Barriers of Market Entry with POCT: A Case Study

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ABSTRACT
MobiHealth developed a communication solution for Point of Care Testing (POCT) devices at the General Practitioner (GP). The communication between the GP and the laboratories changes from manual to digital. Their question was whether their business model translated to a valid business case. This research aims to provide insight in the stakeholders of the MobiHealth case and identify possible barriers of market entry. We performed a literature study and a stakeholder analysis to see what barriers of entry there are. The stakeholder analysis entailed a set of interviews in a broad range to identify stakeholders. The results of the research show that there is a general trend going towards POCT and the interviews find a positive reaction to developments of this kind. We also found more stakeholders through our interviews and worked these into our model. Our e3value models show that the MobiHealth case simplifies the existing situation. Quantification of these models is the next step. We found three barriers of market entry: new solutions need to show their added value, show financial gain, or at least no losses, and prove that there is no concern needed about correct data testing.

Keywords
Point-of-care Testing, Dutch home care market, Stakeholder Analysis, e3value

1. INTRODUCTION
Healthcare costs in the Netherlands, and other developed countries, are rising, and there is a high demand for solutions which help keep these costs within reasonable limits [22] [16] [3], although it must happen without any loss of healthcare quality [4]. Point-of-Care testing (POCT) is one possible solution. It has been defined by numerous authors. Ehrmeyer and Laessig provide an adequate definition with “patient specimens assayed at or near the patient with the assumption that test results will be available instantly or in a very short timeframe to assist caregivers with immediate diagnosis and/or clinical intervention” [7]. The goal of POCT is to provide accurate, reliable, fast, and cost-effective information about patient condition [27]. Many forms of POCT, like glucose testing and urine dipsticks, have been around for a while [2]. As stated above, POCT covers what used to be exclusively laboratory tests, but only focus on measuring the most critical parameters of the designed test. This makes the tests much more specific, faster, and the devices smaller. [5]

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Proven advantages of POCT are fast diagnosis [19], error reduction [6], and reducing hospital stay time of patients [17]. A recent research shows us how POCT, integrated in the healthcare chain for heart patients, provides significant benefits [14]. However, Drenck points out that even though it has many advantages, POCT may not always be a cost-beneficial development [6].

Within POCT there are two variations: self-testing and professional testing, either at the General Practitioner (GP) or at the hospital [18] [21]. Self-testing implies the patient themselves doing the testing, whilst professional testing means a trained healthcare professional will perform the tests.

In self-testing the patient performs what previously used to be laboratory tests himself with a device specifically tailored for that test. Lehmann noticed a growing home healthcare market as early as 2002, with home testing as a possible domain to enter [17]. With technological advancement, nowadays glucose testing by diabetic patients is already a well-accepted practise of self-testing [30]. Hsu et al. show that there is no statistical relevant difference in testing results when self-testing is being done by a patient or a professional compared to laboratory tests [12], which makes self-testing with POCT solutions a viable alternative to laboratory testing.

The second type of POCT is having tests done by a healthcare professional [21]. The main advantage here lies in the fact that healthcare professionals have the test results directly at the point-of-care instead of sending the sample to the laboratory and waiting for the results. This means diagnosis and treatment of patients can begin almost immediately [19]. According to Drenck, other advantages in a clinical setting are a higher diagnostic speed when compared to traditional, broader range tests, and less analytical and transportation errors, [6]. Plebani argues against these statements, stating that POCT alone cannot reduce the rate of errors and sufficient training of clinical staff is essential [25].

A search on the search engine Scopus.com tells us that close to 8000 articles have been published before 2015, when searching with the query TITLE-ABS-KEY ( poct OR “Point of Care” OR “Point-of-care” AND testing ) . The results show a rapid increase in publications after 2005, as shown in Figure 1. A quick limiting of these results with AND (LIMIT-TO( SUBJAREA , “BUSI” ) ) , Scopus shows us 23 publications. Of these publications, only Lehman touches the subject we want to research in, but his focus lies primarily on POCT in the home healthcare market [17]. Lehmanns 2002 research, which mainly uses a resource of 1999 on the home healthcare market, is outdated, as Dondelinger shows many new advancements made in a 2007 study [5]. This paper aims to fill part of this gap by performing a case study on stakeholders in POCT and setting the base for further research if this area of research is relevant for companies willing to enter the market, as innovation in healthcare often meets resistance [11] and knowing these barriers is a valuable thing.
This paper studies the case of MobiHealth, a Dutch company which provides a system which allows POCT devices at the GP to communicate wireless and eliminates a significant amount of human actions. MobiHealth states the amount of human actions goes down to 2 to 5, from 40. They came to us with the question whether their business model could become a viable business case.

Because of the complex relationships between stakeholders and the expansiveness of the market, it can be unclear where to start and who is to gain and lose what from the new technology. The goal of this research is threefold. First it gives an overview of the current POCT market. Second, it maps stakeholder values through a stakeholder analysis and the use of an e3value model in a situation with MobiHealths POCT solution and one in a situation without. Third, it concludes with identifying what possible barriers of entry there are based on the results of the research.

Our research question throughout this paper is “What are barriers of market entry for POCT technology in the Dutch healthcare market?”. To answer this question, we will answer the following subquestions:

1. What is the stakeholder network for the MobiHealth case?
   a. Who are the current stakeholders in the MobiHealth case?
2. How will the e3value model change for the key stakeholders when adopting MobiHealths solution?
   a. What are stakeholder gains and losses when adopting MobiHealths solution?
   b. How will stakeholder relations change when adopting MobiHealths solution?
3. What changing relations will provide stakeholder challenges for similar companies willing to enter the market?

We will approach the questions with various methods. For the stakeholder analysis, we will use Pouloudi’s method of iteration and map the obvious stakeholders first. Then we conduct interviews as well as a literature study on the subject to get a better insight and iterate on our stakeholder list [26].

After these steps we create a set of e3value models, which will map the stakeholders and their relations in both the old and the new situation [9]. From this we hope to extract a more global advise on barriers of market entry and towards further areas of interest for new research.

2. THE CASE: MOBIHEALTH

MobiHealth came to us with their business model. They wanted to know whether their proposed business model was feasible and turn that into several business cases.

2.1 The product

Their product is a communication service for POCT devices at the GP and the clinical laboratory. The full product exists of four components:

1. Bluetooth communication network at the GP.
2. GP software.
3. Laboratory software.

The system starts with the assistant at the GP entering patient BSN and the GP’s AGB-code in the MobiHealth software installed and then performing the test on one of the POCT devices they have. The resulting dataset gives a unique relation.

The data is then automatically sent from the POCT device to the computer through a Bluetooth connection. The test results appear on the screen as soon as they’re available. The data is then sent to the MobiHealth servers.

The MobiHealth servers act as the data hub, where the GP system sends the test data and the laboratories retrieve it. On the laboratory side the data is collected from the server and integrated with their software system. An order number will be generated and the final data is sent to the GP, where it automatically integrates with their systems.

2.2 The Business Case

MobiHealth wanted to know whether this would make a viable business case. To achieve this, we needed to assess what exactly the MobiHealth business case was. Considering the gap in literature regarding business cases and POCT we decided to limit the scope of the research to the conduction of a literature study, a preliminary stakeholder analysis and the creation of an e3value model. This would advance the MobiHealth case as well as give an basis for further research in this area.

3. METHODOLOGY

For choosing the methodology we regarded the scope of the research and its focus. This meant choosing a method of stakeholder analysis that would allow a broad identification of stakeholders and a way to classify the stakeholders.

For the modelling methods we needed something accessible that would at the same time be able to map complex stakeholder relations.

3.1 Stakeholder Analysis Method

We have performed a stakeholder analysis on our case through the methods described by Pouloudi [26] and Alexander [1]. Pouloudi’s method was chosen as it is a method for identifying stakeholders in several tiers, and Alexander provided a framework to categorise them, as shown in figure 2.

Pouloudi gives three stages of stakeholder analysis [26]:

1. **First stage** – Mapping ‘obvious’ stakeholders. Low domain knowledge, single entry point.
2. **Second stage** – Conducting first round of interviews and doing a literature review.
3. **Third stage** – Conferences, further interviews, more in-depth searching.

In his research, Pouloudi shows that each of these stages gradually add more insight into the research subject and give a more complete overview of stakeholders involved. For this
paper, we set out to complete the first two stages and create a model with the information at that time.

Figure 2. The ‘onion’ stakeholder framework [1]

Alexanders model contains four layers, each bigger than the one before, but also consisting of all layers inside it [1]:

1. The kit – The hardware and software of the system. There are no humans in this layer.
2. Our system – The kit with its operators and operation rules.
3. The containing system – Our system plus any human beneficiaries of our system.
4. The wider environment – The containing system plus any other stakeholders.

This model helps us divide the stakeholders into relevant categories. It was developed to identify human roles in system development and suits the MobiHealth case very well on that premise.

There are two definitions given by Mitchell et al. on what a stakeholder is. In the broad view we have an individual or group who can affect or is affected by the achievement of the organisation's objective. As Mitchell et al. states, this definition leaves it open to “include virtually anyone” to be a stakeholder [20]. This definition does not support the creation of a business case, as it is very broad.

The given narrow definition of a stakeholder is a group “on which the organisation is dependent for its continued survival” [20]. This definition suits the need to identify stakeholders for a more specific case and to target them for interviews. This mostly narrows our targeted stakeholders down to the first three layers of the onion framework.

3.2 Modelling Methods

We chose the e3value method after evaluating two options for modelling the outcomes of the stakeholder analysis: the Business Model Canvas outlined by Osterwalder [24] and the e3value model outlined by Gordijn [9]. Both provide a clear insight in a complex business case, though in different ways.

The Business Model Canvas (BMC) aims to give “a transparent picture of a business and to externalize the relationships and dependencies of business elements” [23]. It consists of one page with 9 elements. Central element is the value proposition, with on the left the resources and actors needed to create the value and on the right the outgoing side, where the customer relations and segments and channels of reaching them will be described.

E3value is a modelling technique to visualise stakeholder relations and interests by creating value webs between actors [9]. It originated in the field of e-commerce [28], but it has shown its value in the music business and R&D in recent studies [28] [31].

Comparing the BMC and the e3value models we concluded that their core difference was in the nature of the model. The BMC focuses on the value propositions, where the e3value model focuses on stakeholder relations. With the goal of this research being analysing stakeholders and mapping their relations in an effective way, the e3value model was deemed the best fit.

4. LITERATURE REVIEW

Our literature review consists of a systematic search on several subjects. First, we will start with an overview of the current state of POCT.

We searched for TITLE-ABS-KEY ( poct OR "Point of Care" OR "Point-of-care" AND testing ) on Scopus and made a selection based on abstracts and source of the data. A search for synonyms of point-of-care resulted in the terms near-patient, decentralized, bedside diagnostic, and ancillary site. A quick search for these showed that they are underused and have become out of fashion, with point-of-care as the general accepted term.

From there, we selected papers based on their relevance through their abstracts.

To get a good overview of the state of POCT, Altieri and Camarca [2] give one of POCT being used in hospitals as early as 2001. Luppa et al. [18], Hale and Kost [10] add to that with an overview of more recent developments. These have been published in 2011 and 2009 respectively. They also differentiate clinical testing and personal testing and see possibilities of POCT extending to other areas. This combined gives a historical overview of POCT and how it has changed over the past 10 years, as well as a look into the possible future of POCT.

Visser et al. [30] researched older diabetes patients using POCT and their experiences with the technology. They give a good overview of POCT in practise and user experience with the technology. They show both positive and negative sides of the user experience with POCT and conclude the positives outweigh the negatives. To add to the benefits of POCT, Middendorf [19] discusses the added values of faster diagnostics.

Literature also shows signs of concern regarding the overly optimistic adaptation of POCT. Plebani [25] critiques the positive reception of POCT and calls for careful consideration of it before adopting it. St-Louis [27] did this already in 2000, and gives a detailed overview of pros and cons of POCT, including a cost benefit analysis, and touches on patient self-testing.

When looking at POCT and barriers of market entry, Herzlinger [11] points out the difficulties of introducing new technologies in healthcare, with a focus on the U.S. market. In addition, Francis and Martin state “all PoCT devices will require evidence of cost-effectiveness and delivery of efficiency dividends in order to become widely established in the healthcare system” [8]. This holds true, because the Organisation for Economic Co-operation and Development [22], Kotlikoff and Hagist [16], and Busse [3] stress the importance of savings in healthcare to be able to maintain the current level over a longer period of time. Davis and Erixon [4] conclude that such developments must happen without loss of healthcare quality.

Through personal communications we were alerted to a recent research by Kiwa Carity. It shows how POCT integrated in the healthcare chain for heart patients provides significant benefits.
Not only do they realise 26% savings throughout the whole chain over a 6 months research period, but they also lowered the amount of hospital stays with 52% [14].

5. STAKEHOLDER ANALYSIS
As discussed in the methods we performed two rounds of stakeholder analysis. The first being a preliminary mapping of stakeholders after an introduction to the case and an exploratory literature study. This would be followed by a round of interviews and a more thorough literature review, of which we spoke in chapter 4.

5.1 Preliminary Mapping
We started with a first round of mapping the ‘obvious stakeholders’ [26]. This list is based on the MobiHealth case description and a presentation given by the owner of the company, Peter Lems. A search with Dutch AND “Health care” AND “stakeholder” AND (POCT OR “Point of care”), performed with and without the Dutch keyword, on Scopus, Web of Science and Google Scholar resulted in no results that could be of use.

Table 1 shows the obvious stakeholders, based on the narrow definition we use to define stakeholders in light of the business case. We then continued to define the layer in which all of these stakeholders are categorised and sorted them by layer. The number corresponds with the list of layers.

5.2 First Round of Interviews
The next step in Pouloudi’s approach to identifying stakeholders is conducting the first round of interviews and doing a literature review. The results of our literature review are provided in chapter 3.

The goal of the first round of interviews was to enrich our understanding of the role of these stakeholders and for identifying new stakeholders. Five interviews were conducted formally, of which two by telephone, two at the site of which the stakeholders were employed and one through Skype. During these interviews we used a topic guide as a reference. We took paper notes on all interviews and recorded the non-phone interviews for reviewing purposes. It is worth noting all respondents were very willing to lay out their thoughts and talked freely during the conversations. Their responses were lengthy and they were eager to talk about POCT.

We deliberately contacted a broad sample of respondents, to create a scattered image for a first round of interviews, as this phase is still exploratory in regard to stakeholders.

This round of interviews gave several interesting pointers, building on the stakeholders we analysed as obvious. One respondent, an IT consultant in a lab that uses the MobilHealth system, pointed out that the system relies a lot on a coupling with the government IT infrastructure. It needs to retrieve and check the BSN (Dutch equivalent of U.S. social security number) before confirming the data entered in the laboratory information system. It was specifically mentioned that this dependency did cause at least a day of not being able to use the system.

Another respondent stated that they had a limited amount of simple POCT devices. The MobilHealth solution and POCT in general was deemed “convenient, but not really necessary.” And if the laboratory would be in charge of the operation and responsibilities, it would be an upside to have access to the technology rather than keep on doing it the current way.

Several of the respondents mentioned POCT as being a big up-and-coming development in all areas. They mentioned the rapid development of the technology and the likeness of adaptation on the consumer market was deemed very high. The growth within hospitals was noticeable already and several hospitals and applications were mentioned.

One respondent, a POCT manager, stressed the importance of adequate training for everyone involved in POCT. Coming from the field of laboratory testing, he pointed out that even the slightest of errors can derange the whole test. And this can even be worse when it goes unnoticed.

None of the respondents were negative regarding POCT or, if they used it, MobilHealth. The general tone of the interviews was positive and all were open for and interested in new innovations in this field. There were never any problems mentioned with MobilHealth, the only negative was the downtime on the government systems.

5.3 New stakeholders
Concluding these interview and taking into regard the literature review, we were able to refine our initial list of stakeholders as seen in Table 1, in the rightmost column.

We added the government BSN system and the government as stakeholders as they seem quite important actors. The government is included because of rules and regulations. The BSN system is listed as a specific stakeholder, because the MobiHealth system is largely dependent on it working and it operates independent from the law-making government.

Another stakeholder came forward through the interviews is the hospital. Often laboratories are working with hospitals and GPs or are even based in hospitals. If the laboratory is part of the hospital, the hospital will be the stakeholder with the financial means. On that same note we added the health insurance companies. From the interviews we got that they heavily influence what treatments get paid for and where the money goes.

The last stakeholder we got from the interviews is the GP-laboratory communication system company. This is the company that handles data transactions from the laboratory to the GP in the ‘old’ situation.

From our literature review we concluded that the patient also is an important factor in the system of MobilHealth. Not as a direct player, but as an actor about which the system revolves.

6. E3VALUE MODEL
With the data we collected through the interviews and the literature review, we will construct a set of e3value models correlating to the situation before and the situation after

<table>
<thead>
<tr>
<th>Layer</th>
<th>Obvious stakeholders</th>
<th>First round of interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>GP assistant</td>
<td>Government BSN system</td>
</tr>
<tr>
<td></td>
<td>Lab application manager</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>General practitioner</td>
<td>Patient</td>
</tr>
<tr>
<td></td>
<td>Lab clinical chemist</td>
<td>GP-lab communication system company</td>
</tr>
<tr>
<td></td>
<td>Hospital/Lab POCT manager</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>MobiHealth</td>
<td>Government</td>
</tr>
<tr>
<td></td>
<td>Laboratory (company)</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td>POCT device supplier</td>
<td>Health insurance companies</td>
</tr>
</tbody>
</table>
introducing MobiHealth’s solution for POCT device communication.

Through this we hope to answer the first two research questions and set the basis to answer the third.

Figure 3. Snippet of e3value model for ‘old’ case.

6.1 E3value Models
E3value assigns actors in two possible ways: as an actor or as a market segment. Parties that can consist of multiple actors, which can be grouped together, are displayed as market segments. Actors can have value activities, which are profitable for at least one of the actors. These are connected to value ports, which in turn have value transfers between them. Value actions or actors can have start and end stimuli and a value dependency path goes from one start stimulus to an end stimulus.

The government and the hospital have been extracted from the e3value models, as they are too abstract as entities to add value to this case. The full models are to be found in appendix A.

There are five constant value paths between both value models. The paths from the Patients and the Health Insurance Companies market segments do not change. The Patients need to get tested at the GP and the Health Insurance Companies provide insurance for the Patients and money for the Laboratories. The path from the POCT supplier to the Laboratories and then to the GP does not change either. For this scenario we chose the value model in which the POCT supplier delivers to GP through the laboratory, as the situation where they delivered to the GP directly would stand in the way of clearly outlining the MobiHealth case, without adding any new insights.

In the sections that do change, we see two different happenings. The first is the data, which goes from the GP to a Couriers and then through the Couriers to the Laboratories. This data then has to be entered manually and is then, as second part, sent to the GP through a third party system, as shown in Figure 3. In the new system all these transactions are automated and MobiHealth is the only third party actor in the sequence, displayed in Figure 4. In these models we mapped the value paths through the supplied information from the interviews and data we got from MobiHealth.

Figure 4. Snippet of e3value model with MobiHealth

7. CONCLUSION
We mapped the stakeholder network for the MobiHealth case, using data provided by MobiHealth as well as data gathered through the stakeholder analysis and literature review. This resulted in two e3value models showing a simplification of the current situation. However, due to the new request for faster data processing, checking with the government BSN system has become an external dependency that did not exist in the old situation.

From the interviews we confirm that the main proposition of MobiHealth, cutting down the amount of human actions, holds true. They also eliminate two data transporters in the process, filling the gap with themselves as the single party.

Our literature review showed that there might be oppression for POCT solutions, depending on whether the parties involved have conflicting interests or they are of a more conservative nature. Anything else we could say on changing stakeholder relations would be pure speculation.

We found three barriers of market entry for MobiHealth and other POCT cases:

1. New POCT solutions need to show their added value, as they mean changing systems and having a new
workflow. The value should not only be financial, but the use has to be proven over ‘nice to have’, citing one of the interviewees.

2. To reduce the barrier of entry, it would be advised to approach parties that have financial gain or at the very least no financial losses, but other gains, when adopting the system.

3. Another part to consider is creating a protocol for the use of POCT, as adopters seem to doubt good results from the tests and worry of users making mistakes, even though other research has shown this statement not to hold. Strong proof is needed to take away these concerns.

Companies wanting to enter the market with POCT solutions would do well to take into account these points, as they provide handles for an easier implementation of the product.

7.1 Discussion
This research is what it set out to be, a preliminary research in this area. The result might be highly subjective, due to the small interview sample and the fact that all respondents were willing to cooperate on an interview on POCT, which might give the results a positive bias towards adaptation and use of POCT.

The literary review done is quite an extensive introduction on the topic, but is very broad. It attempted to build an overview of POCT in recent years in a business context and does not take into account technologies that are currently being published about.

The e3value models are built on solid logic, but are not quantified. The modelling technique does lend itself for quantifying the model.

7.2 Future Research
Future research we advise can go in two directions. The first is a more specific look at the MobiHealth casus, including more interviews and quantifying the model. The second would be to reproduce this research using different cases and analysing other (western) healthcare markets to verify the conclusions.

8. REFERENCES


9. APPENDIX A

Appendix A – Figure 1. E3Value model without MobiHealth
Appendix A – Figure 2. E3value model with MobiHealth