

Doctor of Philosophy (PhD) Thesis

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NEMZETI
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**“Analysis of the integration of mobile technology in specialized administration systems,
particularly in e-health in public services”**

Author's summary of the doctoral (PhD) dissertation

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1 Table of contents

Contents

1 Table of contents.....	3
2 Formulating the scientific problem.....	3
3 Purposes of the research	5
4 Hypotheses of the research	5
5 Research methods.....	6
6 Brief description of each chapter of the study carried out	7
7 Summarized conclusions.....	9
8 Practical usefulness of new scientific results, recommendations.....	11
9 Suggestion for further continuation of the research	12

2 Formulating the scientific problem

The M2M acronym originates from the English expression “Machine to Machine”. As it turns out from the translation, the M2M technology gives a solution for the communication of machines between each other. In this case, when we use the “M2M technology” expression we refer to systems, which perform measuring/sensing task on remote endpoints, upload the measured data into a central computer (database) or in the cloud, where data processing is done. Due to the processing of the data the center performs the tasks which have to be implemented in case of the particular service (it controls the remote endpoints in certain cases).

The massive spread of the M2M/IoT technology encounters serious obstacles. The main cause of it is the complexity of the fields and the quantity and the diversity of the cooperating components and sub-systems. These factors make it excessively difficult to state if the related, existing infrastructure elements, the regulatory background, the market conditions stemming from globalization, the local consumption habits and the interoperability of the technologies allow the start-up and the long-term maintenance of a given service. The scientific defining and systematizing of the research of the conditions of the M2M systems, the examination whether the components of the system are available and the examination of their interoperability, the analysis of the best practices and options, and the prototypes of services are of paramount importance. Examining today’s M2M systems we can state that they are typically non-compatible independent systems, which concentrate on a narrow range of applications. This is the reason why M2M systems have to implement every function, and they have to build their own dedicated infrastructure and they cannot apply any cost of cost sharing.

The mobile technology, the M2M/IoT technology in public services, the application of the technology in the fields of medicine, the e-health systems and services currently applied in

health care, the so-called telemedicine systems and the examination of the applied service chain are in the center of my researches.

My research field is the telemedicine ecosystem, where the different optional frameworks, the functional and non-functional requirements defined by medical researchers and professional literature, the capabilities of hardware solutions (e.g. sensor, phone) determinate the state space. I searched organizing principles and regularities in this system, which I could write down as planning patterns (hypothesis). The validation of the hypotheses (measurement of planning patterns) could happen only as I realized the functionalities, given due to the examined planning pattern, in the Uzsoki Street Hospital, and I measured the characteristics of the given planning pattern set. The measurements are derivable from systems which operate and provide real telemedicine services also used by users. For this purpose, I carried out researches within the framework of real clinical researches, with the help of the services provided by the system. After this measurement, I could determine the developed methodology, protocol, software architecture including the weak points of the developed planning patterns by analyzing the measured data. Then I could modify and collect them into a new integration.

More than 200 patients were involved in the research performed in Uzsoki Street Hospital. They were involved in the fulfillment of telemedicine tests performed on real patients. The patients got telemedicine devices during the research performed in Uzsoki Street Hospital. I collected and analyzed the feedbacks from the patients, the physicians and from the telemedicine measuring instruments, and I managed and supported the operability of the telemedicine K+F system. The evaluation of the questionnaires filled in by the patients and the physicians involved in the research, the measurement of user habits and the evaluation of the statistics of the reported errors were one of the main point of the research. The devices applied during the research: personal scales, blood pressure meters, blood glucose meters, ECG devices and medication dispensing units.

The scientifically raising problem of the telemedicine service research is how we could separate the roles of measuring technology, communication, data storage and health care service. One of the main reasons of the separation is the determination of the responsibilities, namely what the given participant in the given service chain is responsible for, furthermore what services, why and how the participant provides.

Protecting the health of the population living in the settlement is a top priority task for the leaders of every local government. I am going to research the simplified telemedicine model of the Uzsoki Street Hospital in the next chapter of the dissertation, based on the case study performed in the government of Csepel, which is the 21st district of Budapest. The essence of the model showed in the case study we transmit the data generated at different places and time from the patients are transferred by us to a central utility factor, where the physicians are able to evaluate the incoming data according to the rules set out by medical experts handling requirements (protocols) and the results of the evaluation – in a clearly understandable way, together with the messages of the local government – are sent to the affected resident and to the professional participants involved in the project too.

3 Purposes of the research

The research objectives of my investigation of M2M: to research and analyse whether the M2M technology is applicable massively and routinely. Furthermore, to define and test concrete systems, algorithms and the prototypes of M2M service in a selected focus area. As an additional objective, I wanted to examine the implementation of the M2M technology in a given segment, in the health care system. The basic objective of my research is the comprehensive analysis of the new methods and principles provided by M2M technologies. Partial solutions exist in this area currently, which do not cover the entire needs of the customer on the one hand, and inhibit the open, standards-based integration on the other hand. The primary aim of my research performed in Uzsoki Street Hospital was to prove that the application of telemedicine devices, the remote monitoring and telecare services improved the patients' condition.

Secondary objectives: to prove that the compliance of patients involved in the research improve during remote monitoring and telecare services, thus their treatment becomes more effective. Another aim was to discover those process and system management tasks, which enable the actual appearance of telemedicine procedures in real health care processes in Remote Patient Monitoring systems. The technological purpose of my research, which covers the whole production chain of telemedicine utility model data collection and service: the data collection, the sensor center, the transfer and the storage of the data and the processing and visualization of the data at multiple levels.

4 Hypotheses of the research

- H1 –

The borderline between the “collection and transmission of the data” function and the “processing of data” function is not entirely clear in case of M2M applications used in health care system.

- H2 –

Savings can be achieved, the quality and the safety of services can be increased and certain areas of the health care system get automatable if we use M2M applications in the field of health care.

- H3 –

The telemedicine service utility model developed during the research separates effectively the four functions which build up the M2M applications used in health care system (measurement technology, communication, data management and health care services) and assigns participants, competence and responsibility to these functions.

- H4 –

The telemedicine utility model which is developed by the local governments and is elaborated and simplified during the research provides an e-health public service which is easy-to-handle,

available for ordinary citizens. This service gives a hand to develop and actualize a long-term, successful prevention and disease-therapy policy for medical professionals and citizens.

5 Research methods

I filled the frames provided by the “System of System” approach with my own practical content in the 1st and 2nd phase of the M2M research, thus my method which I used to solve the research problem was created. We can compile functional models with formal methods in an abstract way by the application of the methodology. These models are suitable for the specification of the connected surfaces, the formal checking of the relation between existing surfaces and formulating processes.

I divided the methodology of my research performed in Uzsoki Street Hospital into two levels depending on the functions and circumstances of testing:

1. Laboratory testing methodology

2. Hospital testing methodology. More than 200 patients of Uzsoki Street Hospital were involved in the research during the performance of telemedicine testing.

I applied living laboratory-based development methodology during the performance of telemedicine testing in Uzsoki Street Hospital. It shows the importance of the methodology that several K+F project in the EU deal with especially living laboratory-based methodology and with the adaptation of them. The iterative, cyclical development model which is the basic idea of the methodology is not new. It has been used for a long time in the world of software development and it practically replaced the traditional waterfall model.

The task of the first phase during telemedicine research protocol performed in Uzsoki Street Hospital was to finalize the research, define the partners and experts, define the development process and to give a final work plan for the second phase. The three main issues of the first phase:

- To develop strategy conception based on common framework and integrated model.
- To select two of the most promising telehealth application types considering technical and market aspects, after reviewing the customer, professional and financial criteria of telemedicine services, and to define service development strategy.
- To develop a pilot project plan for testing the system the aim of which is to support the two selected type of diseases in a telemedical way.

The purpose of the second phase was the development, the living lab experiments and their evaluation. I divided the second phase into three sections considering the living lab methodology and the time constraints:

- The development and the authorization of the protocol of the experimental pilot project.
- Carrying out tests.
- Refine and detail the necessary evaluation and service development strategy based on the evaluation of the tests.

Hospital testing methodology – applicability experiments of Uzsoki Street Hospital:

- Issues of the everyday usage of the device:
- Perform simultaneous measurements in case of inpatients, during which the results are comparable with the values given by other medical devices.
- Collecting the experiences of the users with questionnaire technique.
- Qualitative data collection among the affected physicians (general practitioners, cardiologists), on the basis of a list of questions.

I started the prevention program with the classic waterfall model in the local government of Csepel, 21st district of Budapest, but the closing of the research was uncertain. Iterations were also needed during the research. These iterative circles were moved along the definition of the problem, the analyzation and the weighting of options, the selection of the way to follow, the implementation and the evaluation process. In this respect, process-based (agile) research procession characterizes better my research activity.

6 Brief description of each chapter of the study carried out

The M2M research: the sensor networks based on M2M systems have demonstrated their potential. The public administration and the health care system make the data collecting, - management and – processing areas to face challenges. At the time of the starting of the research, considering that the application of the research results in relation to “System of Systems” were connected almost exclusively to the military industry and the different branches of the army, the civilian application of the methodology and the existing knowledge clearly has a novelty value. The analysis performed in the first phase of the M2M research is an important step forward, during which I systematized and prioritized the potential M2M applications in terms of the domestic market.

I started the research and the analysis of the M2M services with the development of new analytical methodology, which methodology defines ranking and priority between the different M2M applications and services based on the different applicability conditions. I defined the 12 most important M2M services usable in health care system based on my analyses. The developed methods, prototypes and algorithms were integrated into minimum one telemedicine system in the following section of the research, which was performed in Uzsoki Street Hospital.

The research performed in Uzsoki Street Hospital: I emphasized two types of diseases during my researches, monitoring and therapy support of high blood pressure; home monitoring of diabetes. I focused on the analyzation of service-organization models during my research. I modelled a simplified version of the M2M Platform in Uzsoki Street Hospital, in which the services and the products are based on four fundamental and distinct functions. These functions are the following:

1. measuring technology function,
2. communication function,
3. data storage/data protection function,
4. health service function.

We define the functions from 1 to 3 as Telemedicine Monitoring Service Chain. The companies which provide the health service function - which is the fourth function – can be internet consulting firms specializing in prevention, or public or private health service providers, which use the same M2M Platform. The remote monitoring and telecare research performed in Uzsoki Street Hospital start out from the fact that the participation of some of the diabetic patients in the supply system is insufficient, their maintenance is deficient, they do not take advantages of opportunities given by seconder prevention. Due to this fact, their disease which has a progressive nature burdens on the supply system with more and quickly formed complications and with complex and expensive treatment. Ideally, the patient diagnosed with diabetes participates in monitoring and visits consultations with a specialist, with a regularity determined by care protocols. Thus, the progression of the disease can be slowed down as much as possible and the treatments which can be performed at a lower cost may continue for the longest time.

The real-time monitoring of patients was realized in a way that the patient and the care provider had not met, by transmitting the results of the measurement of remote monitoring devices (blood glucose meter, blood pressure meter, peak flow meter, pulseoximeter, spirometer, ECG etc.). In the practice up to now, considering that the patient visits the specialist consultation every three months, the hospital medical team had the possibility to make consequences of the happenings of the period between two appearances every three months, from the care diary which the patient brought with himself. In case of need, the physicians of the institute did not have the possibility to interfere due to lack of information. The telemedicine measurement data of the patients were listed continuously.

The **mobile ECG** test of Uzsoki Street Hospital was a clinical II. Phase test, the aim of which was to form the user interface according to the needs of the physicians besides proving the operability of the system on patients. The target of the system is to satisfy the relevant medical professional need, on the platform adapted to the technical possibilities of the current era. Basically, the conception was well-received among the surveyed patients. As they are afraid of the recurrence of the disease, they would appreciate receiving closer medical control, the continuous monitoring would give them a feeling of safety. An essential condition of the patients considering the mobile ECG was to be comfortable and small, to fit in their pocket. They think that it would be a good solution if it was not necessary to wear it all the time. They would use it only in case of complaints, similarly to blood pressure meters on the market. The system still deals with reliability problems in its testing phase, however, to bring the developed achievement market into a mature state for the market can be a realistic goal. The physical size of the monitoring system is significantly below the expectations of the current era. The current development of the detectors of the device is able to satisfy the need of the classic medical monitoring basically. This development is tolerated by the patients for 1-2 days, but if they wear it for longer time it extensively burdens their tolerance, but the more conscious patients accept the wearing of the system for 5-7 days. It is necessary to develop special electrode placement and mounting system to satisfy other market segments. The classic event recorder-like operation of the system, when only events experienced by patients are recorded – results a wasteful management of resources. The monitoring will have relatively low increment despite the

relatively high power consumption and the prolonged patient discomfort. The development of the home-page is basically user-friendly, the development of the pages proceeds at satisfactory pace.

I could perform **compliance and adherence research** involving 50 people with the help of the medicine dispenser. It is a well-known adherence and compliance research result that the inadequate cooperation of the patients is a serious problem in every country in the world. During my compliance and adherence research performed in the Uzsoki Street Hospital, I created a unique methodology and protocol based on Medimi type medical dispenser of Medicpen company. We could significantly increase the adherence level of the patients involved in the research with the help of this methodology. The research aimed at the measurement of all types of non-adherence with the help of Medimi devices and with the applied protocol. In case of some patients, the so-called drug holiday was recorded during the research. In case of drug holiday, most of the patients do not take their medicine as it was necessary to impart their expected impact. The compliance and adherence research in Uzsoki Street Hospital was performed during the Christmas period, when the drug holiday was really frequent among most of the patients. During the research, we confirmed the adherence level by measurements too, we identified the three factors available in literature during the evaluation of questionnaire surveys and interviews.

1. Commitment – (mental, spiritual and emotional)
2. Costs of the medicines – it was the most important fact in case of 60% of the patients involved in the research
3. Obstacles in care or medication.

One of my tasks during my research of Preventive Program Health Communication based on the **case study performed in the local government of Csepel, 21st district of Budapest** was to examine that how it would be possible to accelerate the processes of the local government, and how we would maintain a more effective prevention communication with patients/citizens. I performed the examinations in two ways: personal interviews and questionnaire surveys.

According to the in-depth interviews, the local government is open to use digital technology in the area of Preventive Program Health Communication. Based on the analysis of the results, we can say that the municipal workers are open-minded and most of them believe that computer science and online services can improve efficiency. One of the most important tasks in today's legislative activity is the modernization of public administration in line with modern requirements and its necessary transformation, and within this framework to create a real servicing state. The relationship between the client (patient) and the local government seems to be the most problematic area among research areas.

7 Summarized conclusions

Clear, professionally established service- and organizational models are needed to provide more and more available telemedicine services and solutions for the market. The multi-player market (the insurer, the customer, the sensor manufacturer, the physician and the info-communication partner) meant a cooperation researching activity.

The interdisciplinary approach of the telemedicine project of Uzsoki Street Hospital based on optimization of many parameters, and the synthesis of medical, engineering, telecommunication, process management, economic and legal knowledge assisted to uncover those reasons or rather to understand the relevant conditions, which stand in the way of the spread of the new procedures which target the diagnostic, monitoring and therapy support, and which also helped to define the focus of the following developments.

More effective methods of measurement have been established compared to previous methods by achieving goals defined during my investigation, I could better get acquainted with the reliability boundaries of telemedicine measurements. The developed hardware and software prototypes can be the basis of carrying out additional measurement series and examinations.

The selected disease groups (heart failure, hypertension) for testing telemedicine applications proved to be suitable for testing telemedicine technology. The tests proved, that the chronic treatment of these diseases is a perspective area, which can demonstrate the efficiency improvements and health profits achievable by using telemedicine application in a further large-sample regional project.

The telemedicine technology proved to be operable, and the services proved to be applicable. The model, the training and the tele-support was sufficient for physicians and nurses with no IT knowledge – after training and installation – to perform the operation and the software update without my personal involvement. Serious difficulties of implementation have not exhausted in the usage of the system.

Ensuring the reality content of the data – bypassing of the patient - proved to be a serious professional advantage for diabetic patients. In case of the conventional blood glucose measurement at home, about 50% of the data written manually in the blood glucose diary is generally false. The reason of that can be that the patient forgot to measure the blood glucose level and tried to disguise it or he or she had bad results and tried to make the results better. It is a very important positive aspect of the mentioned telemedicine system that it is able to produce practically 100% real data, and to log it credibly whether the measurement actually happened. Its medical and therapeutic importance is very significant.

Due to the continuous mobile home monitoring of the blood pressure and the weight of patients with heart failure, in time we are able to identify processes (e.g. abnormal increase of body weight) which would be treatable only with significantly higher medical and financial expenses, if they were revealed much later, in the consulting room.

Beyond concrete, physically tangible telemedicine results, it is important to the same extent to create a research group which is cooperative along the interdisciplinary connections and which has comprehensive knowledge in the field of telemedicine reference architecture. In many cases, the compliance and adherence research in Uzsoki Street Hospital was able to provide more precise data than those provided by many national and international research results available so far. At the same time, the dramatically unfavourable national data of the compliance and adherence pilot project also means a rare possibility, as we could start further researches with the support of the medical profession. The research done so far will be followed by further analyses.

The patients will continue using the Medimi medicine dispenser, produced by the Swedish Medicpen company, on a daily basis and the researchers will work out newer methodology, questionnaire-systems based on the innovative medicine dispensing technology, and they will conduct examinations about newer therapeutic areas.

8 Practical usefulness of new scientific results, recommendations

Applying mobile technology and M2M in health care, exploring the possibilities of telemedical services are such a new innovative area that can radically change the everyday practice of prevention, diagnostics and therapy and at the same time they reserve significant market opportunities for health care service providers and device manufacturers. The condition of using this professional and market potentiality and that of developing the future telemedical and e-health services is the proper integration, testing of already existing technological and service elements, also their integration into the clinical environment. The national small and medium-sized enterprises can start implementing the M2M Platform, defined during this research, also implementing the Telemedical Monitoring Service Chain in health care and they can build up real services using the protocol and research results. During my researches, I have studied not only commercially available telemedical devices but new prototypes as well. Canvas and VIRO models of Medistance service can help the appearance of new market participants. During the analysis of arterial stiffness, on the basis of literature overview, using the results of the deep interviews given by Dr. András Csaba Nagy and Domokos Csuka there was a GINOP application prepared for further development of the Arteriograph device. Beside the traditional manual data entry, it also provides the recording and transferring data which arrive electronically from more developed devices. Beside function serving primer prevention, the complex solution can also be perfectly applied in medical practice for therapy tracking and for improving its effectiveness too.

As a result of the research, a planning sample family were created and with their help the software solution and concrete implementation. The software solution was suitable already in the meantime status to help the medical partner researchers with their fundamental researches aimed by them. As a result of the research, a telemedical planning sample collection is being formed at architectural and operative levels, which concentrates on an environment to be established on outsourced units/mobile phones. With the help of this environment, the phone has become an integral part of the telemedical system.

Compliance and adherence, that is patient cooperation is not a mere health care issue, but it means a borderline area among the ideas of economics, medicine, behavioral and other management sciences. The patients' adherence level was possible to be increased during the research done with the Medimi medicine dispenser. The protocol and methodology which was created can be used in other medical fields as well.

I have simplified the protocol made in Uzsoki Street Hospital and adapted it to the needs of the local government by the request of Csepel Local Government in the 21st district of Budapest and that of Ilona Tóth Health Care Service Specialist Clinic, which operates in the district. Csepel

Local Government of 21st District of Budapest supported the prepared protocol and the start-up of the program the name of which is Prevention Program Health Communication in the form of a decree by the representative board members. The increase of the competence of primary care means increase of the effectiveness, regarding the fact that it creates a more expensive service at a higher level.

9 Suggestion for further continuation of the research

In accordance with my dissertation, I regard the research of the following topics to be expedient, justifiable and opportune:

1. Further analyses of being economical are needed in the field of M2M, because the competitiveness and marketability of M2M systems are defined by their specific total cost of ownership (TCO). In case of M2M systems it is especially important, and in several cases the technology would be given but the high TCO is the one that prevents the successful appearance in the market. Thus, to decrease the TCO is of critical importance for the successfulness of M2M sector.
2. In the next decade the most important challenge and also the great possibility in the market is the cardiovascular prevention. Cardiovascular diseases (CVD) are responsible for 47% of all deaths in Europe. 4 million in Europe, 1.9 million in EU. CVD cause a cost of 196 billion euros in EU countries. 54% of this cost is direct expenses, 24% comes from working impairment and 22% from other expenses. As for Hungary: cardiovascular diseases and the deaths due to them mean the loss of more than 60 000 human lives and 800 billion HUF loss for the economy of the country. Professionally established service-organizational models are required to have more telemedicinal services and solutions available and to be present in the market.
3. Increase of patient education is of critical importance. The condition of active therapy tracking is learning how to use the telemedicinal devices, the education of the patients, also the continuous and uninterrupted provision of IT services.
4. Increasing the motivation of the patients, improving the user experience of telemedicinal systems: Both the user interface and the applied devices have to be chosen in a way that their usage should be optimal for the targeted patients. We especially must take into consideration the patients' health conditions: for instance, in case of diabetic patients visual impairment has to be taken into account, also in case of old people arthritis, which makes the usage of medical devices more difficult. Accordingly, the aim of the telemedicinal system is that the users would be able to use their devices easily, without difficulties.
5. In health care and within it during the researches of telemedicinal services, the interaction of data protection, data security and transparency as well as their judgement is a concern for researchers and experts.