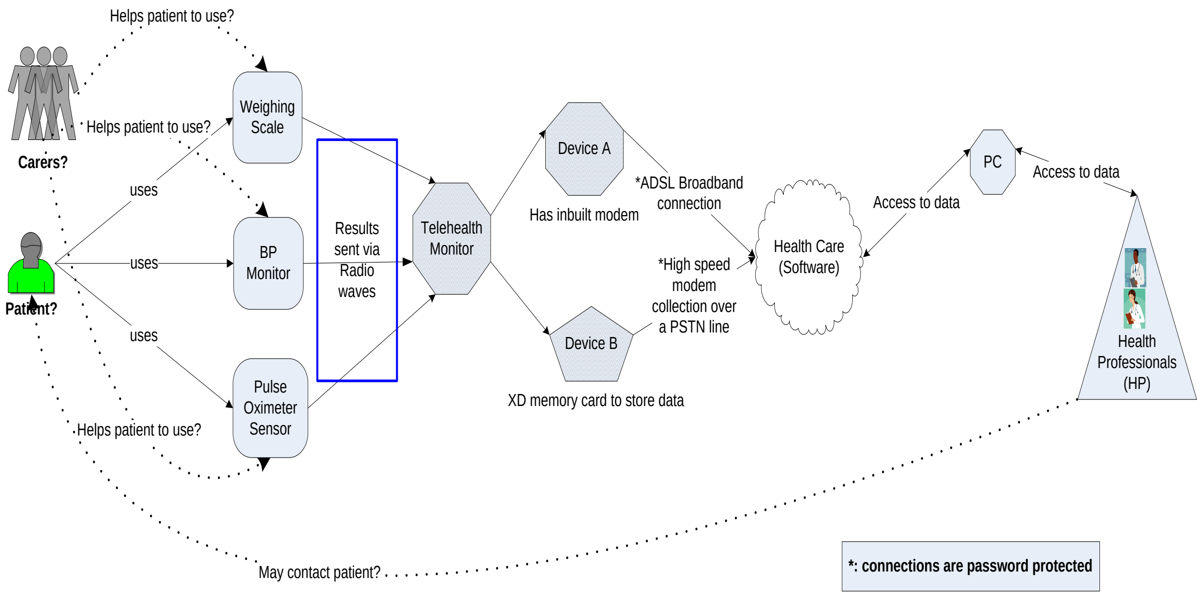

Figure A-10 – Offering J representing a telehealth system for monitoring several chronic conditions

A.11 Offering K

Offering K (Figure A-11) represents a system for managing several chronic conditions.

The process is initiated by the patient who uses five different types of devices, namely weighing scale, BP monitor, glucometer, ECG monitor and pulse oximeter. The results are sent to an intermediate device known as a home hub. Its features include sending reminders to patients to take their medication and providing a questionnaire for patients to complete, based on their condition.

Data from the home hub are forwarded on to a remote monitoring station linked to an EPR provided by the organisation. The EPR can be configured to deal with different chronic diseases and enables health professionals to set up a specific care plan for patients to monitor their own condition The EPR allows the creation of reports from the data collected and it also alerts the health professional of any unusual results. Caregivers are provided access to patient responses from questionnaires through the home hub.

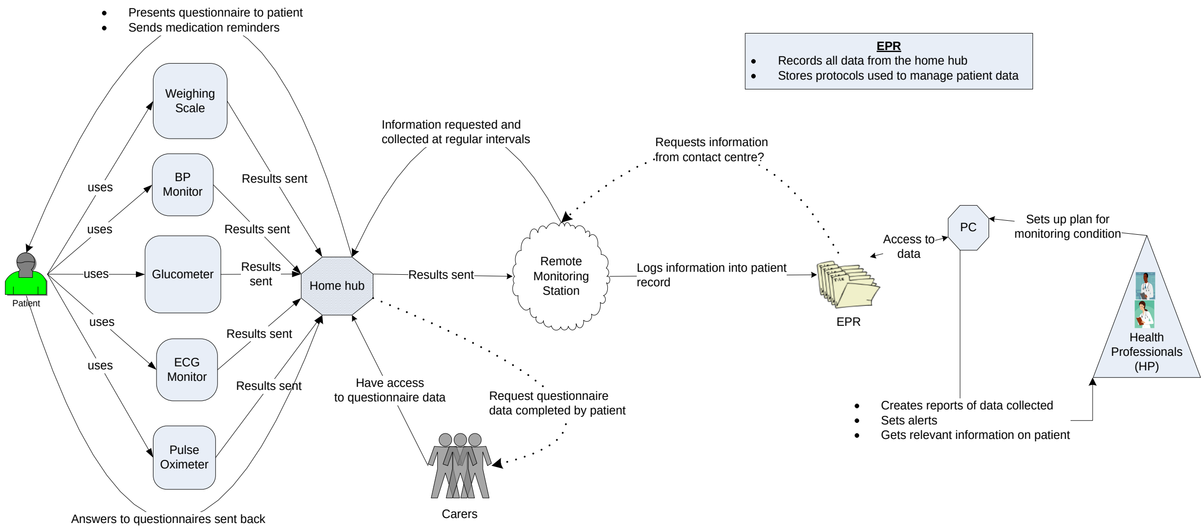

Figure A-11 – Offering K representing a telehealth system for monitoring several chronic conditions

A.12 Offering L

Offering L (Figure A-12) represents a system for monitoring patients with several chronic conditions namely chronic heart failure, diabetes and COPD.

The process begins with the patient using one of the following point-of-care devices: weighing scale, BP monitor, pulse oximeter or glucometer. The results are sent to a set top box wirelessly via Bluetooth for the weighing scale and BP monitor; and via a USB cable for the glucometer. Results from the pulse oximeter and the patient’s responses to health assessment questions are manually entered through a TV channel. From the set top box, the results are forwarded via broadband to a secure server. Results are accessible to authorized health professionals via a web interface. In addition to reviewing results, health professionals can create and modify the patient’s care plan based on their progress. This care plan includes questionnaires which are configured by the health professionals and customized to each patient. Health professionals are alerted when patient’s results do not fall within the specified thresholds and a follow-up questionnaire is sent to the patient to confirm their results.

Using the television and a remote control, the patient can access their results, presented in a graphical format, to compare it with targets set by the health professional. They can also watch educational videos and receive messages from their health professional which may include reminders to take their medication.

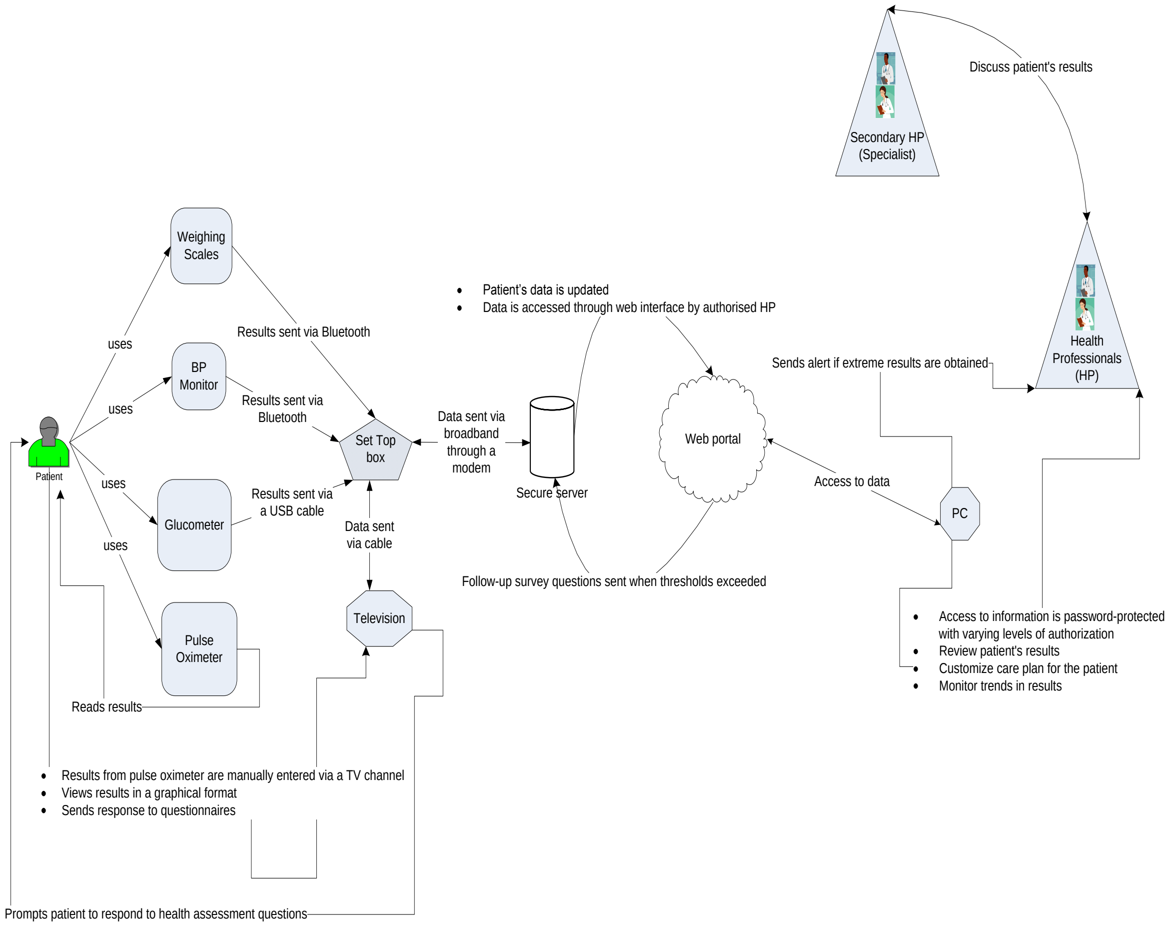

Figure A-12 – Offering L representing a telehealth system for monitoring several chronic conditions

Appendix B (For Chapter 5) – Capabilities of telehealth systems

The following tables represent the categorised capabilities derived from existing telehealth systems.

The table shows the name of the category, its description, the action, the initiating entity, the channel entity, the recipient entity and the outcome. The references to the original telehealth offerings showing these capabilities are also shown. They have been listed in an arbitrary order.

B.1 Capabilities related to the patient (Group P)

Category name	Description of category	Action	Initiator	Channel	Recipient	Outcome	Offering
P1- Intermediate device prompts patients to answer questions	Intermediate device asks patient questions about their condition/ displays questions to patient	asks patient questions	Intermedia te device (with display)	n/a	Patient	Patient answers question	[B,C,E,F,G,H ,I,K,L]
P1- Intermediate device prompts patients to answer questions	Intermediate device prompts patient to answer questions	prompts patient	Web portal	Intermedi ate device (with display)	Patient	Patient answers question	[L]

P2-Patient sends message to health professional	Patients can send additional messages to Health professional via PC through the web portal	send message	Patient	intermediate device (with display), web portal	Health professional	Patient contacts health professional	[A]
P3-Patient establishes their threshold settings	Patients can establish their threshold settings on the portal via an Intermediate device	establish threshold settings	Patient	Intermediate device (with display)	Web portal	Patient controls their care plan/schedule/protocol	[A]
P4-Patient watches informative video	Patients can watch informative videos about their condition on Intermediate device	watch informative video	Patient	n/a	Intermediate device (with display)	Patient knows more about their condition	[I,L]
P5-Intermediate device prompts patients to do test	Intermediate device prompts patient to perform test	prompts patient	Web portal	Intermediate device (with display)	Patient	Patient carries out test	[A,F,G,H,I]
P6-Patient schedules appointments	Patients can schedule appointments online on the portal via PC	schedule appointments	Patient	Intermediate device (with display)	Web portal	Patient has appointment suited to them	[A]
P7-Patient accesses results	Patients can access results directly on intermediate device	access results	Patient	Intermediate device (with display)	Patient	Patient is informed of result	[C,E,F,I]
P7-Patient accesses results	Patients access results via TV	access results	Patient	Intermediate device (with display)	Patient	Patient is informed of result	[L]
P7-Patient accesses results	Patients access results on web portal via PC	access results	Patient	Intermediate device (with display); web	Patient	Patient is informed of result	[A,C,H]

				portal			
P8-Health professional sends message to patient	Health professional sends a message to patient via intermediate device	delivers message to patient	Health profession al	Database ; Intermedi ate device (with display)	Patient	Patient acts on message	[E,F,I,L]
P9-Patient has real-time communicat ion with health professional	Patients can speak to Health professional via LP/in person to obtain advice/support	speak to health profession al	Health profession al	Intermedi ate device (without display)	Patient	Patient acts on advice	[D,H]
P9-Patient has real-time communicat ion with health professional	Patients can speak to Health professional via Intermediate device to obtain advice/support (like video conference)	speak to health profession al	Patient	Intermedi ate device (with display)	Health professional	Patient acts on advice	[I]
P10-Intermediate device prompts patients to take medication	Intermediate device reminds patients of medication to take	reminds patient	EPR	Intermedi ate device (with display)	Patient	Patient takes medication	[B]
P10-Intermediate device prompts patients to take medication	Intermediate device reminds patients of medication to take	reminds patient	Web portal	Intermedi ate device (with display)	Patient	Patient takes medication	[A,K,L]
P11-Health professional creates patient care plan	Health professional configures specific care plan for patient via pc	configures care plan	Health profession al	Intermedi ate device (with display)	EPR	patient's care plan is set up	[K]

P11-Health professional creates patient care plan	Health professional creates care plan for patient/customises questions to assess patient's condition	creates care plan	Health professional	Intermediate device (with display)	Web portal	patient's care plan is set up	[E,G,I,L]
P12-Health professional modifies patient care plan	Health professional can modify patient's medication/routine on web portal via pc	modify patients' medication / routine	Health professional	Intermediate device (with display)	Web portal	patient's care plan is updated	[E,I]
P13-Health professional sends message to patient to modify care plan	Health professional sends message to patient to update their routine	sends message	Health professional	Web portal	Patient	patient's routine is updated	[E,I]
P14-Patient enters responses into the system	Patients enter the response to questions which is sent to a web service	enter responses	Patient	Intermediate device (with display)	Web portal	questionnaire responses added to the telehealth system by patient	[B,C,G,H,K]
P14-Patient enters responses into the system	Patients enter the response to questions to server/web service	enter responses	Patient	Intermediate device (with display)	Database	questionnaire responses added to the telehealth system by patient	[E,F,I,L]
P15-Patient saves results	Patients transfer the results from the point-of-care devices into a server via an intermediate device	save results	Patient	Intermediate device (with display)	Database	results are saved by patient	[E,F,I,L]

P15-Patient saves results	Patient saves results to intermediate device (without display)	save results	Patient	n/a	Intermediate device (without display)	results are saved by patient	[D]
P16-Patient enters/transfers results into the system	Patients enter/transfer results into the system via intermediate devices	enter/transfer results	Patient	Intermediate device (with display)	Web portal	test results added to the telehealth system by patient	[A,B,C,G,H,K]
P17-Patient transfers results within the system	Patients transfers results from the POC device to an Intermediate device via another Intermediate device	transfer results	Patient	Intermediate device (with display)	Intermediate device (with & without) display	test results added to the telehealth system by patient	[D,J]
P17-Patient transfers results within the system	Patients transfer results of POC device to a call centre	transfer results	Patient	Intermediate device (with display)	Call centre	test results added to the telehealth system by patient	[D]
P18-Health professional configures intermediate device for patient	Health professional configures hub via pc	configures hub	Health professional	Intermediate device (with display)	Intermediate device (with display)	Hub is set up to suit patient's needs	[F]

Table B-1 – Categories of capabilities related to the patient (Key: POC=point-of-care; EPR=electronic patient record; PC=personal computer; LP=landline phone; TV=television)

B.2 Capabilities related to the Caregiver (Group C)

Category name	Description of category	Action	Initiator	Channel	Recipient	Outcome	Reference
C1-Caregiver accesses results	Caregivers access results on web portal via PC	access results	Caregivers	Intermediate device (with display)	Web portal	Caregiver is informed about results	[A,F,H,K]
C2-Caregiver receives alerts	Web portal sends alerts to caregiver to notify them of unexpected results via email/SMS	sends alert to caregiver	Web portal	Intermediate device (with display)	Caregiver	Caregiver acts on alert	[A,F]

Table B-2 – Categories of capabilities related to the caregiver (Key: PC=personal computer)

B.3 Capabilities related to the health professional (Group H)

Category name	Description of category	Action	Initiator	Channel	Recipient	Outcome	Reference
H1-Health professional reviews/ analyzes results	Health professional access/review/ analyze results on web portal via PC	access/ review/ analyze results	Health professional	Intermediate device (with display)	Web portal	Health professional is informed of results	[A,C,D, E,F,G, H,I,J,L]
H1-Health professional reviews/ analyzes results	Health professional access/review/ analyze results and create reports on the EPR via PC	access/ review/ analyze results	Health professional	Intermediate device (with display)	EPR	Health professional is informed of results	[B,F,K]
H1-Health professional reviews/ analyzes results	Intermediate device makes results available at the call centre so they are evaluated by Health professional	evaluate results	Intermediate device (without display)	Intermediate device (with display)	Health professional	Health professional is informed of results	[D]
H2-Health professional receives immediate clinical support	Primary care clinicians consult specialists	consult	Health professional	n/a	Health professional	Health professional receives clinical support	[E,G,I, L]
H3-Health professional sets up alerts	Health professional can create triggers on patients' results	creates trigger	Health professional	Intermediate device (with display)	EPR	Health professional is alerted	[B]
H3-Health professional sets up alerts	Health professional sets up alerts to be triggered by unusual results on web portal	sets up alert	Health professional	Intermediate device (with display)	Web portal	Health professional is alerted	[F]

H4-Health professional receives clinical support via a report	Specialists send detailed report to GP via email/fax	send report	Health professional	Intermediate device (with display)	Health profession al	Health profession al receives clinical support	[D]
H5-Intermediate device sends results to health professional	Intermediate device sends data to Health professional	send results	Intermediate device (with display)	n/a	Health profession al	Health profession al acts on results (as required)	[F]
H5-Intermediate device sends results to health professional	Intermediate device sends data to Health professional via Intermediate device	send results	Intermediate device(witho ut display)	Intermediate device (without display)	Health profession al	Health profession al acts on results (as required)	[D]
H6-System alerts health professional	EPR sends alerts to Health professional based on predefined triggers via PC/MP	sends alert	EPR	Intermediate device (with display)	Health profession al	Health profession al acts on alert (as required)	[B,K]
H6-System alerts health professional	Web portal sends alerts to Health professional to notify them of unexpected results via email/SMS	sends alert to health profession al	Web portal	Intermediate device (with display)	Health profession al	Health profession al acts on alert (as required)	[A,D,E, F,G,H,I ,L]
H7-Health professional transfers data into the system	Health professional transfers results to call centre via LP	transfer results	Health professional	Intermediate device (without display)	Call centre	Health profession al adds test results to the system	[D]

Table B-3 – Categories of capabilities related to the health professional (Key: EPR=electronic patient record; PC=personal computer; LP=landline phone; MP=mobile phone)

B.4 Capabilities related to other system entities (Group S)

Category name	Description of category	Action	Initiator	Channel	Recipient	Outcome	Reference
S1-Results saved to EPR	database forwards results to be stored in EPR	forward results	Database	n/a	EPR	results are saved	[F]
S1-Results saved to EPR	Intermediate devices transfer results to EPR via web services	transfer results	Intermediate device (with display)	Web portal	EPR	results are saved	[B,K]
S1-Results saved to EPR	web portal forwards results to be stored in EPR	forward results	Web portal	n/a	EPR	results are saved	[A,B,K]
S2-Results saved to server	Results from a server are sent via a firewall to another server	send results	Database	Firewall	Database	results are saved	[F]
S2-Results saved to server	Results saved to database	save results	Intermediate device (with display)	Web portal	Database	results are saved	[H]
S2-Results saved to server	Data (sometimes Encrypted) sent from Intermediate device to server	send results	Intermediate device (with display)	n/a	Database	results are saved	[E,F,I]
S2-Results saved to server	Data (sometimes Encrypted) sent from Intermediate device to server	send results	Intermediate device (without display)	n/a	Database	results are saved	[L]
S3-Results saved to intermediat e device	Intermediate device sends data to be stored on another Intermediate device	send results	Intermediate device (with display)	n/a	Intermediate device (with display)	results are saved	[J]

S3-Results saved to intermediat e device	Intermediate device sends data to be stored on another Intermediate device	send results	Intermediate device (with display)	n/a	Intermediate device (without display)	results are saved	[J]
S4-Server data transfer	Database sends results to intermediate device	send results	Database	ID (without display)	Intermediate device (with display)	results transferred to another componen t of telehealth system	[L]
S4-Server data transfer	Database sends results to intermediate device	send results	Database	n/a	Intermediate device (with display)	results transferred to another componen t of telehealth system	[E,F,I]
S5-Intermediat e device data transfer	Intermediate Device sends results to another Intermediate Device	send results	Intermediate Device (without display)	n/a	Intermediate device (with display)	results transferred to another componen t of telehealth system	[L]
S5-Intermediat e device data transfer	Intermediate device sends data to web portal via Intermediate device	send results	Intermediate device (with display)	Intermediate device (with display)	Web portal	results transferred to another componen t of telehealth system	[J]
S6-EPR data transfer	EPR sends information back to intermediate device	sends informati on	EPR	n/a	Intermediate device (with display)	results transferred to another componen t of telehealth system	[A,B,F,K]

Table B-4 – Categories of capabilities related to other system entities (Key: EPR=electronic patient record)

Appendix C (For Chapter 7) – Supplementary material of the flow path diagrams showing the arrangement of entities and the type of intermediate devices connecting them.

C.1 Intermediate devices located between the patient and multiple entities

There are two examples where intermediate devices on receiving data from the patient exchange data with another intermediate device before this is transmitted to another entity.

(i) TV receives data from with the patient, before forwarding this on to PD-N and this is forwarded on to be stored in a database.

(ii) PD-D receives data from the patient, before forwarding it on to PC which can be accessed by the health professional.

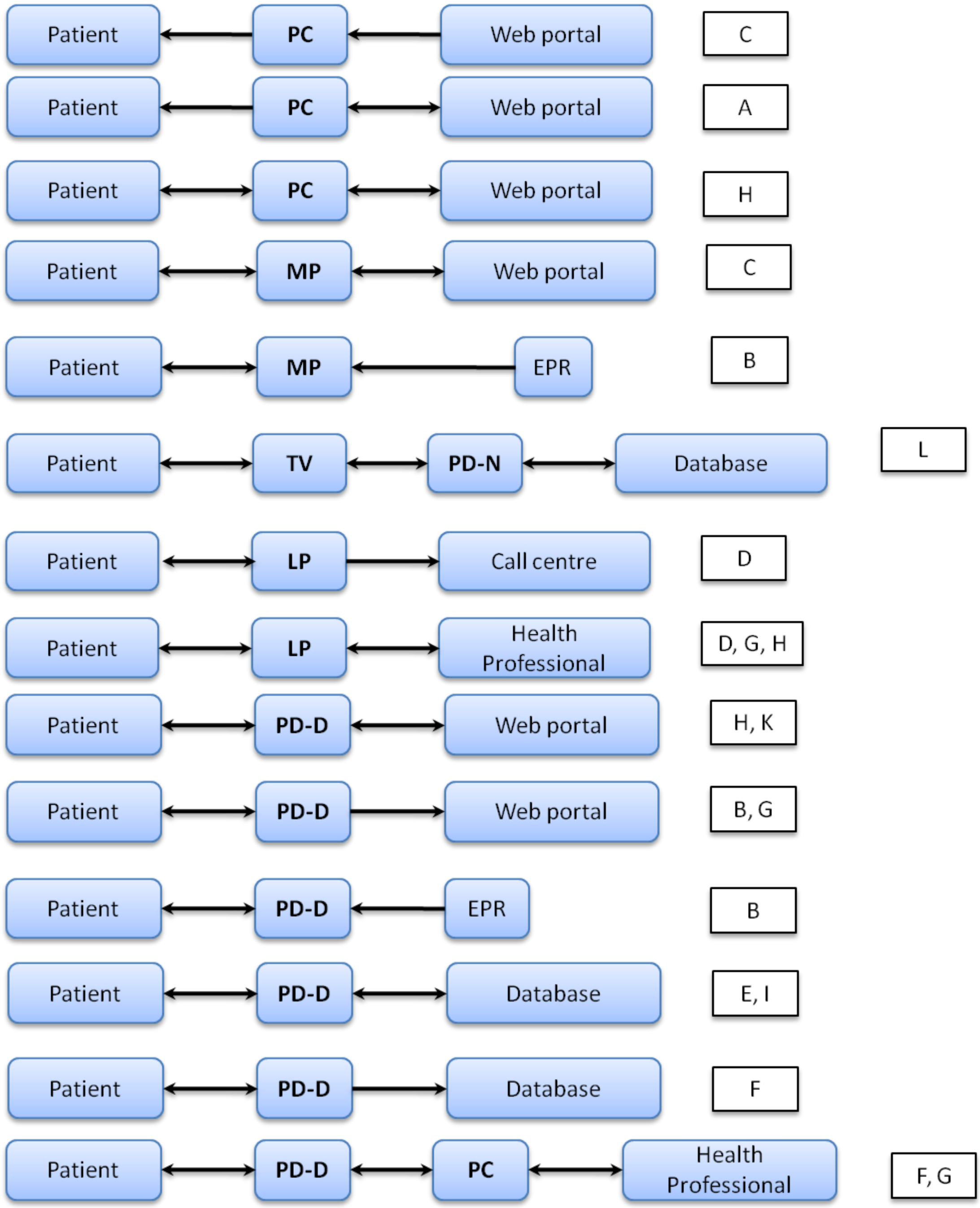

Figure C-1 – Intermediate devices located between patients and other entities

C.2 Intermediate devices located between the caregiver and web portal

In one instance, data exchange is bidirectional between caregiver and PC and web portal and PC. In the third instance, data exchange is bidirectional between web portal and PD-D and it is assumed to be bidirectional between caregiver and PD-D.

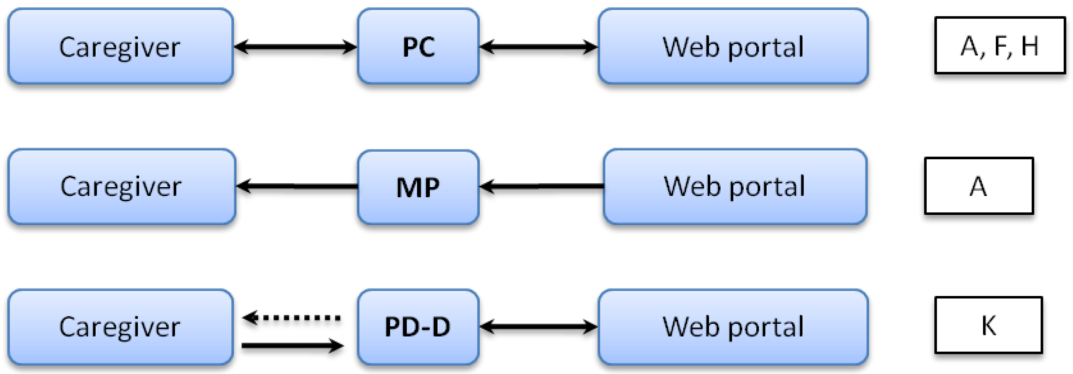

Figure C-2 – Intermediate devices located between caregivers and web portals (The dotted arrow indicates that this direction was assumed.)

C.3 Intermediate devices located between the health professional and multiple entities

PC and MP connect the health professional to EPR. The data flow between PC and the two entities is bidirectional; while the data flow from EPR to the health professional via MP is unidirectional.

There were two examples of MP located between the health professional and web portal. In the first, data flow was unidirectional from the web portal to the heath professional; while in the second, the data flow was bidirectional.

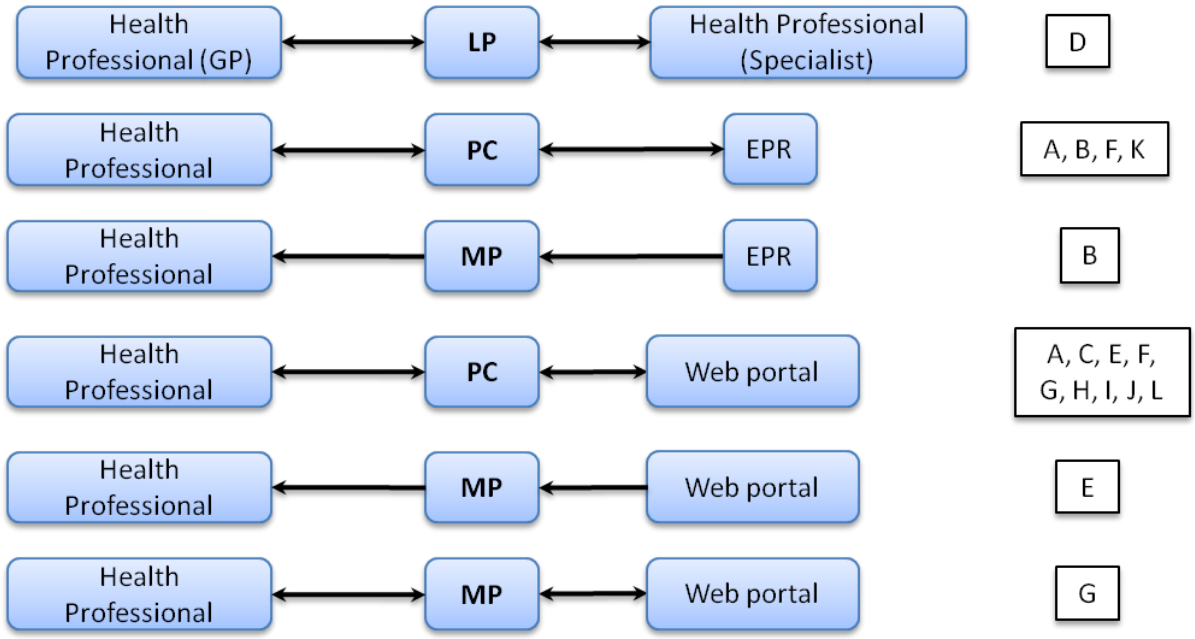

Figure C-3 – Intermediate devices located between the health professional and multiple entities.

C.4 Intermediate devices located between a point-of-care device and multiple entities

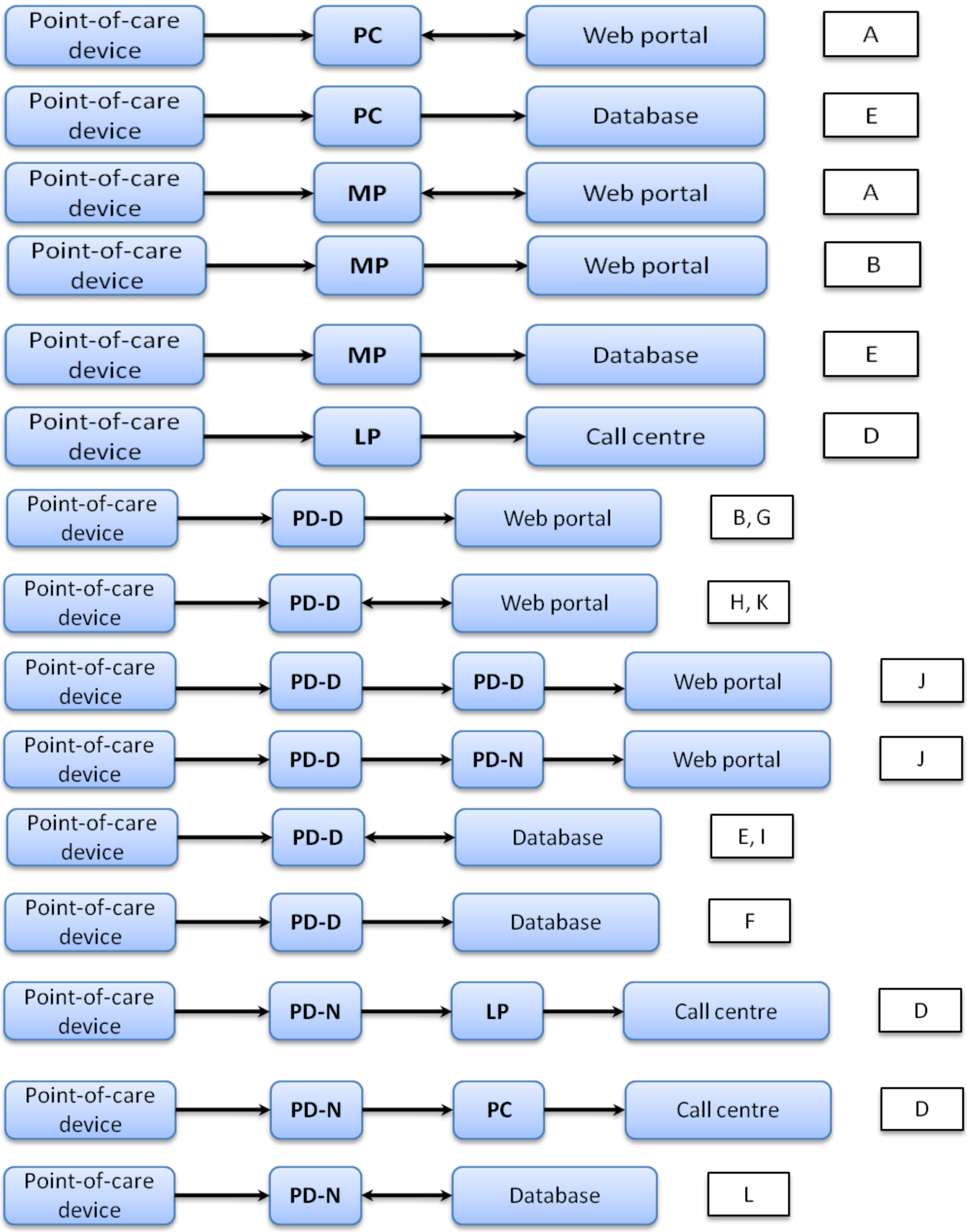

Figure C-4 – Intermediate devices located between point-of-care devices and other entities

C.5 Intermediate devices located between web portal and multiple entities

Figure C-5 – Intermediate devices located between web portals and health professionals

Appendix D (For Chapter 9) – Applying capabilities of telehealth systems to a healthcare policy

Steps 1-3 of the methodology applied to government objectives.

D.1 Steps 1 – 3 of the method illustrated by the healthcare objective "Rights for patients".

Government objective one: "rights for patients".

Figure D.1-1 represents the first three steps of the methodology. It shows the objective with one key statement followed by the details of how this objective could be achieved.

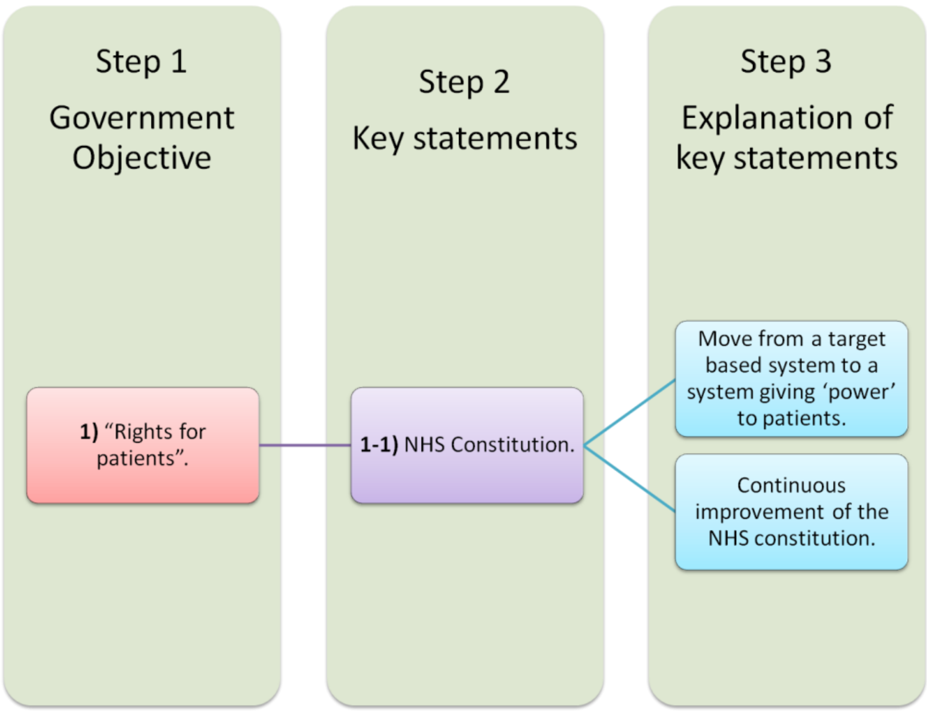

Figure D.1-1 – Methodological steps 1 to 3 in developing the government objective "rights for patients" into detailed explanations

There is no table to show the matching of possible actions to existing capabilities of telehealth systems for key statement 1-1 because a telehealth solution was seen as not feasible.

D.2 Steps 1 – 3 of the method illustrated by the healthcare objective "Responsibilities of patients".

Government objective two: "responsibilities of patients".

Figure D.2-1 represents the first three steps of the methodology. It shows the objective with one key statement followed by the details of how this objective could be achieved.

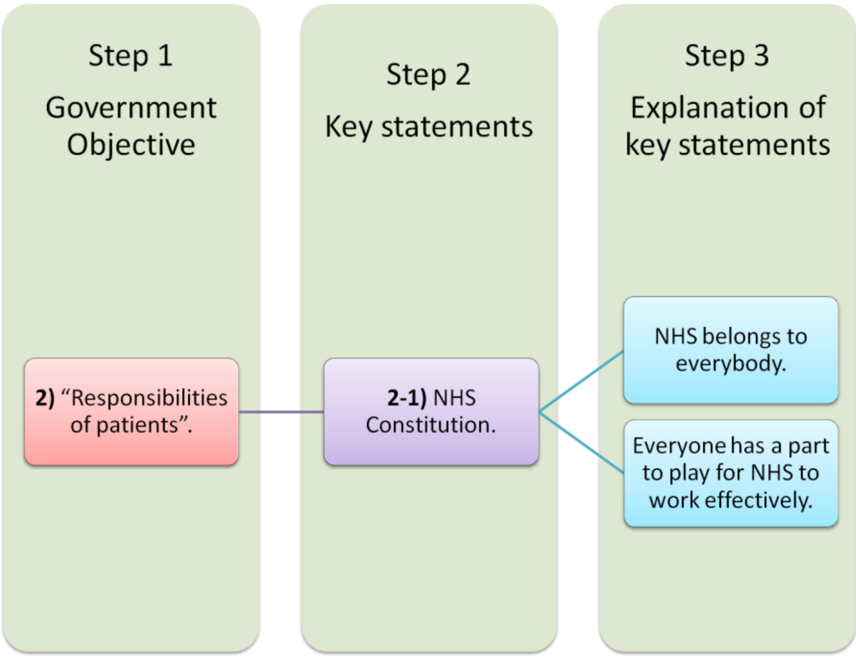

Figure D.2-1 – Methodological steps 1 to 3 in developing the government objective "responsibilities of patients" into detailed explanations

There is no table to show the matching of possible actions to existing capabilities of telehealth systems for key statement 2-1 because a telehealth solution was seen as not feasible.

D.3 Steps 1 – 3 of the method illustrated by the healthcare objective "A preventative, people-centred, productive NHS".

Although this government objective was used as the worked example in the main document, it is included here for completeness.

Government objective three: "a preventative, people-centred, productive NHS".

Figure D.3-1 represents the first three steps of the methodology. It shows the objective with three key statements followed by the details of how this objective could be achieved.

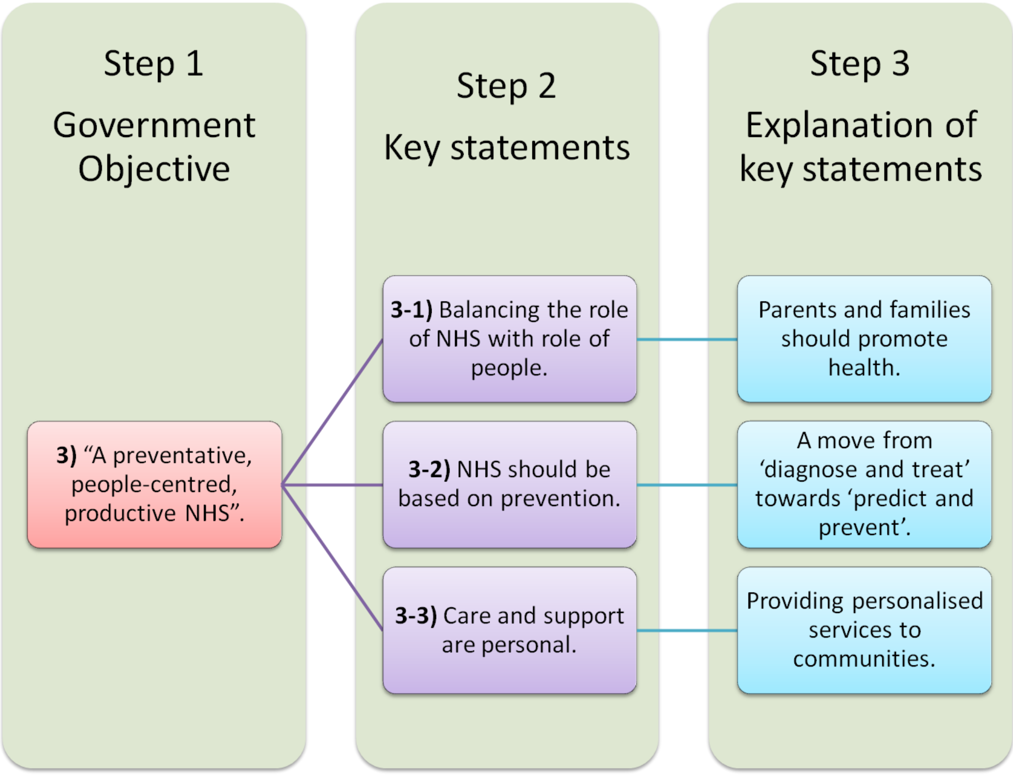

Figure D.3-1 – Methodological steps 1 to 3 in developing the government objective "a preventative, people-centred, productive NHS"

There is no table to show the matching of possible actions to existing capabilities of telehealth systems for key statement 3-2 because a telehealth solution was seen as not feasible.

D.3.1 Matching possible actions to existing capabilities of telehealth systems (3-1)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
Parents and families should promote health.	Health professionals send information to people early to raise awareness about certain conditions.	P11-Health professional creates patient care plan.	
	Patients receive information about conditions	P8-Health professional sends message to patient.	
	Family members should support each other		There isn't a capability that meets this action. A suggestion is made: Caregiver receives messages.

Table D.3-1– Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 3-1

D.3.2 Matching possible actions to existing capabilities of telehealth systems (3-3)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Providing personalised services to communities.	Health professional raises awareness of the appropriate programmes to suit the needs of families.	P11-Health professional creates patient care plan.
	People are aware of the programmes.	P8-Health professional sends message to patient.

Table D.3-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 3-3

D.4 Steps 1 – 3 of the method illustrated by the healthcare objective "Supporting people to get and stay healthy".

Government objective four: "supporting people to get and stay healthy".

Figure D.4-1 represents the first three steps of the methodology. It shows the objective with three key statements followed by the details of how this objective could be achieved.

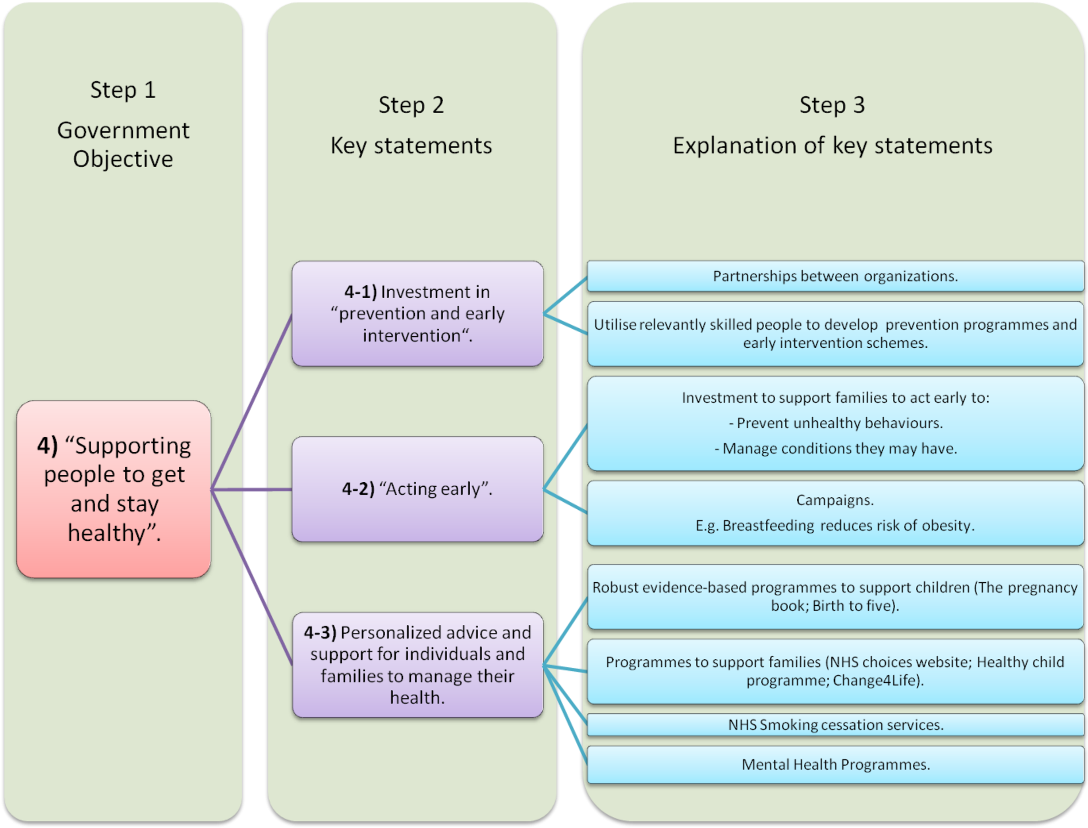

Figure D.4-1 – Methodological steps 1 to 3 in developing the government objective "supporting people to get and stay healthy"

There is no table to show the matching of possible actions to existing capabilities of telehealth systems for key statement 4-1 because a telehealth solution was seen as not feasible.

D.4.1 Matching possible actions to existing capabilities of telehealth systems (4-2)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Investment to support families to act early to prevent unhealthy conditions; Campaigns.	Health professionals send information to people early to raise awareness about certain conditions.	P11-Health professional creates patient care plan.	
	Patients receive information about conditions.	P8-Health professional sends message to patient.	
	Family members should support each other.		There isn't a capability that meets this action. A suggestion is made: Family members/Caregivers receive messages to help improve patient care.
Investment to support families to act early to manage conditions they may have.	Health professionals should assess the status of the patient's health regularly.	P11-Health professional creates patient care plan. P1-Intermediate device prompts patients to answer questions. P8-Health professional sends message to patient. P12-Health professional modifies patient care plan.	
	Patient monitors their condition through regular testing.	P16-Patient enters/transfers results into the system. P14-Patient enters responses into the system. H5-Intermediate device sends results to health professional.	
	Patient may contact health professional to discuss health status	P2-Patient sends message to health professional. P9-Patient has real-time communication with health professional.	
	Family members should support each other.		There isn't a capability that meets this action. A suggestion is made: Family members/Caregivers receive messages to help improve patient care.

Table D.4-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 4-2

D.4.2 Matching possible actions to existing capabilities of telehealth systems (4-3)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Robust evidence-based programmes to support children (The pregnancy book; Birth to five).	-	-
Programmes to support families (NHS choices website; Healthy child programme; Change4Life).	Health professional raises awareness of the appropriate programmes to suit the needs of families.	P11-Health professional creates patient care plan.
	People are aware of the programmes.	P8-Health professional sends message to patient.
NHS Smoking cessation services.	-	-
Mental Health Programmes.	-	-

Table D.4-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 4-3

D.5 Steps 1 – 3 of the method illustrated by the healthcare objective "Delivering through partnerships".

Government objective five: "delivering through partnerships".

Figure D.5-1 represents the first three steps of the methodology. It shows the objective with five key statements followed by the details of how this objective could be achieved.

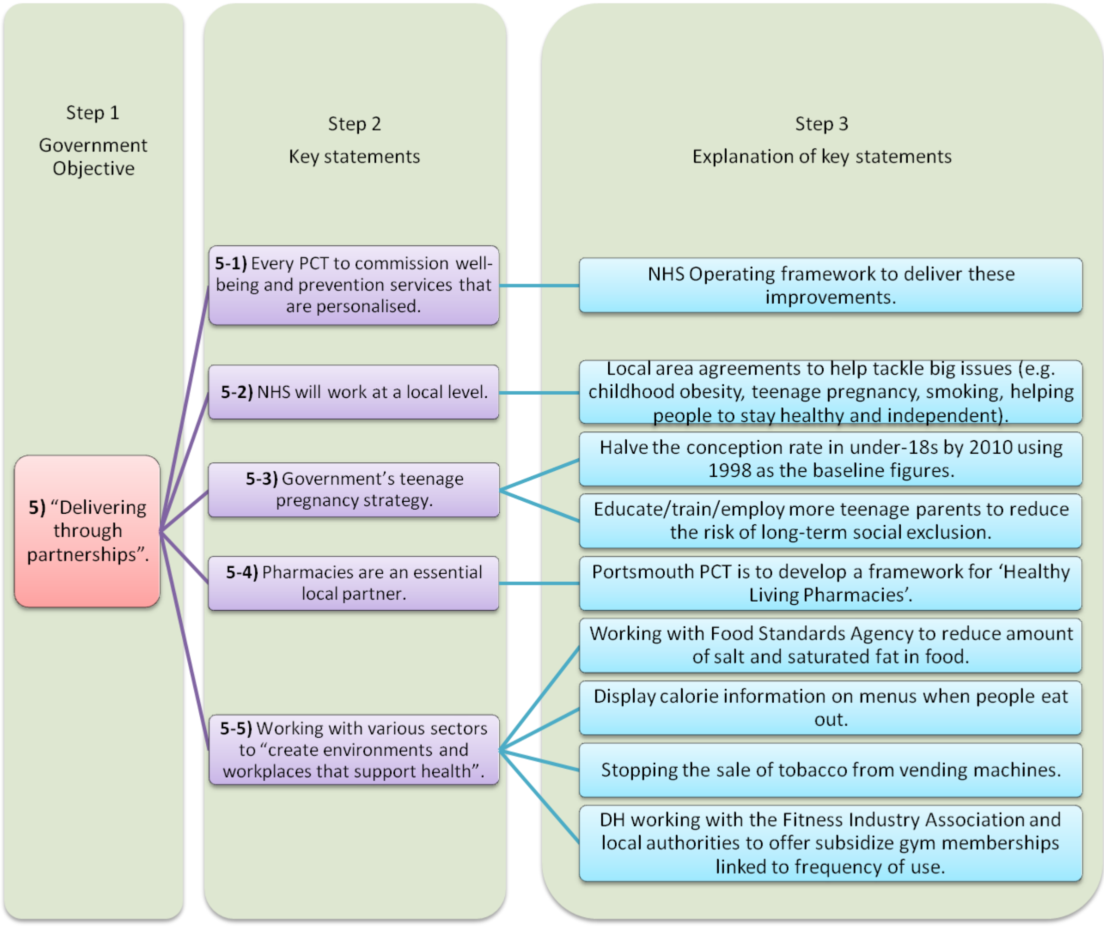

Figure D.5-1 – Methodological steps 1 to 3 in developing the government objective "delivering through partnerships" into detailed explanations

There are no tables to show the matching of possible actions to existing capabilities of telehealth systems for key statements 5-1, 5-2 and 5-4 because a telehealth solution was seen as not feasible.

D.5.1 Matching possible actions to existing capabilities of telehealth systems (5-3)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Halve the conception rate in under-18s by 2010 using 1998 as the baseline figures.	-	-
Educate/train/employ more teenage parents to reduce the risk of long-term social exclusion.	Teenagers will receive information about issues related to parenting a child. They can receive information about the services and support available.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient.
	Teenagers can ask health professionals questions.	P2-Patient sends message to health professional.
	Health professionals and teenagers can discuss issues.	P9-Patient has real-time communication with health professional.

Table D.5-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 5-3

D.5.2 Matching possible actions to existing capabilities of telehealth systems (5-5)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	Possible action	Equivalent capability	
Working with Food Standards Agency to reduce amount of salt and saturated fat in food.	-	-	
Display calorie information on menus when people eat out.	People receive information about foods through a specific scanning device or adapted device.	P8-Health professional sends message to patient.	
	People enter details of types of food consumed.		There isn't a capability that meets this action. A suggestion is made: Patient enters additional details into the system.
	People can view trends of food consumed.	P7-Patient accesses results.	
Stopping the sale of tobacco from vending machines.	-	-	
DH working with the Fitness Industry Association and local authorities to offer subsidize gym memberships linked to frequency of use.	People check and receive information about local places for exercise.		There isn't a capability that meets this action. A suggestion is made: People make enquiries from the system; People receive information from the system.
	People can view trends of amount of calories burnt.	P7-Patient accesses results.	

Table D.5-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 5-5

D.6 Steps 1 – 3 of the method illustrated by the healthcare objective "Reaching out to people".

Government objective six: "reaching out to people".

Figure D.6-1 represents the first three steps of the methodology. It shows the objective with four key statements followed by the details of how this objective could be achieved.

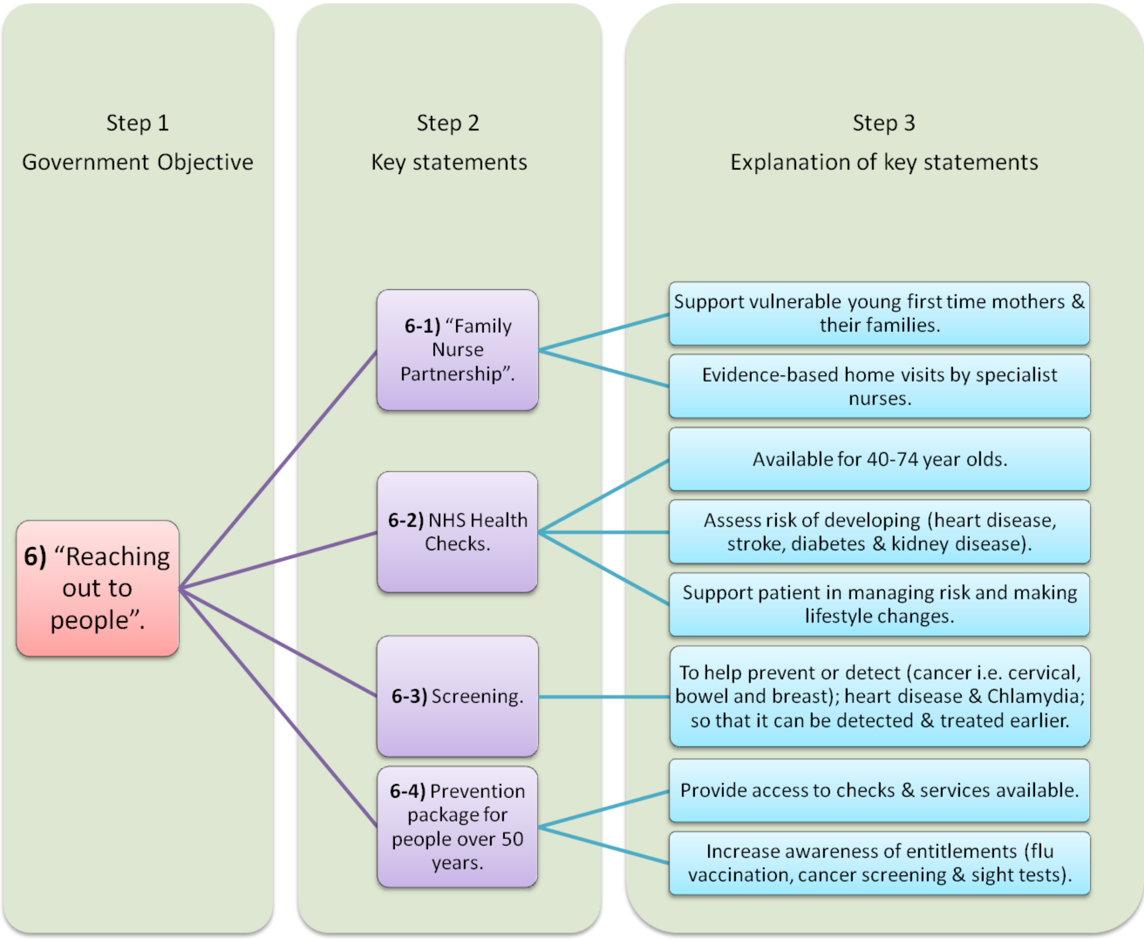

Figure D.6-1 – Methodological steps 1 to 3 in developing the government objective "reaching out to people" into detailed explanations

D.6.1 Matching possible actions to existing capabilities of telehealth systems (6-1)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Support vulnerable young first time mothers and their families.	Health professionals provide relevant information about pregnancy.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient.
	Patients can ask questions.	P2-Patient sends message to health professional.
Evidence-based home visits by nurse specialists.	Health professionals assess patient's needs and customise information for the patient.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient. P9-Patient has real-time communication with health professional.

Table D.6-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 6-1

D.6.2 Matching possible actions to existing capabilities of telehealth systems (6-2)

Step 3	Step 5	Step 6	
Explanation of key statement	Possible action	Equivalent capability	Additional Capabilities
Available for 40-74 year olds.	Health professionals search patient records to determine if they are within the appropriate age range.		There isn't a capability that meets this action. A suggestion is made: Health professional searches patient records.
	Health professionals send message to patient informing them of their eligibility.	P8-Health professional sends message to patient.	
	Health professional advices patient to book appointment.	P8-Health professional sends message to patient. P9-Patient has real-time communication with health professional.	
Assess risk of developing (heart disease, stroke, diabetes & kidney disease).	Health professionals analyze patients' results for risk of the conditions.	H1-Health professional reviews/ analyzes results. H5-Intermediate device sends results to health professional. P16-Patient enters/transfers results into the system.	
Support patient in managing risk and making lifestyle changes.	Health professionals provide advice to the patient following test results about maintaining existing lifestyle habits or changing it.	P11-Health professional creates patient care plan. P9-Patient has real-time communication with health professional. P8-Health professional sends message to patient. P12-Health professional modifies patient care plan.	

Table D.6-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 6-2

D.6.3 Matching possible actions to existing capabilities of telehealth systems (6-3)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
To help prevent or detect (cancer i.e. cervical, bowel and breast); heart disease & Chlamydia; so that it can be detected & treated earlier.	Health professionals can search patients' EPR to identify the target population.		There isn't a capability that meets this action. A suggestion is: Health professional searches patient records.
	Health professionals can set up triggers for when new patients fit into target population.		There isn't a capability that meets this action. A suggestion is: Health professional sets up alerts on patient records.
	Patients are notified of screening appointments.		There isn't a capability that meets this action. A suggestion is: Patient is reminded of appointment.
	Patients are notified of their results.	P8-Health professional sends message to patient.	
	Health professionals provide advice to the patient following results.	P9-Patient has real-time communication with health professional.	

Table D.6-3 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 6-3

D.6.4 Matching possible actions to existing capabilities of telehealth systems (6-4)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
Provide access to checks & services available.	Health professionals can search patients EPR to identify the target population.		There isn't a capability that meets this action. A suggestion is: Health professional searches patient records.
	Health professionals send message to patient informing them of their eligibility.	P8-Health professional sends message to patient.	
Increase awareness of entitlements (flu vaccination, cancer screening & sight tests).	Patients are informed of entitlements and available services.	P8-Health professional sends message to patient.	

Table D.6-4 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 6-4

D.7 Steps 1 – 3 of the method illustrated by the healthcare objective "Diagnosing early".

Government objective seven: "diagnosing early".

Figure D.7-1 represents the first three steps of the methodology. It shows the objective with four key statements followed by the details of how this objective could be achieved.

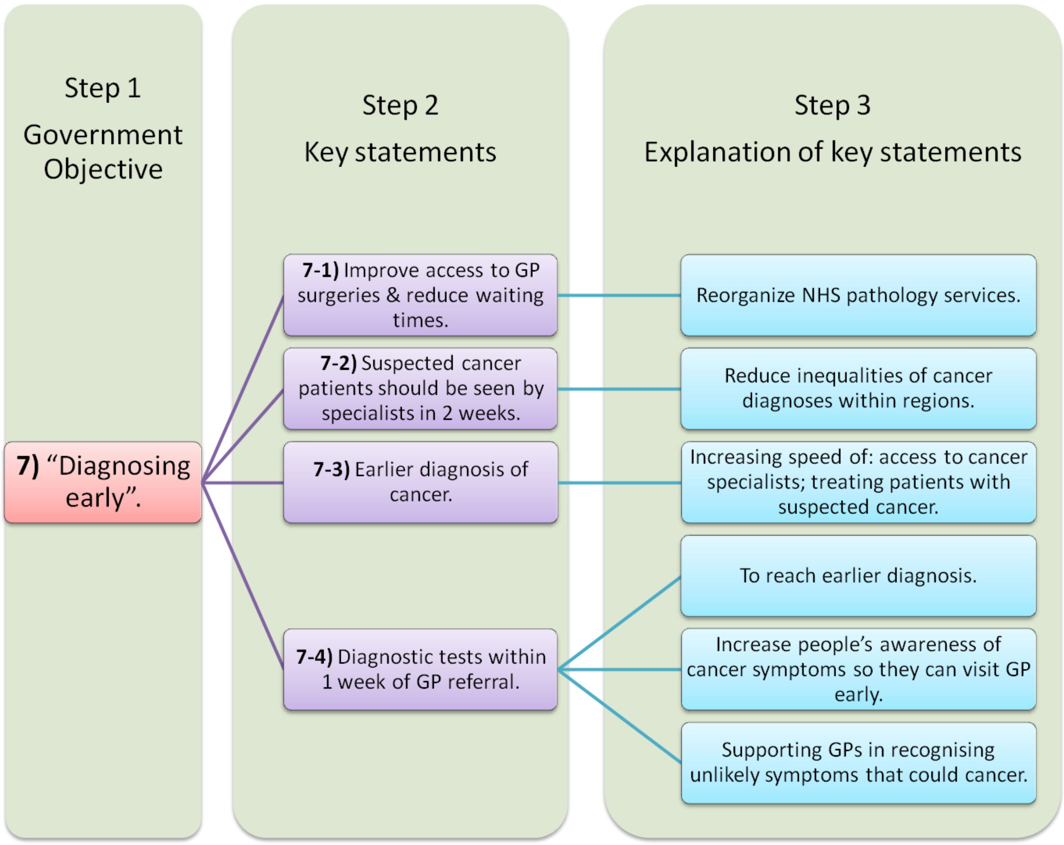

Figure D.7-1 – Methodological steps 1 to 3 in developing the government objective "diagnosing early" into detailed explanations

There are no tables to show the matching of possible actions to existing capabilities of telehealth systems for key statements 7-1 and 7-2 because a telehealth solution was seen as not feasible.

D.7.1 Matching possible actions to existing capabilities of telehealth systems (7-3)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Increasing speed of: access to cancer specialists; treating patients with suspected cancer.	The telehealth system should provide a feature for health professionals to triage patient's results to identify those that should be seen earlier.	H3-Health professional sets up alerts. H1-Health professional reviews/ analyzes results. H5-Intermediate device sends results to health professional. H6-System alerts health professional.	
	Patient should receive message asking them to visit their GP.	P8-Health professional sends message to patient.	
	Patient could receive information updates about coping with cancer.	P8-Health professional sends message to patient.	
	Patients should be able to ask questions and receive advice about their condition.	P9-Patient has real-time communication with health professional.	An additional capability is needed here: Patient contacts other patients via forum. (In this case, the patient receives approved information via a forum from others who may be going through a similar experience).

Table D.7-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 7-3

D.7.2 Matching possible actions to existing capabilities of telehealth systems (7-4)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
To reach earlier diagnosis.	(see Table D.7-1)		
Increase people's awareness of cancer symptoms so they can visit GP early.	Health professional raises awareness of cancer symptoms.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient.	
Supporting GPs in recognising unlikely symptoms that could cancer.	GPs receive updates via the system of uncommon cancer symptoms.	H4-Health professional receives clinical support via a report	
	GPs may discuss patient symptoms with colleagues.		There isn't a capability that meets this action. A suggestion is made: Health professional receives clinical support verbally.
	GPs can search medical software application to help reach a conclusion about a patient.		There isn't a capability that meets this action. A suggestion is made: Health professional searches medical application for information.

Table D.7-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 7-4

D.8 Steps 1 – 3 of the method illustrated by the healthcare objective "Providing high quality services – treating patients well".

Government objective eight: "providing high quality services – treating patients well".

Figure D.8-1 and Figure D.8-2 represent the first three steps of the methodology. It shows the objective with six key statements followed by the details of how this objective could be achieved. For visibility, the key statements are shown in two diagrams.

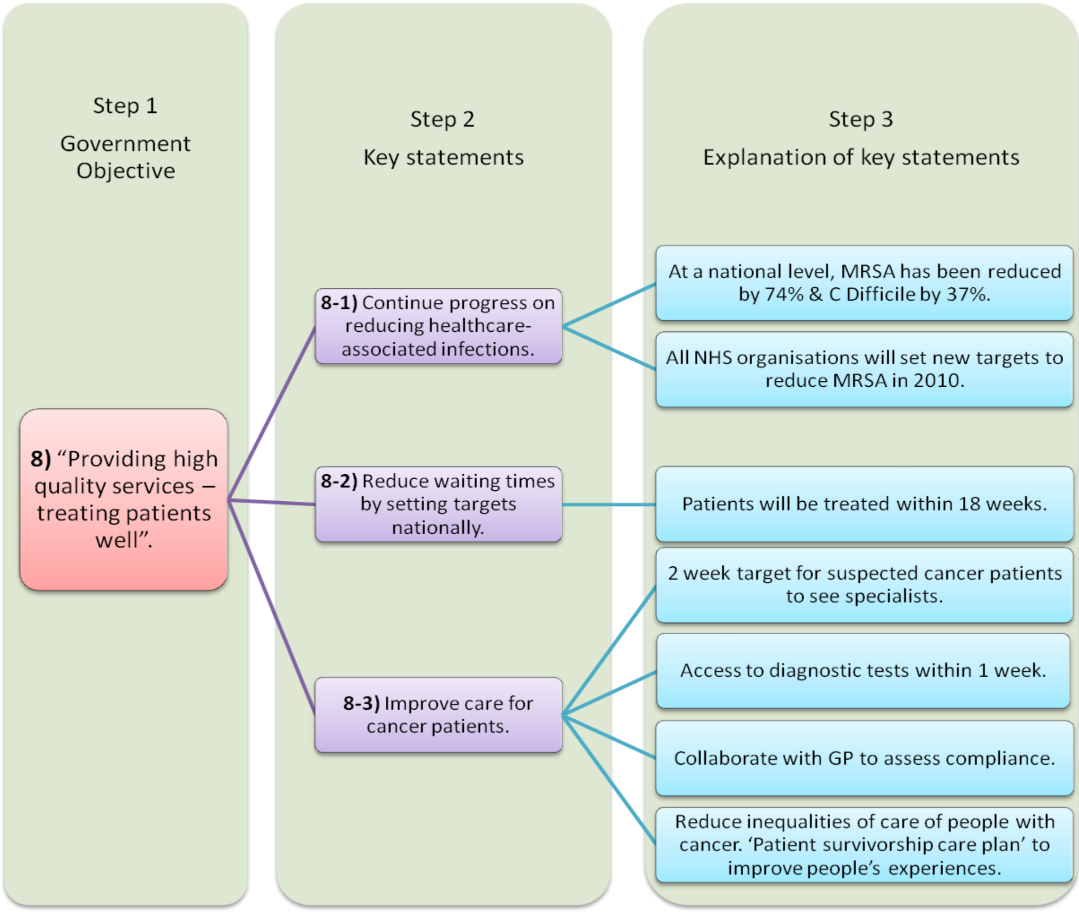

Figure D.8-1 – Methodological steps 1 to 3 in developing the government objective "providing high quality services – treating patients well" into detailed explanations (part 1)

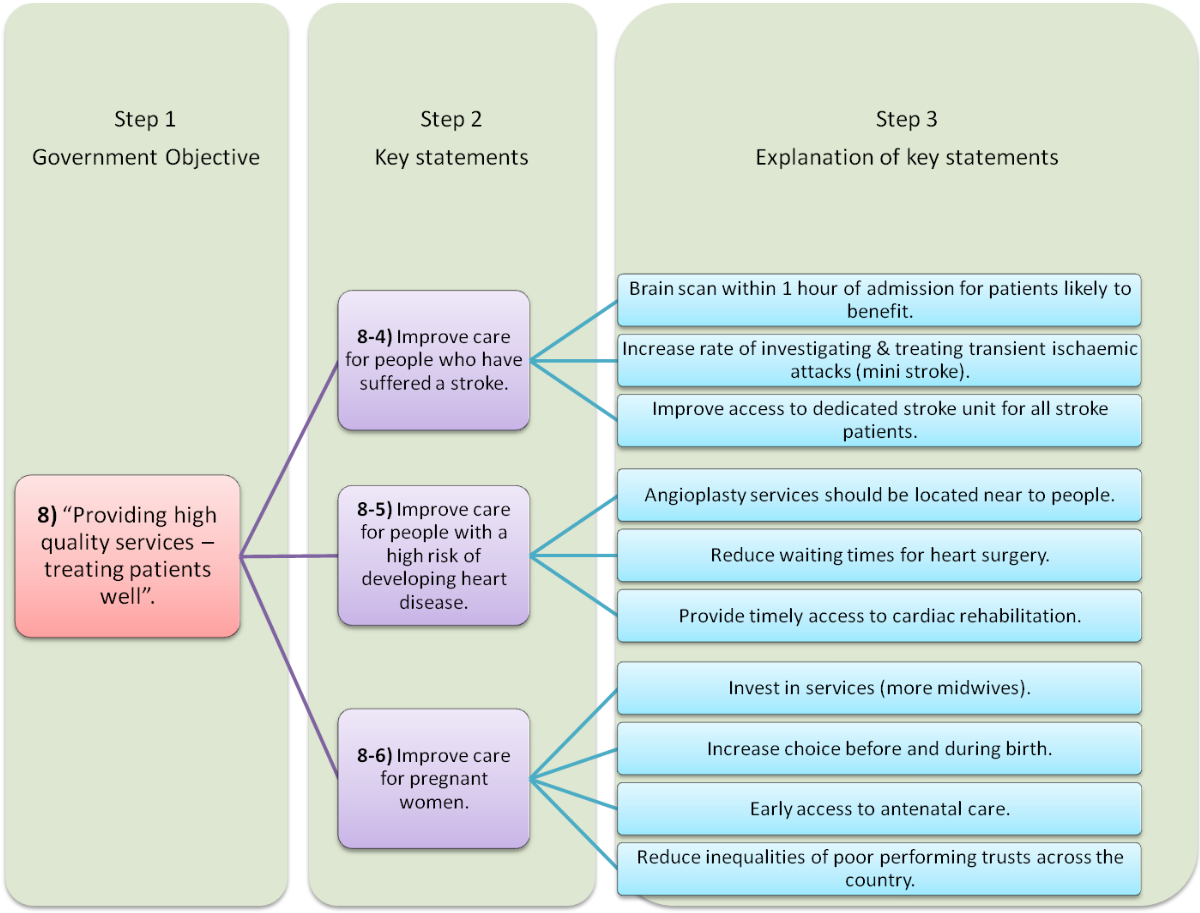

Figure D.8-2 – Methodological steps 1 to 3 in developing the government objective "providing high quality services – treating patients well" into detailed explanations (part 2)

There are no tables to show the matching of possible actions to existing capabilities of telehealth systems for key statements 8-1, 8-2, 8-3 and 8-5 because a telehealth solution was seen as not feasible.

D.8.1 Matching possible actions to existing capabilities of telehealth systems (8-4)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Brain scan within 1 hour of admission for patients likely to benefit.	-	-	
Increase rate of investigating & treating transient ischaemic attacks (mini stroke).	-	-	
Improve access to dedicated stroke unit for all stroke patients.	Patients can receive educational tips on how to monitor their health to prevent further occurrences of stroke.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient.	
	Caregivers may also receive this information depending on the severity of the stroke.		There isn’t a capability that meets this action. A suggestion is made: Caregiver receives messages to help improve patient care.
	Patients can receive information about the nearest stroke unit to them.	P8-Health professional sends message to patient.	

Table D.8-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 8-4

D.8.2 Matching possible actions to existing capabilities of telehealth systems (8-6)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Invest in services (more midwives).	-	-
Increase choice before and during birth.	Health professionals provide information about pregnancy.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient.
	Patients can ask health professionals questions about pregnancy care.	P2-Patient sends message to health professional
	Health professionals and patients can discuss issues.	P9-Patient has real-time communication with health professional
Early access to antenatal care.	-	-
Reduce inequalities of poor performing trusts across the country.	-	-

Table D.8-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 8-6

D.9 Steps 1 – 3 of the method illustrated by the healthcare objective "Safer care".

Government objective nine: "safer care".

Figure D.9-1 represents the first three steps of the methodology. It shows the objective with seven key statements followed by the details of how this objective could be achieved.

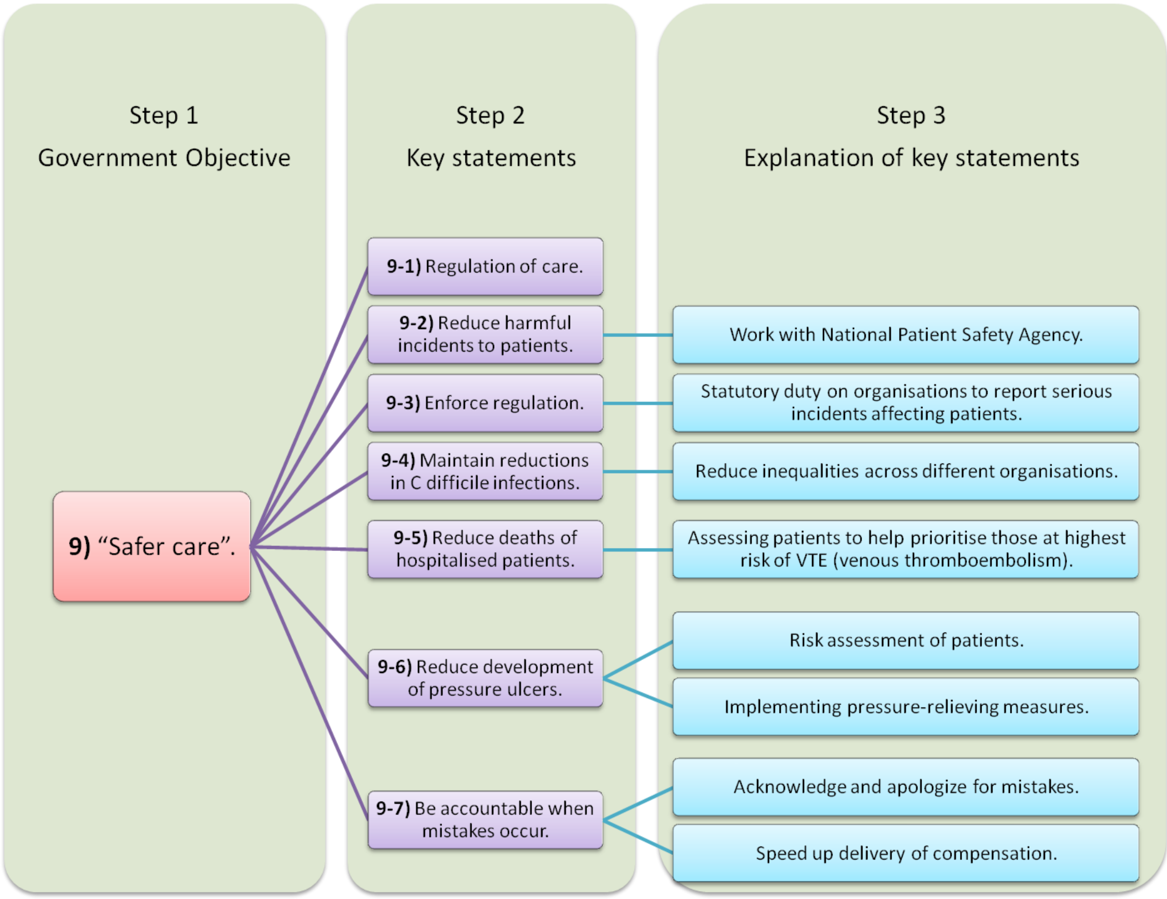

Figure D.9-1 – Methodological steps 1 to 3 in developing the government objective "safer care" into detailed explanations

There are no tables to show the matching of possible actions to existing capabilities of telehealth systems for key statements 9-1, to 9-7 because a telehealth solution was seen as not feasible.

D.10 Steps 1 – 3 of the method illustrated by the healthcare objective "Improving patient satisfaction – increasing choice and control"

Government objective ten: "improving patient satisfaction – increasing choice and control".

Figure D.10-1 and Figure D.10-2 represent the first three steps of the methodology. It shows the objective with six key statements followed by the details of how this objective could be achieved. For visibility, the key statements are shown in two diagrams.

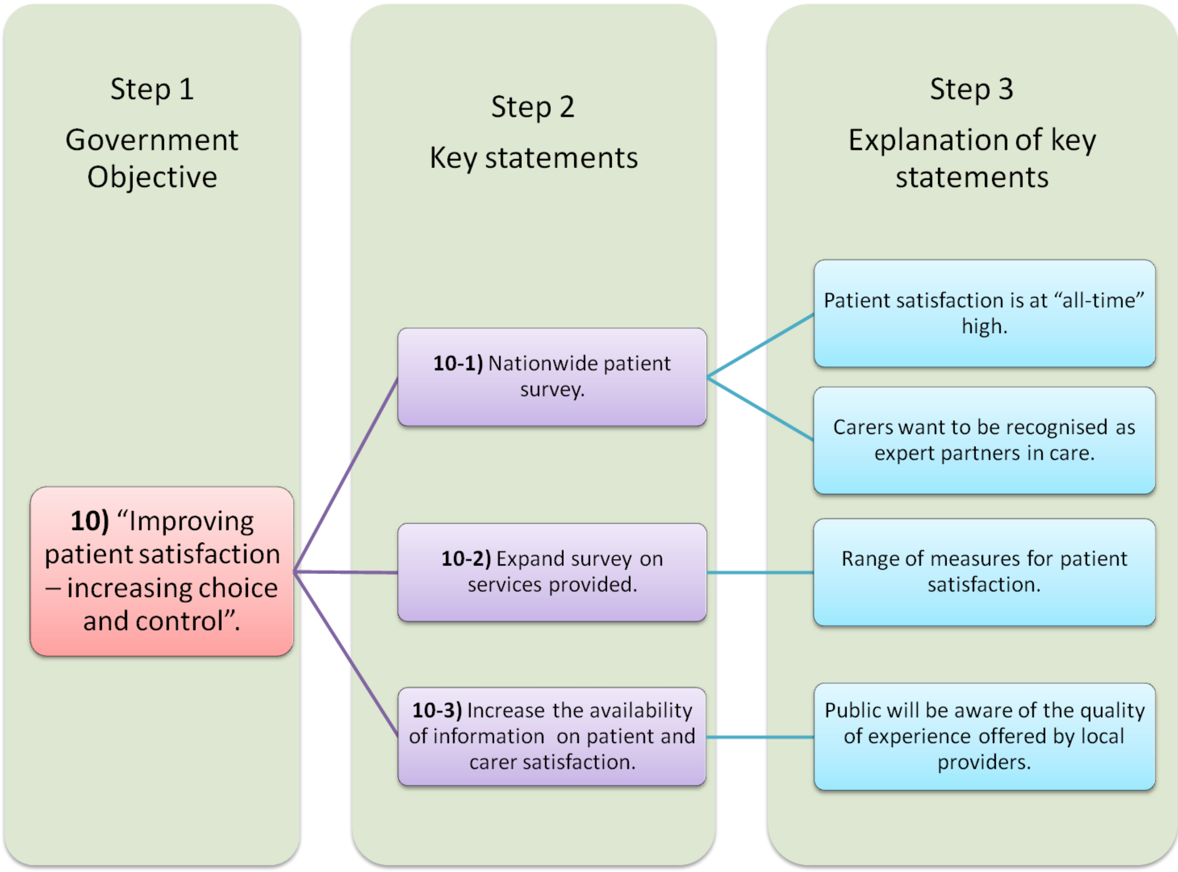

Figure D.10-1 – Methodological steps 1 to 3 in developing the government objective "improving patient satisfaction – increasing choice and control" into detailed explanations (part 1)

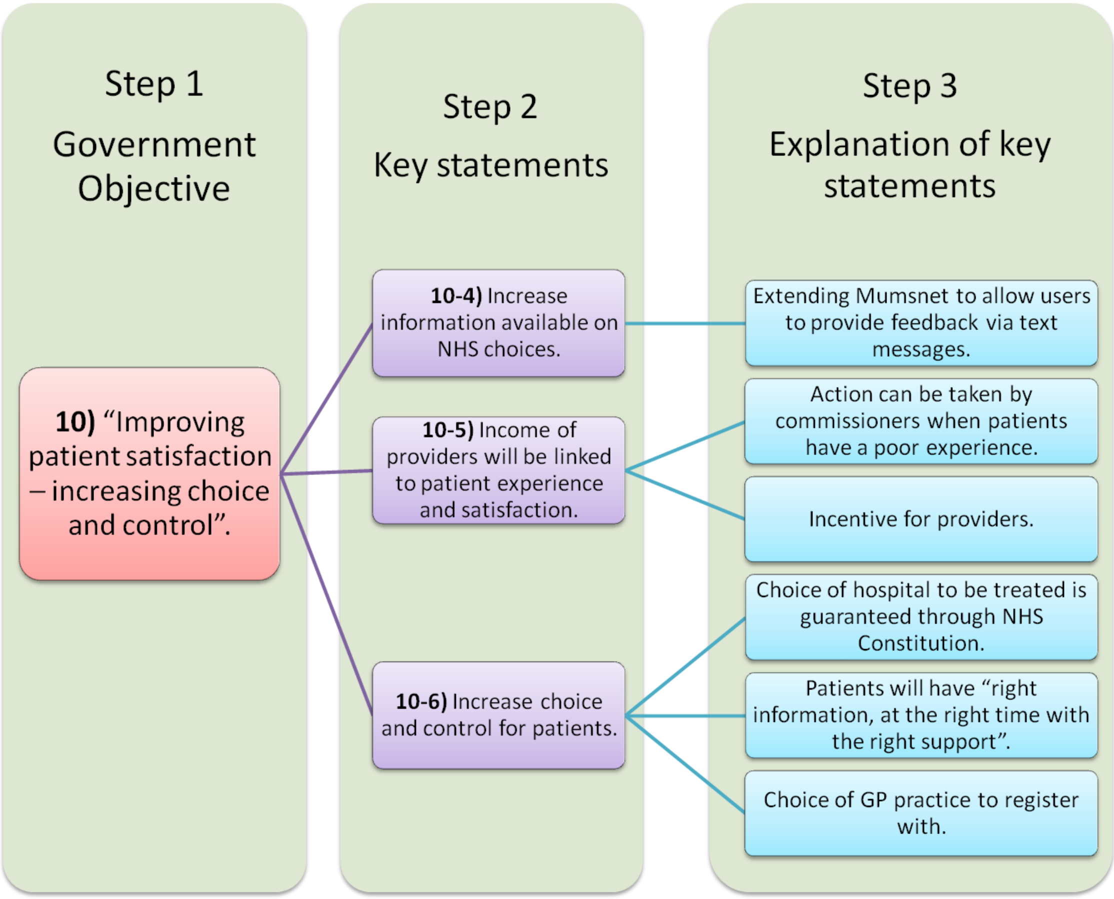

Figure D.10-2 – Methodological steps 1 to 3 in developing the government objective "improving patient satisfaction – increasing choice and control" into detailed explanations (part 2)

There are no tables to show the matching of possible actions to existing capabilities of telehealth systems for key statements 10-1, 10-5 and 10-6 because a telehealth solution was seen as not feasible.

D.10.1 Matching possible actions to existing capabilities of telehealth systems (10-2)

Step 3	Step 5	Step 6
Explanation of key statement	**Possible action**	**Equivalent capability**
Range of measures for patient satisfaction.	Health professionals can compile questionnaires to ascertain patient satisfaction.	P11-Health professional creates patient care plan.
	Patient is prompted to answer questions.	P1-Intermediate device prompts patients to answer questions.
	Patient adds their feedback into the system.	P14-Patient enters responses into the system.

Table D.10-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 10-2

D.10.2 Matching possible actions to existing capabilities of telehealth systems (10-3)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
Public will be aware of the quality of experience offered by local providers.	Telehealth system is incorporated with information of local services.	H7-Health professional transfers data into the system. S4-Server data transfer.	An additional capability is needed here: Information about local services is added to the system.
	Patient receives relevant information.	P8-Health professional sends message to patient	

Table D.10-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 10-3

D.10.3 Matching possible actions to existing capabilities of telehealth systems (10-4)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
Extending Mumsnet to allow users to provide feedback via text messages.	Parents can provide feedback into system of the care they have received.	P14-Patient enters responses into the system	
	Parents can access the information provided by other parents.		There isn't a capability that meets this action. A suggestion is made: Patients access feedback provided by other patients.

Table D.10-3 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 10-4

D.11 Steps 1 – 3 of the method illustrated by the healthcare objective "Effective care – transforming the lives of patients with long-term conditions".

Government objective eleven: "Effective care – transforming the lives of patients with long-term conditions".

Figure D.11-1, Figure D.11-2 and Figure D.11-3 represent the first three steps of the methodology. It shows the objective with 5 key statements followed by the details of how this objective could be achieved. Due to the number of explanations, the key statements are shown in three diagrams.

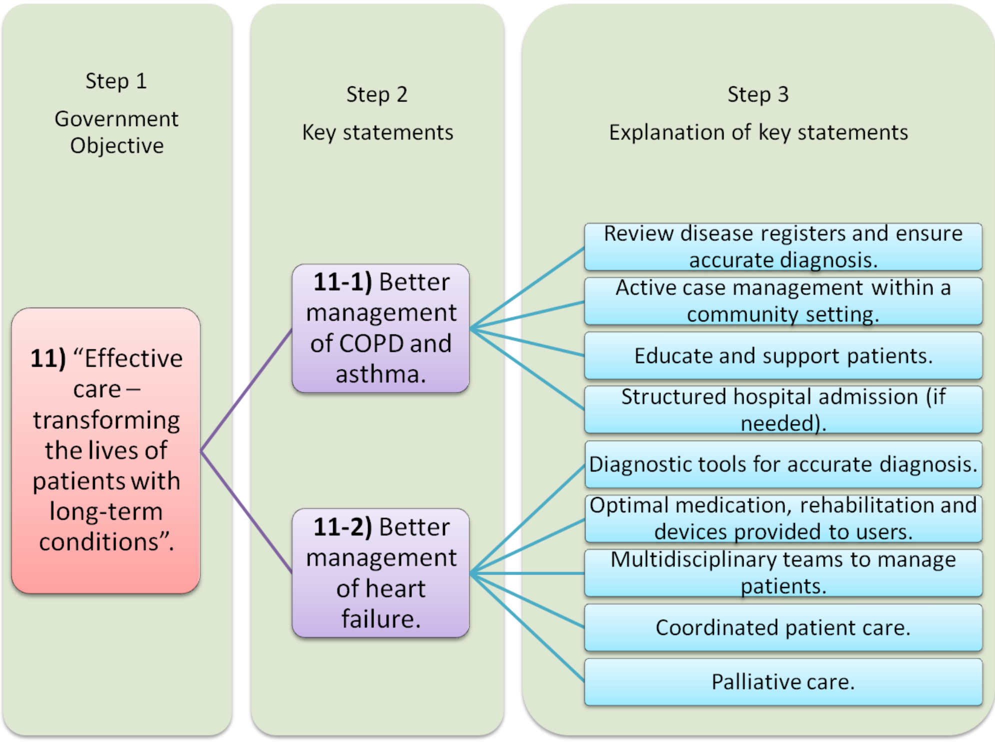

Figure D.11-1 – Methodological steps 1 to 3 in developing the government objective "effective care – transforming the lives of patients with long-term conditions" into detailed explanations (part 1)

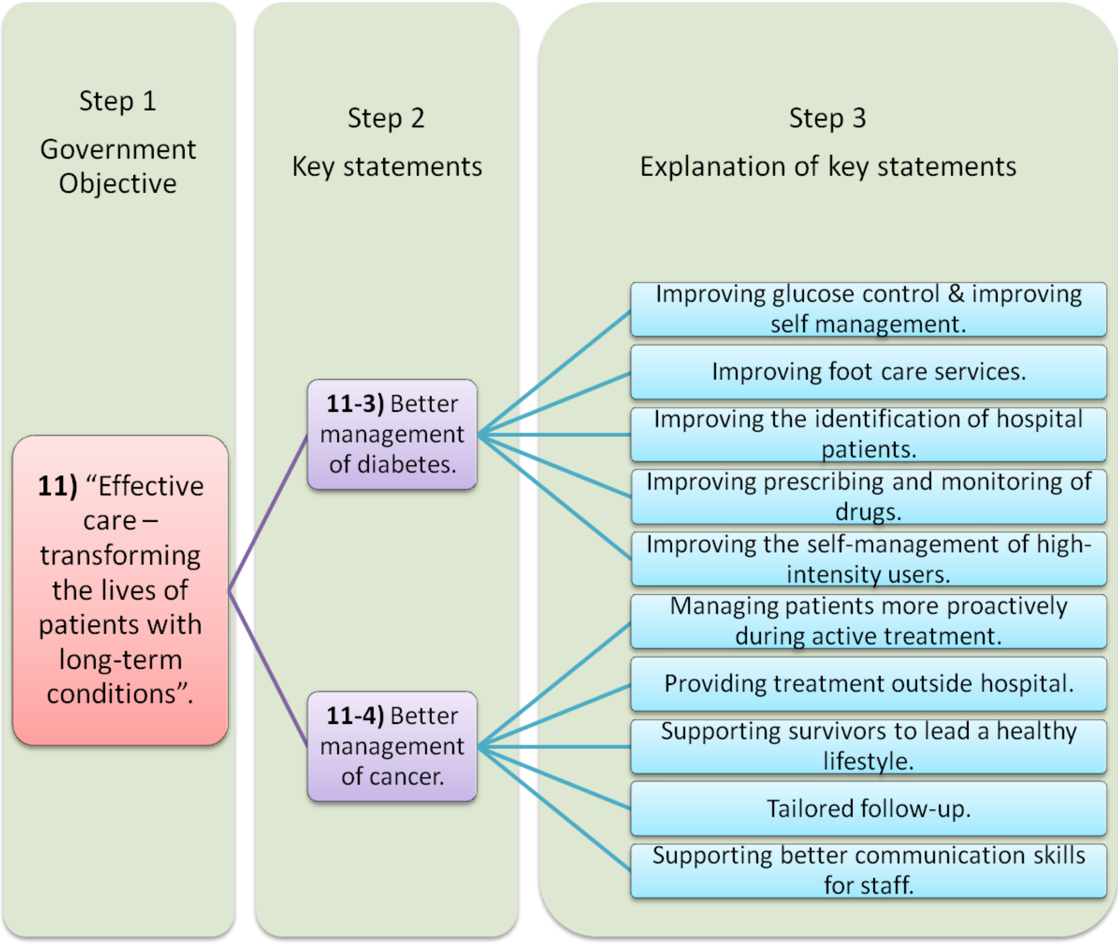

Figure D.11-2 – Methodological steps 1 to 3 in developing the government objective "effective care – transforming the lives of patients with long-term conditions" into detailed explanations (part 2)

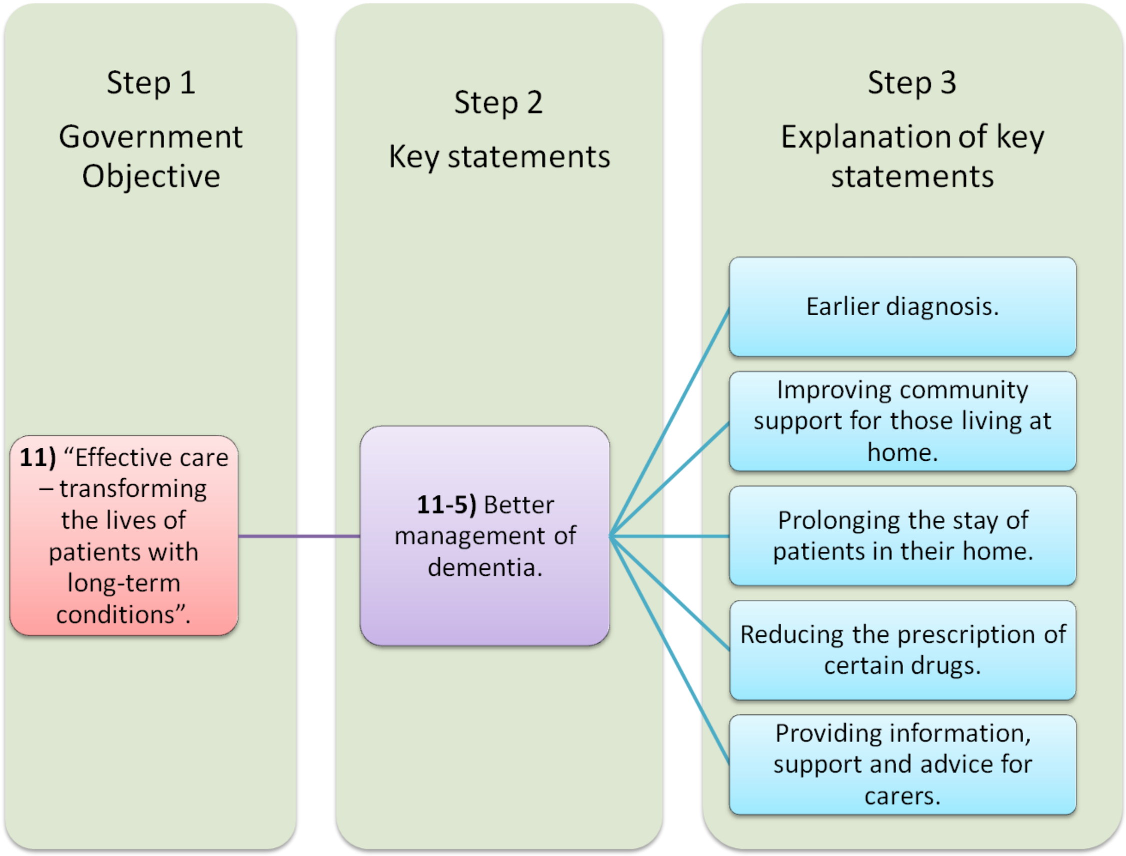

Figure D.11-3 – Methodological steps 1 to 3 in developing the government objective "effective care – transforming the lives of patients with long-term conditions" into detailed explanations (part 3)

D.11.1 Matching possible actions to existing capabilities of telehealth systems (11-1)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Review disease registers and ensure accurate diagnosis.	Health professionals can search EPR to identify the appropriate people.		There isn't a capability that meets this action. A suggestion is: Health professional searches patient records.
Active case management within a community setting.	-	-	
Educate and support patients.	Health professionals disseminate relevant information to patients.	P11-Health professional creates patient care plan.	
	Patients can access information tips about COPD & asthma and how to better manage it.	P8-Health professional sends message to patient.	
Structured hospital admission (if needed).	-	-	

Table D.11-1 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 11-1

D.11.2 Matching possible actions to existing capabilities of telehealth systems (11-2)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Diagnostic tools for accurate diagnosis.	Health professionals use appropriate devices to test patients.	H7-Health professional transfers data into the system.	
	Health professionals discuss results with patient.	P9-Patient has real-time communication with health professional.	
Optimal medication, rehabilitation and devices provided to users.	Patients are prompted to take medication.	P10-Intermediate device prompts patients to take medication.	
	Patients are prompted to establish rehabilitation routines.		There isn't a capability that meets this action. A suggestion is: Patient is prompted to establish a routine.
Multidisciplinary teams to manage patients.	Health professionals provide clinical support to each other.		There isn't a capability that meets this action. A suggestion is made: Health professional receives clinical support verbally.
Coordinated patient care.	-	-	
Palliative care.	-	-	

Table D.11-2 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 11-2

D.11.3 Matching possible actions to existing capabilities of telehealth systems (11-3)

Step 3	Step 5	Step 6	Additional Capabilities
Explanation of key statement	**Possible action**	**Equivalent capability**	
Improving glucose control & improving self management.	Patients are trained in self management by health professionals.		There isn't a capability that meets this action. A suggestion is: Health professional trains patient.
	Health professionals discuss progress with patients.	P9-Patient has real-time communication with health professional.	
	Patient adds their results into the system.	P16-Patient enters/transfers results into the system.	
Improving foot care services.	-	-	
Improving the identification of hospital patients.	-	-	
Improving prescribing and monitoring of drugs.	Health professional has a record of drugs prescribed to patients and is notified if they haven't taken their medication.	P12-Health professional modifies patient care plan. H3-Health professional sets up alerts. H6-System alerts health professional.	
Improving the self-management of high-intensity users.	-	-	

Table D.11-3 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 11-3

D.11.4 Matching possible actions to existing capabilities of telehealth systems (11-4)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Managing patients more proactively during active treatment.	Patients receive information about recovery, chemotherapy and other options available for cancer treatment.	P11-Health professional creates patient care plan. P8-Health professional sends message to patient.	
Providing treatment outside hospital.	Patients are informed of alternative locations to receive treatment and available services.	P8-Health professional sends message to patient.	
Supporting survivors to lead a healthy lifestyle.	Patient should receive information about coping with cancer and leading a healthy lifestyle.	P8-Health professional sends message to patient.	
	Patient discusses progress of health with health professionals.	P9-Patient has real-time communication with health professional.	
	Patients should be able to ask questions and receive advice about their condition.	P9-Patient has real-time communication with health professional.	An additional capability is needed here: Patient contacts other patients via forum. (In this case, the patient receives approved information via a forum from others who may be going through a similar experience).
Tailored follow-up.	Health professionals can search EPR to identify the appropriate people and provide relevant treatment for them.	P11-Health professional creates patient care plan.	An additional capability is needed here: Health professional searches patient records.
Supporting better communication skills for staff.	Health professionals provide clinical support to each other.		There isn't a capability that meets this action. A suggestion is made: Health professional receives clinical support verbally.

Table D.11-4 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 11-4

D.11.5 Matching possible actions to existing capabilities of telehealth systems (11-5)

Step 3 Explanation of key statement	Step 5 Possible action	Step 6 Equivalent capability	Additional Capabilities
Earlier diagnosis.	-	-	
Improving community support for those living at home.	Patients and caregivers should be aware of available services.	P8-Health professional sends message to patient.	An additional capability is needed here: Caregiver receives information.
Prolonging the stay of patients in their home.	-	-	
Reducing the prescription of certain drugs.	-	-	
Providing information, support and advice for carers.	Caregivers should receive information to support patients.		There isn't a capability that meets this action. A suggestion is made: Caregiver receives information.
	Caregivers should have an avenue to share tips with other caregivers.		There isn't a capability that meets this action. A suggestion is made: Patient contacts other patients via forum. (In this case, the patient receives approved information via a forum from others who may be going through a similar experience).

Table D.11-5 – Methodological steps 5-6; i.e. possible actions and equivalent capabilities for the proposed telehealth system for 11-5

D.12 Steps 1 – 3 of the method illustrated by the healthcare objective "Social care"

Government objective 12: "Social care".

Figure D.12-1 represent the first three steps of the methodology. It shows the objective with one key statement followed by the details of how this objective could be achieved.

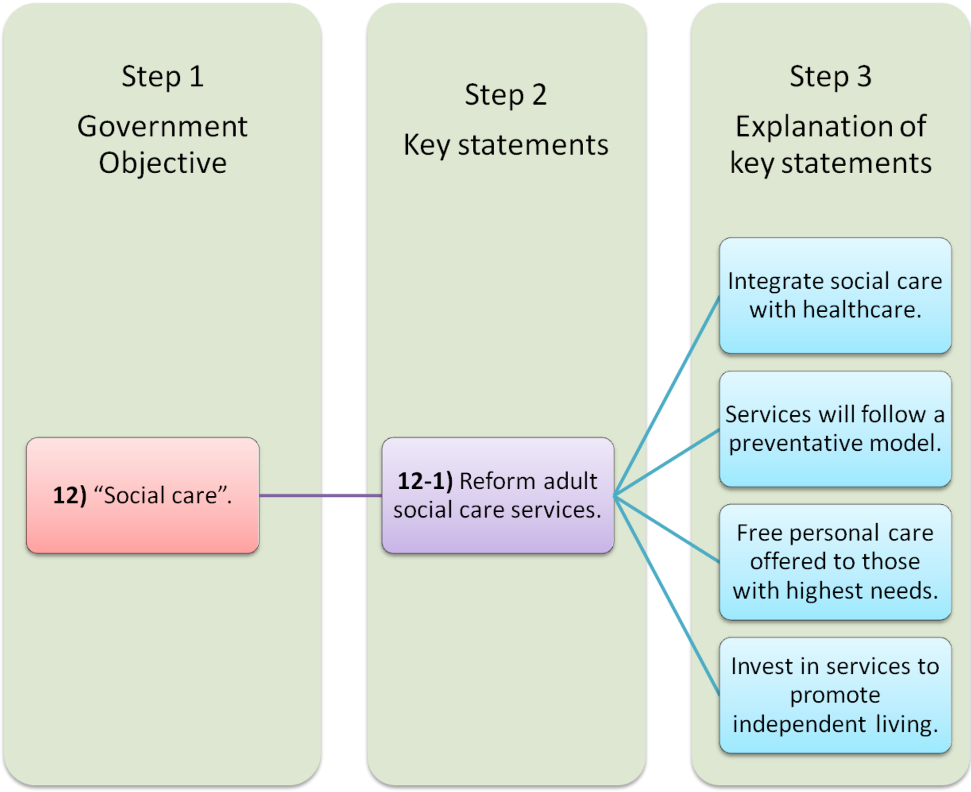

Figure D.12-1 – Methodological steps 1 to 3 in developing the government objective "social care" into detailed explanations

There is no table to show the matching of possible actions to existing capabilities of telehealth systems for key statement 12-1 because a telehealth solution was seen as not feasible.

D.13 Questionnaire used for validation.

To avoid repetition of diagrams and tables, only one question is shown is shown in the appendix.

D.13.1 Can telehealth solutions be used to deliver objectives from a healthcare policy?

I am a PhD researcher investigating informatics for point-of-care devices which are suitable for home use.

My research has derived capabilities of telehealth systems from existing telehealth offerings. These capabilities have been applied to a healthcare policy through a systematic methodology. The focus now is on obtaining experts opinion within the healthcare industry about this.

In order to achieve this, I am inviting you to complete a questionnaire. The questionnaire aims to seek your viewpoint on the suitability of telehealth solutions in meeting policy.

The questionnaire should take about 25 minutes to complete. Before completing the questionnaire, please watch the short 4 minute video which I've attached to aid your understanding.

Twelve sets of questions are presented (A1 – A12). In each one, a diagram is shown indicating the steps of how I worked from the government objective to the explanations given in the policy (steps 1-3). Following this, a table is shown asking you whether a telehealth solution can contribute to meeting the key statements of each government objective.

For each key statement, please could you provide an answer of whether a telehealth solution can contribute to meeting the objective by selecting either 'yes' or 'no' or 'don't know'? If your answer is no, please could you provide reasons for your answer? If your answer is yes, could you state the relevant capabilities that would be expected of the telehealth system?

For the purpose of my research, I have considered telehealth systems as those that enable medical care to be provided to patients via information, computing and telecommunications technologies where the patients and health professionals are separated by a distance.

Your contribution would be very valuable to my research. The results from this questionnaire will be made available to you in a document as a sign of my appreciation for your help. All data will remain completely anonymous.

If there are any queries, please do not hesitate to contact me Oluseun Adeogun at the following email address o.adeogun@cranfield.ac.uk

Please return your responses by email to the address above. Thank you.

D.13.2 "Rights for patients".

Government objective one is "rights for patients". Figure D.13-1 represents the first three steps of the methodology. It shows the objective with one key statement followed by the details of how this objective could be achieved.

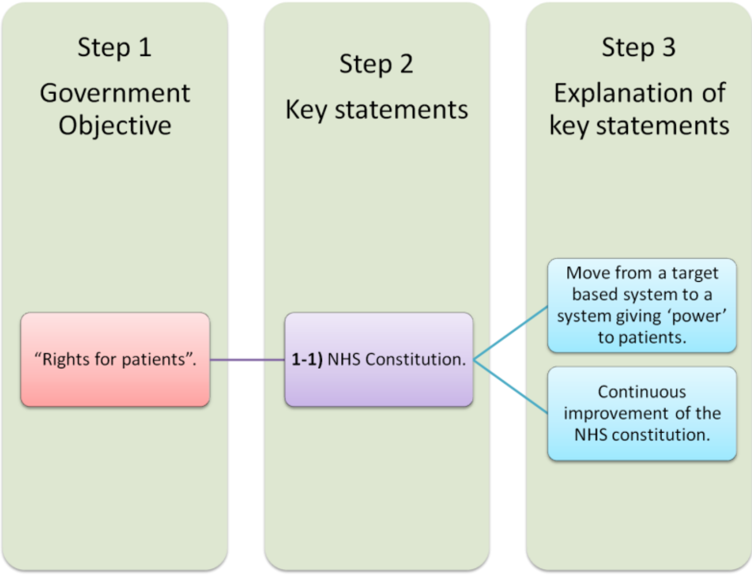

Figure D.13-1 – Methodological steps 1 to 3 in developing the government objective "rights for patients" into detailed explanations

(Objective #- Key statement #)	Can a telehealth solution contribute to meeting this objective's key statement?	If you select no, please provide reasons for your answer? If you select yes, state the relevant capabilities that would be expected of the telehealth system?
1-1	Choose an item	Click here to enter text.