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THE RESPONSIBILITY OF TELEMEDICINE FOCUSED ORGANIZATIONS IN REGARDS TO CREATING COMPLIANT END USERS PRODUCTS AND SERVICES

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Abstract

The main purpose of the present study is to provide a highly comprehensive methodological solution for carrying out products/services which fully comply with customers (i.e. end users) functional and performance requirements in Telemedicine field, and furthermore to satisfy multitude end users simultaneously. By bringing into the light Systems Engineering (SE) as a multidisciplinary theory used preponderantly in the aero-space segment for realization of complex projects, the paper illustrates the way it can be fulfilled the Functional and Performance Requirements of the end users from Romanian (non) emergency medicine services in order to develop an innovative telemedicine product. The case study is based on two sets of qualitative researches as interviews in order to validate the telemedicine triggering idea among users, and to classify them, and secondly, as ample observations in order to gain insights on the users' scenarios and further to elaborate user requirements. Both sets of researches undertaken from users' specific environments were backed up with secondary information gained through document analysis. Relevant for this telemedicine research, it is the fact that the results of this survey have been already successfully used as a baseline to prototype the telemedicine product for Romanian market, in a European Space Agency (ESA) Project.

Keywords: end users/customers, telemedicine, Systems Engineering (SE), Portable Telemedicine Workstation (PTW), organizations' responsibility.

JEL Classification: M11, M15, O31, O32

Introduction

The nowadays businesses are defined not by means of organizations' name and statute, but through the extent the organizations' products and services satisfy the customers. In this respect, organizations' responsibility is very important to be taken in consideration in order to obtain a positive customer satisfaction, and implicitly, as consequence of applying customer centered strategies (Drucker, 2007). The strategies built around the customers are

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seen as of paramount importance in dealing with the increased competition, namely by focusing firstly on the users' needs, values and expectations in creating products and services according to specific user requirements, and gaining competitive advantage as result (McCann, 2011).

One of the most current thriving industries to which it needs to be paid considerable attention with regard to organizations' responsibility to consumers/end users and additionally to governments' specific regulatory (e.g. products safe and appropriate use and disposal as shown in World Health Organization - WHO, 2003), consists in medical devices and telemedicine industries. Thus, it is contended that Health Industry based on information technology brought significant contributions in the nowadays knowledge economy (Dinu and Curea, 2007; Zaharia et al., 2011). As it is evidenced by Vizitiu et al., 2013, via advanced telecommunication technologies, telemedicine has great impact on diagnostics and therapeutics by enhancing medical capabilities "across geographic, time, social and cultural barriers" (AMedP-37, 2012 p.1-1), as long as the medical devices and other technologies enclosed shall not jeopardize the safety of patients or end users (i.e. medical professionals), or worsening the clinical condition of the patients (WHO, 2003). Taking into account that the Telemedicine products and services are actually developed for increasing healthcare for society and implicitly bringing major economic benefits, the organizations within this industry have to deal with great challenges regarding engineering high tech telemedicine products and services for fulfilling the stringent needs of the medical end-users from emergency or non-emergency medicine branches. Thus, the real problems of Telemedicine organizations emerge in designing the proper products and services to comply with the medical end users' requirements in order to satisfy their expectations, whereby to undertake properly the medical activities for the patients/casualties.

This study proposes a specific solution based on the multidisciplinary Systems Engineering (SE) methodology used preponderantly in the last decades in aero-spatial segment for complex systems realization, as a solution to fully satisfy the end user both *Functional Requirements* with respect to "what is needed" for a product/service to accomplish certain activities, and *Performance Requirements* regarding "in what extent" are performed those activities by the future product/service. The paper provides as well an important research in the Telemedicine field with respect to successfully creation a Portable Telemedicine Workstation (PTW) which satisfies a wide range of Romanian medical end users' expectations with regard to the product functional and performance requirements.

The research consists in the application of the SE methodology with certain novel improvements for tackling multitude types of end users simultaneously, and based on two sets of qualitative surveys among Romanian emergency and non-emergency medicine branches, it is illustrated the whole information treatment process elaborated, as follows: end users identification and classification; the approach used to determine the end users responsibilities, roles, current procedures and technological means in use; the elaboration of end users requirements along with the PTW proof-of-concept realization. Relevant for this PTW Telemedicine research originality, it is the fact that the results of this survey have been already used as a baseline for PTW prototyping within a European Space Agency (ESA) Project oriented exclusively towards the Romanian medicine market.

1. Telemedicine and the need of developers to initiate an end user centered approach

Generally, organizations have developed complex internal regulations in terms of audits and self evaluations in order to assure that their products stand at the top with regard to customers' preferences, mainly through quality safety standards imposed even from designing phase of the products and in this way to improve the quality of products and their trademarks (Pamfilie, 2010). Also, for increasing customers' satisfaction and confidence in certain products and services, organizations undertake both corporate social responsibility by implementing ISO 26000 (Smeureanu, et al., 2011), and efficient marketing by taking into account in a certain extent the customers' needs and promotional strategies (Plăiaș et al., 2011), and by targeting a combination of marketing communication through virtual social media and relational marketing in order to establish long-term profitable relationships with users (Popescu et al., 2013). More than that, some of the organizations focus on creating originality with respect to their products' design for impressing the customers (Pamfilie et al., 2013), while others appeal to European Eco-Label to improve their market image and implicitly, to enhance the credibility extent before the users (Dinu et al., 2012). Even if most of the nowadays companies tackled all kind of internal regulations to be end user/customer centered, this is just their perception, in reality continuing to carry out products and services and afterwards to search their customers (Slywotzky, Wise, & Weber, 2003; McCann, 2011).

Drucker (2007) asserted that the best approach to be fully oriented to customers is to get honest answers from them by means of specific methodologies and tools and not just reading their minds.

In this context, it has to be distinguished the Telemedicine field in which organizations' capabilities regarding products and services implementation shall deal not only with technological issues, but also with the medical users technology acceptance due to their unfamiliarity with high technology or conservative attitudes, and actually, that is why the physicians shall have "the most significant role in the implementation process" (Payton, 2000, p.315). As it is mentioned by the American Telemedicine Association (ATA), the solution for gaining acceptance consists in involving deeply in all the Telemedicine products/services development phases, the medical end users as *local champions* and obtaining certain support from medicine unit administrative institution in order to ensure the Telemedicine Systems acceptance and implicitly their total satisfaction (ATA, 2006).

Telemedicine, considered one of the greatest techniques in medical practice in our decade, encompasses numerous uses in diverse medical specialties in the frame of both emergency and non-emergency medicine, and through which it can be undertaken audio, video tele-interactions and medical data transmissions between patients and physicians or between medical professionals in order to strongly enhance the current healthcare quality level (Yeboah et al., 2003), but also to improve health care access and in the same time reducing costs (Whitacre, 2011; Paul et al., 1999).

As it is illustrated in "Report on the second global survey on eHealth" (WHO, 2010), according to the individuals involved in, Telemedicine can be classified into professional-to-health professional or health professional-to-patient, or from point of view of interaction timing, Telemedicine encompasses store-and-forward or real time systems. The types of the latter classification as real-time regard synchronous Telemedicine with little or insignificant latency (e.g. video-conferencing, telephone conversation etc.), whereas store-and-forward is

about collecting and storing offline medical data, and with a latency of even more than 24 hours, the data is forwarded to destination (e.g. e-mails, voice-mails etc.) (Barratt and Pool, 2008). These overall classification types emphasize the fact that besides different standards and regulations which Telemedicine products and services shall comply, the requirements of medical professionals (i.e. end users) and their affiliated medical units and institutions are to be taken seriously and actively in consideration by the Telemedicine Industry.

Thus, Telemedicine represents a tool developed by companies for health providers (i.e. the end-users' entities who are directly using the telemedicine systems/services) in the frame of their medical intervention activities to enlarge the traditional practice of medicine by means of wide variety of services as expressed by the American Telemedicine Association: Specialist referral service in terms of specialists assistance to general practitioners; Direct patient care between physicians and patients located in remote clinics, homes; Remote patient monitoring (i.e. "home telehealth") including telemetry devices to measure specific medical parameters and data transmission to physicians; Medical education and mentoring regarding medical seminars or second opinions between medical professionals; Consumer medical and health information with respect to informing properly the consumers and enabling peer-to-peer support in online conversations (ATA, 2006).

It has to be also mentioned that besides the fact that the major problem of Telemedicine organizations is to cope with gathering and understanding the end users' needs and requirements, they have also to take into consideration certain standards concerning medical devices safety and as well governmental regulations, aspects which at their turn shall be reflected in the end users' functional and performance requirements. The safety aspect regards the technical performance and effectiveness of the medical devices in their whole life span from conception to disposal as intended by manufacturers with respect to medical purposes, while the national regulations are based on regulatory controls towards the products safety, performance, quality and labeling requirements (WHO, 2003).

As consequence, the technical products residing to Telemedicine field shall stringently comply with the medicine end users' requirements, and in the same time with a very high extent of reliability, performance and functions, important aspects to be taken into account within organizations' responsibility in the telemedicine industry for fulfilling the needs of the targeted customers/end users. Furthermore, the Telemedicine products development phase shall involve, as expressed in "*Medical device regulations: global overview and guiding principles*" (WHO, 2003), specific processes as verification, validation and clinical trials.

2. Systems Engineering methodology as comprehensive solution for fulfilling end users' satisfaction regarding functional and performance requirements of products/services.

As it has emerged in literature, the real problem in Telemedicine field consists in utilizing a proper methodology for gathering and understanding end users' requirements, in order to convert these in products and services and fulfill the users'/medical units' expectations.

One of the main contributions of this paper, besides the depicted subsequent Telemedicine Case Study, consists in providing a methodological solution based on Systems Engineering (SE) theory as a comprehensive solution for organizations to end users'/customers' satisfaction issue.

SE is defined as an interdisciplinary and holistically approach for carrying out successful systems focusing concurrently on *"understanding stakeholder needs; exploring opportunities; documenting requirements; and synthesizing, verifying, validating, and evolving solutions while considering the complete problem, from system concept exploration through system disposal"* (Pyster et al., 2012, p. 1). In other words, SE is based on a sequence of activities and decisions towards identifying technological and market opportunities, and converting customers' operational needs into system specifications and configurations. In this context, a "system" has a broad meaning that could transcend the concept of simple technological equipment, and referring to complex composites of people, products, knowledge, and processes in order to obtain a solution to specific customers' needs (Department of Defense, 2001).

According to The International Council on Systems Engineering (INCOSE), SE has been developed 6 decades ago within aero-space and military sectors, and nowadays it is applied also in other areas where there is the real need to fulfill end users' strict requirements regarding functions and performance, and overall to provide the methodological capability to efficiently balance within three main project factors: users' needs, technological advance and resources (INCOSE, 2000).

Taking into consideration that a requirement is seen as an unambiguous statement identifying the future system characteristics for further validation with stakeholders (INCOSE, 2006), in this paper there are tackled only two types of requirements with direct influence on users' satisfaction, implicitly to be stressed in the organizations' responsibility to their customers/end users, namely requirements from the point of view of functions and performance. According to The National Aeronautics and Space Administration (NASA), Functional Requirements *"define what functions need to be done to accomplish the objectives"*, while Performance Requirements *"define how well the system needs to perform the functions"* (NASA, 2007, p.42). Hence, Functional Requirements express the future system capabilities in the users' specific environment taking in consideration aspects as standards, system boundaries, system security, constraints etc. (INCOSE, 2006), whereas Performance Requirements define quantitatively the extent of performing the required functions, by answering to some of the questions as follows: how well, what accuracy, what quality/quantity, under what stress, what capacity etc. (NASA, 2007)

The main SE function is *"to guide the engineering of complex systems"* (Kossiakoff et al., 2011, p.3), and includes besides a wide variety of engineering disciplines needed according to specific systems developments, also a management part with regard to guiding and leading the engineering effort itself. SE methodology demands both outside and inside perspective orientations upon the products in terms of taking into account the specific customers' operational needs and capabilities, environment constraints etc., but also the engineering design issues with regard to subsystems compatibility and interactions, along with qualitative judgments. Thus, SE encompasses in the same extent both engineering disciplines and as well, complex project planning and control management aspects, but also fields as quality management, human resource management, financial management, and others.

According to a research performed by Systems Engineering Effectiveness Committee, it was highlighted the importance of SE best practices from the quantitative point of view in terms of SE capabilities on Project Performance, as it is illustrated in the Figure no. 1. The numerically ordering of SE capabilities and Project Performance scores were labeled with

terms as "Lower", "Moderate" and "Higher" corresponding to the third interval of the responses. The Project performance was evaluated in terms of projects cost, schedule and scope performance, whereas SE capabilities with regard to Project Planning, Risk Management, Requirements Development and Management, Trade Studies, Product Architecture, Technical Solution, Product Integration, Verification, Validation, Configuration Management, Integrated Product Team-Related Capability whose relationships to Project Performance were positively assessed, and regard to Project Monitoring and Control whose relationship to Project Performance was negatively determined (Elm et al., 2008).

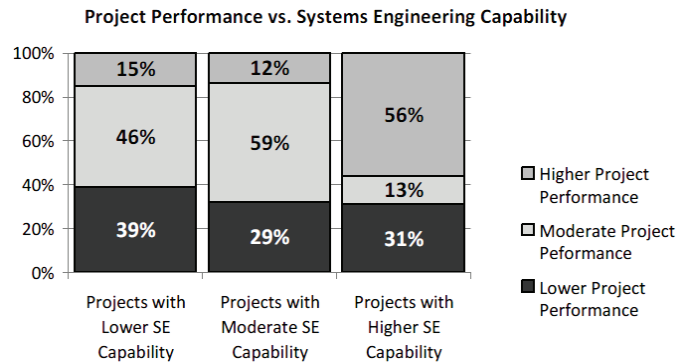


Figure no. 1: Project Performance versus Systems Engineering Capability.

Source: Elm et al., 2008, p. xxiv.

As arise from the previous research, and also as National Aeronautics and Space Administration (NASA) asserted (NASA, 1995; 2007), SE main objective consists in realization of products responsive to customers' interests by targeting the highest Project Performance and cost-effective solutions.

Taking into account that a project life cycle in SE field encompasses the distinct phases of a project along with corresponding control gates, in order to reflect the evolution of a product/service from conception to disposal (Pyster et al., 2012; NASA, 1995), one of the most popular life cycle process models which is entitled "Vee Model" and tackles exploratory research, concept, and development phases of SE, and emphasize vital aspects as continuous risk and opportunity evaluation, verification planning, and as well continuous validation with the end users (INCOSE, 2006).

It has been distinguished *as critical activities* within SE process, the identification of users and gaining insights on their needs and requirements in order to define the proper products/services specifications and to support the further main SE activities (Vizitiu et al., 2013). Furthermore, requirements defined as statements that identify product/service capabilities or characteristics which bring value or have utility for users or customers, influence directly and positively the product/service success with respect to customers' satisfaction, but also the project cost and schedule (Young, R.R., 2004).

The significant importance of the requirements process is proved also by the following two statistics from the literature: 66% of IT based systems fail in fulfilling the end users' needs or by inducing project cost and schedule overruns due to deficit requirements, changing

requirements, and lack of users involvement; another research shows that 40 to 60% of systems developments defects stem from scarce requirements determination, which at their turn account around 40% of the total project budget (McAlliste, 2006).

According to the idea that on-time, on-budget and successfully projects are based on a solid detailed requirement process, The Standish Group Report based on 8380 applications asserted as it is shown in the Figure no. 2, that around 31% of projects are failures, around 53% with incomplete requirements implementations and as well cost and schedule overruns, and just 16% of the projects with all initial requirements implemented (The Standish Group, 1995).

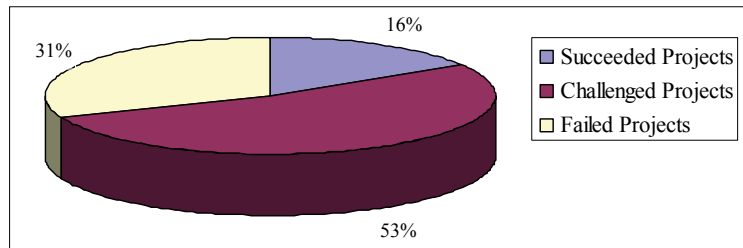


Figure no. 2: Results of the survey based on elaboration requirement process.
Source: Adapted from (The Standish Group, 1995)

Hence, one of the most delicate aspect of a project in influencing the customers' satisfaction and implicitly, the cost and schedule of a project consists in End-Users Requirements Definition Process whose activities lay in identifying the interested stakeholders and their needs, elicit requirements by creating scenarios and concept documents, indentifying constraints of environment, defining the product definition and establishing effectiveness measures objectives in order to measure as well the end users' satisfaction (INCOSE, 2006). Thus, determining correctly the user requirements is crucial in organizations' responsibility with regard to customer increased satisfaction, and succeeding in this way both to maintain the existing customers, but also to gain successfully new others.

3. Research methodology.

The herein case study residing to Telemedicine field illustrates a successfully way based on the application of SE methodology in practice, in order identify and classify the end users, to elicit and analyze specific end user needs, as well integrate and validate the functional and performance requirements to the users accordingly, with the purpose to gain maximum end user satisfaction on functional and performance niche. This case study provides a better understanding in applying the SE methodology upon the complex Telemedicine field, whose actual origin is the aero-space segment.

Within the case study there are used two sets of qualitative research methodologies used separately, with different purposes as it is explained in the followings.

Thus, the 1st set of information has been collected by means of 21 semi-structured interviews undertaken through direct and open conversations with medicine actors whose medical activities were assumed at the beginning of the survey to be influenced in certain extent by Telemedicine. It was utilized the qualitative method of interviews in order to

gather as much as possible significant and objective information for validating firstly the medical users' need for mobile telemedicine in remote areas and in the same time deepening more in the users' telemedicine related problems and needs, and secondly, to identify the type of activities and roles of the interviewed medicine users within the medicine intervention situations for a subsequently classification of the end users. The questionnaires have been analyzed and the results were backed up with secondary information gained through document analysis research regarding internal and strategic documents. Important and relevant to the information credibility, it is the fact that the types of interviewed medical actors were experienced medical professional individuals, medical team members and/or their managers from different medicine services.

The 2nd set of information has been collected after the end users were classified based on the 1st set of information, by means of qualitative participant observation during circa three weeks in the users' specific environments with the purpose to gain in depth insights upon their specific scenarios. These scenarios, also called "use cases", have been very useful in determining users' technological means in use and in the same time usability targets. During the naturalistic observation, the procedures used by experienced medicine professional individuals in different events and environments were captured in the qualitative observation grills, developed as use case flowcharts. In order to gain proper and objective information, the results stemmed from participant observations were backed up with secondary information gained through document analysis research regarding internal medicine operational unit documents with respect to detailing users' responsibilities and roles. Hence, it has been developed 9 use case flowcharts with regard to established scenario medicine interventions. The results of the 2nd set of qualitative research strongly contributed to identify users' technological limitations in use, fact of extreme importance to express the users' functional and performance requirements.

In both sets of qualitative research surveys, the possible limitations could arise from the medical users' limited time available for the interviews, and also available to host the researchers as observers taking into consideration the complexity of intervention medicine procedures. Regarding a limitation of document analysis, it can be emphasized the restricted access of researchers to internal documents. The names of the professional individuals and their residing medicine services entities as participants to this survey are confidential, and in consequence will not be disclosed within this paper. Although, it has to be emphasized that all the end user participants and their corresponding medicine services are exclusively from Romania.

In the following Telemedicine case study, it will be illustrated the whole information value chain based on SE methodology and capitalized the two sets of qualitative research information for achieving satisfaction upon end users' functional and performance requirements.

4. Specific Systems Engineering methodology applied within Telemedicine Field. Case Study

4.1 Case Study Overview. Mobile Telemedicine

The present case study provides a comprehensive image upon the realization of a state-of-the-art mobile telemedicine concept called Portable Telemedicine Workstation (PTW) whose purpose was to satisfy the functional and performance requirements according to a

wide range of end users' needs with regard to medical pre-hospital assistance for medicine emergencies, but also to support health screening activities in Romania, both type of activities undertaken in remote areas. Relevant to the survey accreditation is that the study deployment and results were capitalized and further supported by a European Space Agency (ESA) Project into developing a Telemedicine service for Romanian tackled end users, as shown in (ESA Contract, 2010).

The triggering factors of the PTW feasibility study consisted in the opportunity to capitalize satellite communication and navigation advanced technologies in Telemedicine field based on the premise that Romania encompasses numerous remote areas with un(under)developed terrestrial communication infrastructures (i.e. over 50% of the country out of 3G telecommunication network) where certain medical end users are unable to perform Telemedicine acts. It has to be also emphasized the fact that the end users identification and classification process is made by means of a specific approach brought by the project team (Vizitiu et. al, 2013; ESA Contract, 2010) in the SE methodology, it is seen as a methodological improvement by taking into consideration simultaneously the needs of multitude end users mainly from Emergency Medicine (EM), and also from Non-Emergency Medicine (N-EM), as very few Telemedicine products are capable of. Thus, this study represents a benefit that can be used in fulfilling the organizations' responsibility to the targeted end users/customers.

4.2 Systems Engineering Information Treatment Chain Illustration

4.2.1 End Users Identification and Classification Process

It has been identified end users residing to EM and N-EM services as professional individuals, medical team members, chef units, such as to reflect the point of view of major actors from their specific groups. These end users were subjected to the semi-structured interviews undertaken through direct and open conversations (i.e. the 1st set of research methodology) in order to find out whether there is a need for mobile Telemedicine within remote areas, and also about their specific roles within the medical value chain.

The information from interviews was analyzed by passing it through three procedures as data reduction, data display and conclusions verification. The conclusions were verified also with findings from different documents, and as result, these have emphasized almost among all the subjects the difficultness of undertaking medical interventions in remote, inaccessible-by-vehicle areas in order to deploy telemedicine acts due to the fact that their specific telemedicine equipments are not suited for the long range pedestrian approach or non-existent, and secondly, all of them acknowledged the real benefit of deploying telemedicine acts especially in remote areas. The interviews provided also information (also called "*primary information*") about the end users' units roles and type of interventions, very useful actually for classifying the identified selected medical actors into a bottom-up approach, namely into collective end users (i.e. entities grouping individual actors with similar actions in their interventions), categories (i.e. entities grouping collective end users with similar roles) and branches distinguishing among end user categories residing to EM and N-EMS, respectively, as it is illustrated in the Figure no. 3.

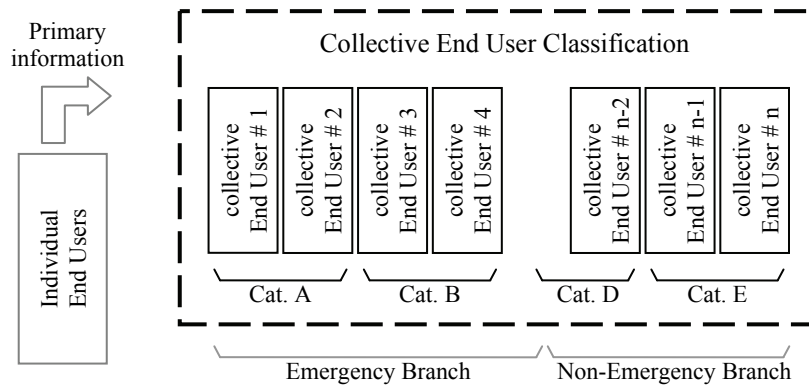


Figure no. 3: Specific SE methodology regarding end users classification.
 Source: ESA Contract, 2010.

As the interview provided several patterns of similarities among the questioned actors, this classification was undertaken in order to avoid duplication and to streamline the requirement process. Thus, the end user classification summary is the following: CATEGORIES encompassing *Medical Dispatchers (as Emergency Medicine Dispatchers-EMD, Telemedicine Centers etc.)*; *Intervention Teams (as EM Services, Mountain and Cave Rescuers etc.)*; *General Practitioners Wards*; *Disaster Management Commands* in the frame of EM Branch, while the last Category entitled *Health Screening Teams (as General Health Screening Teams, Cancer Screening Teams etc.)* in the frame of N-EM Branch.

4.2.2 Use Cases

Based on the 2nd set of information collected by means of participant observation at users, it has been developed use case flowcharts corresponding to specific scenarios as are expressed in the Figure no. 4.

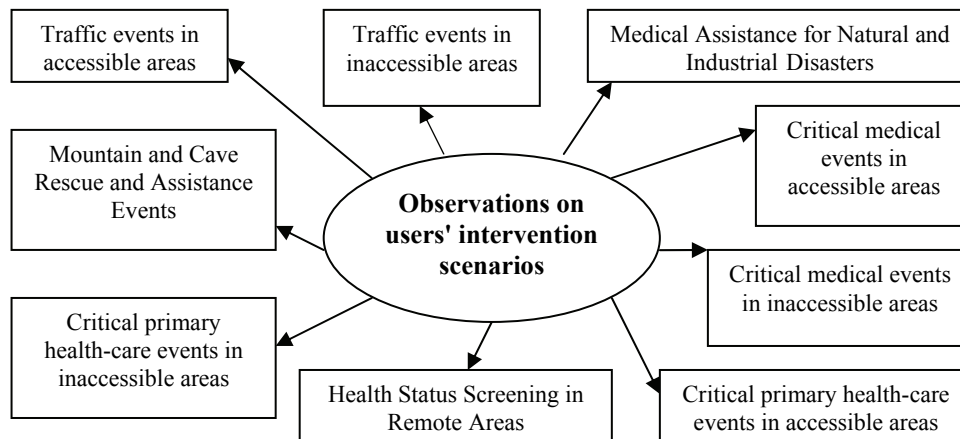


Figure no. 4: Overview on structuring the Use Cases.

By means of use cases, it has been gained in-depth insights about users' procedures and their technological means in use. Of great importance is the fact that the telemedicine products developers can obtain in this manner a human centered design perspective which at its turn could be very useful in achieving end users' satisfaction. The main outputs of use cases corresponding each to a relevant intervention scenario consist in identifying users' technological limitations in use, implicitly their problems, but also how they work around for overcoming certain problems or limitation.

Hence, by use cases there is gained comprehensive understanding on users' problems and needs, fact of extreme importance to express further the functional and performance requirements.

4.2.3 End Users Functional and Performance Requirements

User Requirements are statements expressed by the product/service developer in an unambiguous and verifiable way, describing the future system so that to satisfy integrally or partially the user needs.

Summarizing User Requirements elaborated within the Telemedicine Project, it can be highlighted the distinction between functional and performance aspects, as well the fact that the statements do not show how to implement the system, but what the system shall be able to do and the performance extents, accordingly.

The Functional Requirements of the telemedicine system regarded functions as: audio/video transmission-reception in real time and unidirectional medical data (as determined within the user needs) transmission from in field intervention scene towards a dispatcher in order to deploy telemedicine acts; the capability of the system to communicate data also from areas with un(under)developed mobile telephony infrastructures (the developer taking into consideration the satellite communication technology); the capability of the system to provide navigation and localization information, as well very important to have the capability to be carried also in the pedestrian approach. Other Functional Requirements took into account also constraints aspects (e.g. physical limitations, environmental impacts etc), human interface aspects, system compatibilities with the users' infrastructures, standards with respect to medicine field etc.

As concerning the Performance Requirements, these reflected specific attributes of the future telemedicine product as follows: weight, autonomy, broadband capacity, video accuracy, medical data transmission latency, communication deployment, and a certain water ingress protection and mechanical impact protection corresponding to operational users' environments. All the Performance Requirements were defined quantitative as threshold value (i.e. minimum value needed for the system) or baseline (i.e. maximum value needed).

Important to be mentioned is the fact that the documented requirements, also traceable to end user needs, use cases, collective end users, were firstly agreed by the end users in a meeting, before the developer to start validating them from the technical point of view.

4.2.4 Requirements Validation

Once the list of User Requirements has been developed, it has been built a technical PTW "proof-of-concept", also called PTW-FM (i.e. PTW-Functional Model which was actually a partial implementation of PTW), based on which it were tested the requirements considered

vital in demonstrating the technical PTW concept specificity. PTW-FM was developed to technically validate and refine, if the case, the User Requirements in order the developer to forward to prototyping and pilot application phases. Based on the PTW-FM, it has been made several tests campaigns within end users' infrastructures and in their specific environments (i.e. remote, inaccessible areas, urban areas), being simulated distinct medicine situation with one or more casualties/patients. The functional tests were performed using the approach of black box technique, in which it was focused exclusively on the tests outputs sought to be identical with the expected outputs according to the vital Requirements, ignoring the subsystems encompassed by the PTW-FM. Based on this successfully demonstration and acceptance on behalf of users, the PTW concept was forwarded to the next developing phases.

Conclusions

The PTW Case Study based on two sets of qualitative researches, and residing to Telemedicine field, points out how based on the SE methodology with origins in aero-space segment, can be developed a successfully mobile telemedicine system in order to fully satisfy the Romanian targeted Medicine End Users from the point of view of functionality and performance. Furthermore, relevant for the PTW feasibility, is the fact that the initiatives to further prototype and perform a pilot application have got already underway under ESA Programmes.

The SE based solution used within this Telemedicine Case Study contains specific improvements in order to develop a Telemedicine product capable to fulfill the needs of a wide range of end users simultaneously, and this is a major benefit for Telemedicine Industry where the competition is fierce.

The summarizing mechanism based on SE methodology and resulting from this Case Study is extremely influenced by aspects as verification, validation, re-iteration, traceability, as shown in the below Figure no. 5.

To mention the fact that the idea validation is based on 1st set of qualitative research, whose purpose was also to gather information about the end-users' roles and responsibilities in order to classify them, while use cases were elaborated through the 2nd set of qualitative research, important to gain insight upon end users' scenarios, problems and needs.

The novel approach described in this Case Study could contribute to real business practice from Telemedicine field and not merely, having the main purpose to make the organizations to gain huge end users' satisfaction in terms of functionality and performance upon their products and services, and furthermore to gain competitive advantage by satisfying multitude end users simultaneously.

The resulted mechanism represents a methodological tool based on IS, which can be used by organizations in the field of telemedicine and not merely, in order to be fulfilled the organizations' responsibility towards the targeted customers/end users, and in this way to gain maximum satisfaction from them on the functional and performance niche, implicitly to develop successfully technological products/services on the market.

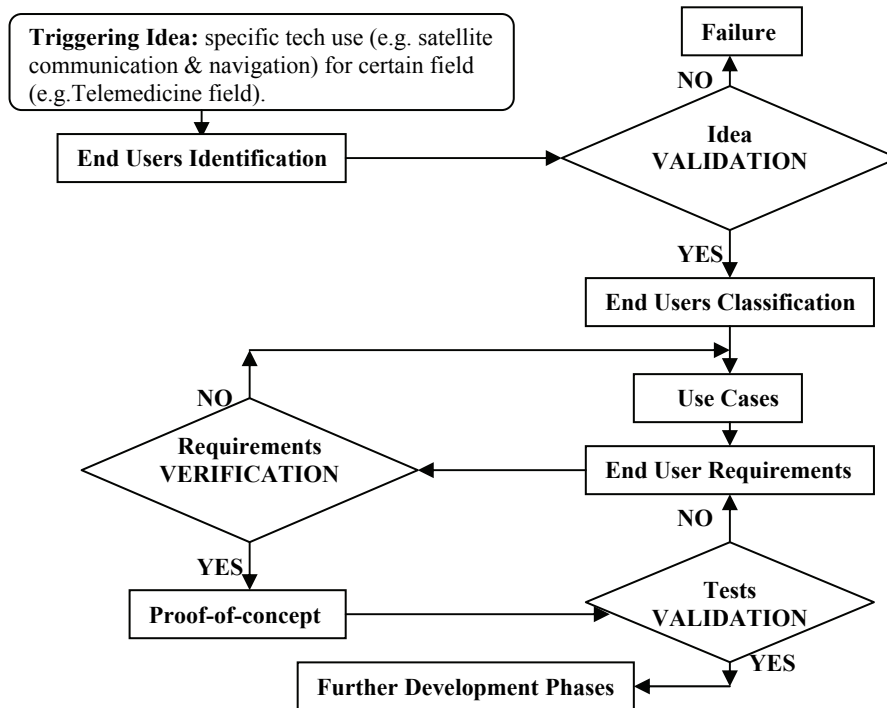


Figure no. 5: The Mechanism resulted from the PTW Case Study.

Acknowledgement

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References

AMedP-37, 2012. *Development and implementation of teleconsultation systems*. AlliedMedical Publication, Published by NATO Standardization Agency (NSA).

ATA - The American Telemedicine Association, 2006. *Telemedicine, Telehealth, and Health Information Technology*. [online] Available at: <<http://www.americantelemed.org/docs/default-source/policy/telemedicine-telehealth-and-health-information-technology.pdf?sfvrsn=8>> [Accessed 14 August 2013].

Barratt, M.R. and Pool, S.L., 2008. *Principles of Clinical Medicine for Space Flight*. NewYork, NY: Springer Science+Business Media, LLC.

Clark, J.O., 2013. System of Systems Engineering and Family of Systems Engineering from a Standards, V-Model, and Dual-V Model Perspective. *The Journal of Reliability, Maintainability & Supportability in Systems Engineering*, Spring 2013, pp.7-13.

- Department of Defence, 2001. *Systems Engineering Fundamentals*. Fort Belvoir, Virginia: Defense Acquisition University Press.
- Dinu, E. and Curea, C., 2007. Key success factors in the knowledge economy. *Amfiteatru Economic*, IX(22), pp. 163-166.
- Dinu, V., Schileru, I., Atanase, A., 2012. Attitude of Romanian Consumers Related to Products' Ecological Labelling. *Amfiteatru Economic*, XIV(31), pp. 8-24.
- Drucker, P.F., 2007. *The practice of management*. New York: HarperCollins Publishers.
- Elm, J.P., Goldenson, D., El Emam, K., Donatelli, N., Neisa, A., and NDIA SE Effectiveness Committee, 2008. *A Survey of Systems Engineering Effectiveness - Initial Results*. Software Engineering Institute. Paper 299. [online] Available at: <<http://repository.cmu.edu/sei/299>> [Accessed 14 August 2013].
- INCOSE, 2000. Systems Engineering Applications Profiles. Version 3.0. Commercial and Public Interest Working Group.
- INCOSE, 2006. *Systems Engineering Handbook. A Guide For System Life Cycle Processes And Activities*. INCOSE-TP-2003-002-03, version 3, USA.
- Kossiakoff, A., Sweet, W. N., Seymour, S. and Biemer, S.M., 2011. *Systems Engineering Principles and Practice*. 2nd Edition. New Jersey: John Wiley & Sons, Inc.
- McAlliste, C.A., 2006. *Requirements Determination of Information Systems: User and Developer Perceptions of factors contributing to misunderstanding*. ProQuest Information and Learning Company, USA.
- McCann, J.T., 2011. Product or Customer centered Organizations and Leadership Styles. *Journal of Multidisciplinary Research*, 3(1), pp. 65-80.
- NASA/ SP-610S, 1995. *NASA Systems Engineering Handbook*. Washington: National Aeronautics and Space Administration NASA Headquarters.
- NASA/SP-2007-6105 Rev1. 2007. *NASA Systems Engineering Handbook*. Washington, D.C: National Aeronautics and Space Administration NASA Headquarters.
- Pamfilie, A.M., 2010. Multinational Companies Responsibilities Regarding Consumers Safety. *Amfiteatru Economic*, XII(28), pp. 466-478.
- Pamfilie, R., Procopie, R., Bobe, M., Vişan, S. and Bumbac, R., 2013. Design: the answer of contemporary businesses to the requirements of sustainable development. *Amfiteatru Economic*, XV(Special Issue 7), pp. 573-582.
- Paul, D.L., Pearson, K.E. and McDaniel, R.R., 1999. Assessing Technological Barriers to Telemedicine: Technology-Management Implications. *IEEE Transactions on Engineering Management*, 46(3), pp. 279-288.
- Payton, F.C., 2000. Lessons learned from three interorganizational health care information systems. *Information & Management* 37 (2000) 311-321.
- Plăiaş, I., Pop, C.M., Băbuţ, R. and Dabija, D.C., 2011. Employers' Perception of Competences Acquired through Academic Marketing Training in Knowledge Based Economy. *Amfiteatru Economic*, XIII(30), pp. 448-463.
- Popescu, I.C., Dumitru, I., Vegheş, C. and Kailani, C., 2013. Marketing Communication as a Vector of the Romanian Small Businesses Sustainable Development. *Amfiteatru Economic*, XV(Special Issue 7), pp. 671-686.

- Portable Telemedicine Workstation Feasibility Study, Definition and Specification-PTW. Internal ESA document Contract PECS Arrangement No 4000101997/10/NL/HE.
- Pyster, A., D. Olwell, N. Hutchison, S. Enck, J. Anthony, D. Henry, and A. Squires, eds. 2012. Guide to the Systems Engineering Body of Knowledge (SEBoK) version 1.0. Hoboken, NJ: The Trustees of the Stevens Institute of Technology 2012. [online] Available at: <<http://www.sebokwiki.org>> [Accessed 14 August 2013].
- Slywotzky, A., Wise, R. and Weber, K., 2003. *How to grow when markets don't*. New York: Time Warner Book Group.
- Smeureanu, I., Dioşteanu, A., Delcea, C. and Coffas, L., 2011. Business Ontology for Evaluating Corporate Social Responsibility. *Amfiteatru Economic*, XIII(29), pp. 28-42.
- The Standish Group, 1995. *The Standish Group Report*. [online] Available at: <http://www.spinroot.com/spin/Doc/course/Standish_Survey.htm> [Accessed 14 August 2013].
- Vizitiu, C., Văleanu, V. and Tanţău, A.D., 2013. Space based mobile telemedicine assisted by specific Systems Engineering approach. In: *6th International Conference on Recent Advances in Space Technologies (RAST) 2013*. Istanbul, Turkey, 12-14 June 2013, pp. 789-783.
- Whitacre, B.E., 2011. Estimating the Economic Impact of Telemedicine in a Rural Community. *Agricultural and Resource Economics Review*, 40/2, pp.172-183.
- WHO - World Health Organization, 2003. *Medical device regulations: global overview and guiding principles*. Geneva: Library Cataloguing-in-Publication Data.
- WHO - World Health Organization, 2010. *Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth*. Geneva: WHO Library Cataloguing-in-Publication Data.
- Yeboah, F.A., Sem, O.O. and Asare, N.K., 2003. Telemedicine: impact and limitation in modern medical practice. *Journal of science and technology*, 23(1), pp. 26-28.
- Young, R.R., 2004. *The Requirements Engineering Handbook*. Artech House Publishers.
- Zaharia, R., Avram, E.M. and Eftimie, R.C., 2011, Developing a Conceptual Model Based on the Correlations between Marketing Higher Education and Knowledge Based Economy. *Amfiteatru Economic*, XIII(30), pp. 437-447.