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

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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.

Keywords:
Informatics, Point-of-care testing, Medical Device, PSS, Product-Service System

1 INTRODUCTION

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' [1].

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' [2]. Point-of-care testing (POCT) has been defined as 'diagnostic testing at or near the site of patient care' [3]. Point-of-care devices form a sub-class of medical devices used to carry 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 [4].
- 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 [5].

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.

1.2 Medical informatics

'Medical informatics' or 'health informatics' is 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.

1.3 Product-service systems

A product-service system (PSS) 'is an integrated product and service offering that delivers value in use' [6]. 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 [6].

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 [6]. Services provided through point-of-care devices should aid in 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' [7]. 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.

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?
- 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 THE CURRENT MODEL OF USAGE OF HOME ENVIRONMENT POINT-OF-CARE DEVICES

Blood glucose measurement devices (blood glucometers) provide an example of the current model of usage of POCT devices in the home environment. Glucometers are used on a regular basis by diabetics 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 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 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 [8]. 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 [9]. Diabetic care is particularly suited as an application for informatics because 'its management is characterised by quantifiable outcomes' [9]. 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. 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 order to ascertain the degree of servitization of glucometers, the state-of-the-art in informatics in glucometers was evaluated in a recent study by the authors [10]. This established that many glucometers provided 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. 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 [10].

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

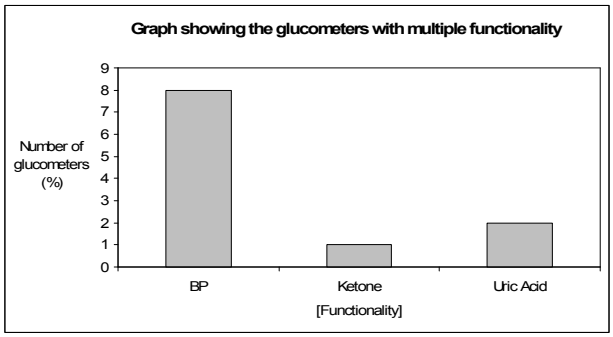

Figure 1: Glucometers with multiple functionality.

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.

4 POINT-OF-CARE TESTING DEVICES IN A RESULT-ORIENTED PRODUCT-SERVICE SYSTEM

4.1 Drivers for change

Wakefield noted that there were multiple drivers for change in healthcare [11]. Although they were mentioned in relation to the nursing sector, they are also applicable to POCT devices. They included:

- Cultural diversity – society is becoming increasingly multicultural with more integration between different races and ethnic origins. Consequently, healthcare services are being tailored to meet this transition.
- Aging population – the trend in the age of members of society is generally becoming older. The World Health Organization (WHO) notes that an aging population is a challenge that will impact the current century and requires 'joint approaches and strategies' [12]. 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 [13]. 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 noted that the challenge of time and distance within healthcare was 'irrelevant' because of the use of technology [11]. Information technology has been successfully applied in other industries such as banking, travel and communications; however healthcare informatics is still lagging behind [14]. For instance, people are able to monitor their bank accounts and carry out transactions online through the internet. The healthcare environment also needs to be streamlined so that services are delivered accordingly. 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.

Following these drivers for change, a shift in the perspective of POCT devices to a result-oriented PSS whereby customer value is achieved through the provision of services, rather than the purchase of a product is proposed.

4.2 Examples of services

Whitney [15] notes 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 also provides 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 [15].

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 (medication management).
- 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 the user 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, and the three latter services have emerged through the gaps found in the literature. In principle, the above services could also be applied to other POCT devices.

5 INFORMATICS RESOURCES REQUIRED FOR POCT DEVICES TO SUPPORT A MOVE TOWARDS A RESULT-ORIENTED PSS

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 care 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 then 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 [16, 17].

Bryant, et al [18] 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 [19].

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:

- 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 the raw data entered by the patient. Alternatively, the POCT device could be designed in a way that ensures data is entered in a standardised way thus reducing ambiguity and allowing efficient data/information transfer and exchange.
- 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.

5.1 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 2. 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. Health professionals are then alerted through the system whenever new results are added to the database that appear to be outliers or show an inconsistency to regular results. Advice is then provided to the patient via a wireless communication link.

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.

6 BENEFITS TO USERS OF RESULT-ORIENTED PSS FOR POCT DEVICES

Kilbridge and Classen [20] noted that the benefits of informatics in healthcare are to improve 'access to information, reduce reliance on memory, increase awareness' and allow procedures to be standardized. Each one is considered from the perspective of point-of-care testing devices.

6.1 Improving access to information

Blumenfeld [21] discussed how information can be best utilized for point-of-care treatment and describes an example from a health professional's perspective. When health professionals are attending to patients, many issues and questions are considered in order to make a diagnosis. Although information resources are available, access to them may not necessarily be easy and efficient, as health professionals must enter specific search terms in order to find the correct information.

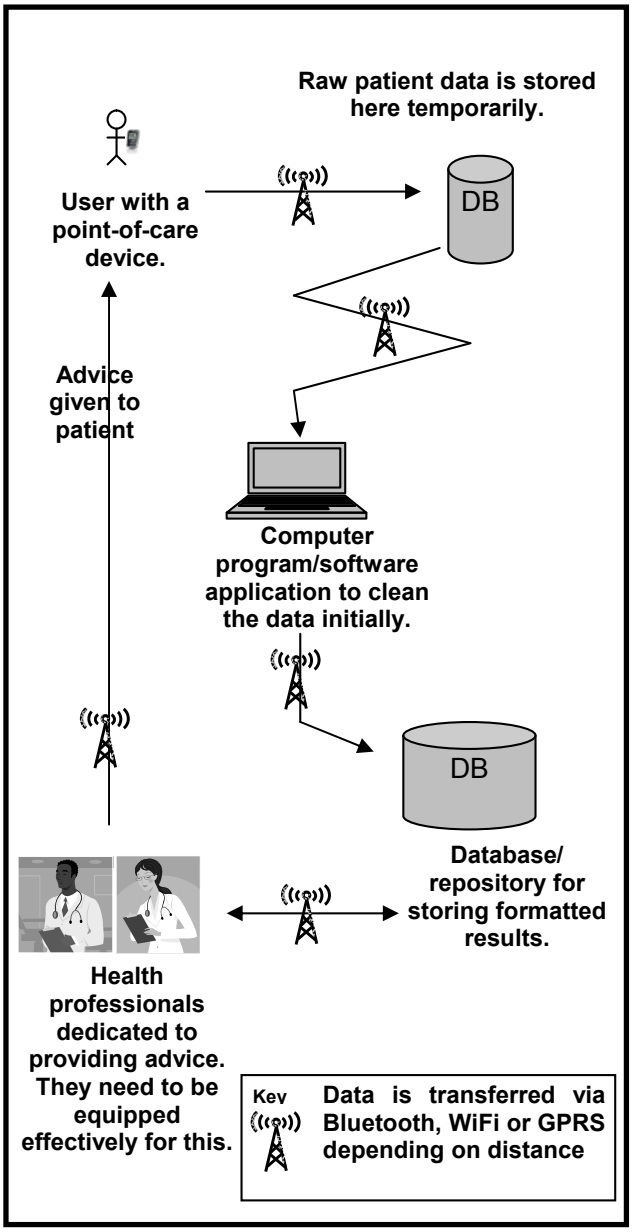

Figure 2: A proposed view of PSS for home care devices.

This view was echoed by Poon, et al [22], who, in addition, noted that due to the short amount of time available for doctors to spend with patients, some of the questions may remain unanswered.

Blumenfeld [21] discussed knowledge bases and how they may be used to aid in decision support within the health context. One example was that of a knowledge base that could be used to check whether a new drug prescribed to a patient does not interfere with the actions of current medications. This is of particular importance to aging populations whose members are on multiple medications. Such a base may also provide knowledge as to whether the prescribed dose is suitable for the patient, thus also reducing the chances of an adverse drug reaction.

Although the example described above was related to point-of-care devices used by health professionals it could be envisaged that the approach could be used for devices used by non-health professionals. However, clearly, the informatics challenges would be considerably greater.

6.2 Reduce reliance on memory

Point-of-care devices may incorporate data storage facilities thus reducing the information load on users of the device. For example, glucometers used by diabetics have memory facilities to store the blood glucose results. Therefore users do not need to manually keep a record of their results. Memory facilities on devices will reduce the pressure on users of devices thus facilitating a faster way of health monitoring.

6.3 Increase awareness

Informatics enables the addition of alerts into electronic data. Incorporating automated features on point-of-care devices may help to alert users to events that may otherwise go unnoticed. Ford described how the introduction of an electronic system with wireless capabilities to a hospital, alerted health professionals when there were irregularities in patient data (i.e. if a patient's results fall outside the normal specified threshold) [23].

6.4 Standardize procedures

Informatics enables the standardization of processes. Handheld devices such as PDAs, even though they are not point-of-care devices per se are an example of using informatics in healthcare to standardize procedures. Lapinsky, et al [24] gave an example through a case-study of how a Palm PDA was used in an ICU.

Patients' safety issues may arise when using automated processes. Kilbridge and Classen [20] described several cases where automated processes have been used successfully in healthcare. They are for reporting 'safety-related' events and for training health professionals. In addition, an automated process can be used to identify clear-cut outliers when analysing data.

7 LIMITATIONS AND EXTENSION TO PAPER

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.

8 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 care 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.

9 ACKNOWLEDGMENTS

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