Conceptual framework for user based RPM

Beniamino Pacifici
Department of Innovation and Information Engineering
Guglielmo Marconi University
Rome, ITALY
b.pacifici@unimarconi.it

Chiara Parretti
Department of Innovation and Information Engineering
Guglielmo Marconi University
Rome, ITALY
c.parretti@unimarconi.it

Andrea Girgenti
Department of Innovation and Information Engineering
Guglielmo Marconi University
Rome, ITALY
a.girgenti@unimarconi.it

Alessandro Giorgetti
Department of Innovation and Information Engineering
Guglielmo Marconi University
Rome, ITALY
a.giorgetti@unimarconi.it

Gabriele Arcidiacono
Department of Innovation and Information Engineering
Guglielmo Marconi University
Rome, ITALY
g.arcidiacono@unimarconi.it

Abstract

Nowadays, new conjunctions between communication technologies and devices in the health care context, and between health and social care, create important opportunities concerning the development of frameworks and devices/interoperable systems (eHealth systems), particularly in the ever increasingly Remote Patient Monitoring (RPM) systems environment. However most of users' needs and requirements are not really satisfied with a poor customization of solutions in according to specific cluster of users. This is mainly due to a lack of truly interoperable tools that allow a horizontal integration between the various medical / specialized tools and utilities. This paper introduces an effective conceptual framework to manage the many stakeholders connected to the development of RPM solutions.

Keywords
RPM System, holistic framework, eHealth, health care

1. Introduction and literature review

In the present socio-economic context, health systems face significant challenges that have been creating concerns about the sustainability of the provision of health care (Morgan et al., 2007). The combination of both an increase in chronic diseases and of aging population are compounding the burden for the provision of health care, causing at the same time a critical growth of health-care system costs. As regards costs, previous studies have debated scientific tools to reduce waste in several contexts of national health care systems (Hicks et al., 2015; Wijma et al., 2009), among which costs related to operating rooms (Arcidiacono et al., 2015c).

The development of frameworks and devices/interoperable systems (eHealth systems) to support integrated health and social services, can be one of the possibilities to address these new challenges, even helping to realize a more customized health care model and to develop a more efficient and widespread prevention system (World Health Organization Report, 2011).

The motivation and involvement of the users remain a critical key to fulfill a truly effective health care system. In fact, the adoption of RPM devices, in an increasingly digital environment, can positively affect the patient's behavior. Their lifestyle can be improved, allowing remote treatment of chronic diseases and equipping caregivers with tools that make faster clinical decisions, with a higher degree of reliability (Vavilis et al., 2012). Moreover, the goal of making the cure "patient-centric" can be achieved, so that patients can be actively involved in managing their health to eliminate the so-called "information asymmetry" that usually characterizes the doctor-patient relationship.

For these reasons, the diffusion of RPM will be desirable, but many occurring barriers must be considered to promote RPM, and to take actual advantages from the eHealth systems (Currie et al., 2014).

The impact of eHealth technologies is sometimes questioned (World Health Organization report, 2010), due to a divergence between the expected benefits and actual results. A lack of evidence about the distinct effects of eHealth technologies on health and health care is evident (Atienza et al., 2010; Black et al., 2012; World Health Organization report, 2010). Health care professionals are often skeptical and show little support for eHealth, because technology does not seem to work for them or for the benefit of their patients (Chaudhry et al., 2007). Thus, eHealth technologies often face adoption problems.

Also based on concepts and tools of Lean Six Sigma (LSS) methodology (Arcidiacono et al., 2016b), the aim of this paper is to introduce a conceptual framework to manage multiple stakeholders in connection with the development of RPM solutions. Evidence discussed in previous studies has demonstrated the versatility of such tools, which are suitable for being applied to various contexts for effective processes optimization and reliability (Arcidiacono et al., 2016a).

2. Limitations and research scope

Despite the business opportunity and the economic benefits that the widespread adoption of mobile Health systems could lead, their widespread implementation is hampered by some obstacles and adoption barriers, causing only partial expression of their potential market possibilities (Table 1 (PWC report, 2013)).

The lack of interoperability and commonly accepted standards between applications are certainly important limits that determine a slowdown in these services to be spread, thereby affecting the quality and increasing the costs of health care systems (Chan et al., 2011).

The use of international standards would be a way to ensure the general interoperability of solutions, but often these standards are not sufficiently detailed. Furthermore, there are many categories of barriers to the diffusion of the standards:

- Political barriers: national and local health systems often have different standards and, generally, health policies offer little incentive to the homogenization of these standards;
- Definitional barriers: health and medicine are complex areas, which have many dimensions, so both categories are difficult to define and categorize due to cultural, social and contextual differences (since medical experts can change and evolve rapidly). Moreover, standards for mobile Health must adapt as much rapidly through frequent revisions;
- Users barriers: health workers often are not satisfied by devices and medical IT solutions that are not so specific and the end users often think that systems are too complex.

Beside the section on the adoption of standards, the development of adequate standards supported by interoperability tests as well as classification and certification of processes is also essential.

Moreover, there are no clear rules of mobile application management in the health and wellness industry, and there is a lack of transparency on the use of data recorded with these applications.
Currently, concerning legal issues, there are inadequate guarantees regarding the employment of such data in health care applications. In fact, the full protection of sensitive data is not guaranteed, this fact has a negative impact on the confidence that users (both patients and health workers) have about the use of these systems. Also, an inadequacy and fragmentation of legislating, regarding reimbursement schemes of e-health services, is found in legal matters.
The lack of clear standards, both technical and legal, and the requirement for major investments in the first phase of distribution of health systems have led to a slowdown in a widespread use of these solutions. However, a study conducted in the USA in 2007 estimated that the implementation of full interoperability through multiple areas, together with their full deployment, would produce an annual saving of 5% of the country's health expenditure (Di Carlo, 2012).

Table 1. Summary of the main barriers to the development of mobile Health systems (PWC report, 2013).

Flow of information	**Regulatory**	**Economic**	**Structural**	**Technological**
• Health care provider	• Lack of clarity on certification • Lack of Interoperability • Lack of compensation mechanism	• Need for further evidence • Conflicting incentives • Change management	• Low cohesion across levels and regions	• Late involvement of doctors in solution design
• Solutions vendor				• Interoperability
• Mobile service provider		• Lack of clear reimbursement mechanism		• Standardization • Interoperability
• Medical devices vendor				• Standardization • Interoperability
• Doctors/ Patients		• Lack of awareness of system benefits for the Doctors and patients		• Significant training needs

3. Functional needs

The analysis of the global context, regarding both users' needs and health systems requirements, identify that the creation of a network for health and social services and integrated devices/interoperable systems should focus on the following types of functionality:
• Health monitoring and comfort: systems involving patient monitoring, through the direct employment of health professionals, when the complex/chronic patients have left the hospital. These systems should create a continuous supervision of the user's situation by means of various indicators, recorded and analyzed and the continuous availability of a support (not intrusive) and intervention. Thus, these devices can greatly enhance the users' perception of their security, who receive ongoing monitoring of their situation. Also, diagnostic systems and collection of information on the symptoms, which can be used by health care professionals are integrated.
• Safety and speed of interventions in emergencies: systems enabling the monitoring of early warning indicators related to critical situations (i.e. usage of bathroom and no long-term movement), through which it is possible to recognize false alarms, to avoid, for example, unnecessary trips to the hospital.
• Knowledge of useful information: qualified support systems at home will help users to solve everyday problems and concerns or to receive instructions and assistance from family. Most of these systems for information exchange about the patient's condition or treatment plan are shared through websites, patient portals and mobile applications.
• Support the performance of an activity: systems for the organization of daily activities that help to manage smartly: time, nutrition, hydration, taking medication, etc. based on user specificity.
• Simplification of the necessary actions: systems for automatic reordering of drugs with verification of stocks present and the eating plan.

• Prevention tips and stimulus: systems that suggest how to perform normal daily activities to get a rehabilitative effect or make the necessary fun activities (i.e.: using a video games approach, often used in rehabilitation contexts (De Vito et al., 2014) or for operations to be carried out by children). Systems which provide information of alert (for example, identify the acceptable daily sugar intake as a function of move activity performed), that suggest to do certain exercises at certain times, or occur when a certain operation is made, and invite to correct it. Self-testing systems for the monitoring of the current situation and its evolution in time.
• Compensation and assistance: systems that address/alleviate the difficulties due to a certain disease by acting for example on environmental conditions. Programs designed for highly complex patients (for example, those with a functional or multiple disability) that provide the employment of installed devices that control their ability to live independently.
The features presented above have not the same impact in terms of users served and cost/benefit for the health care service. In order to make this type of services effective, having clear alignment between the patient's severity and technological complexity of the system is crucial (see Figure 1) (Gheorghiu et al., 2015, Ernst & Young LLP, 2014).

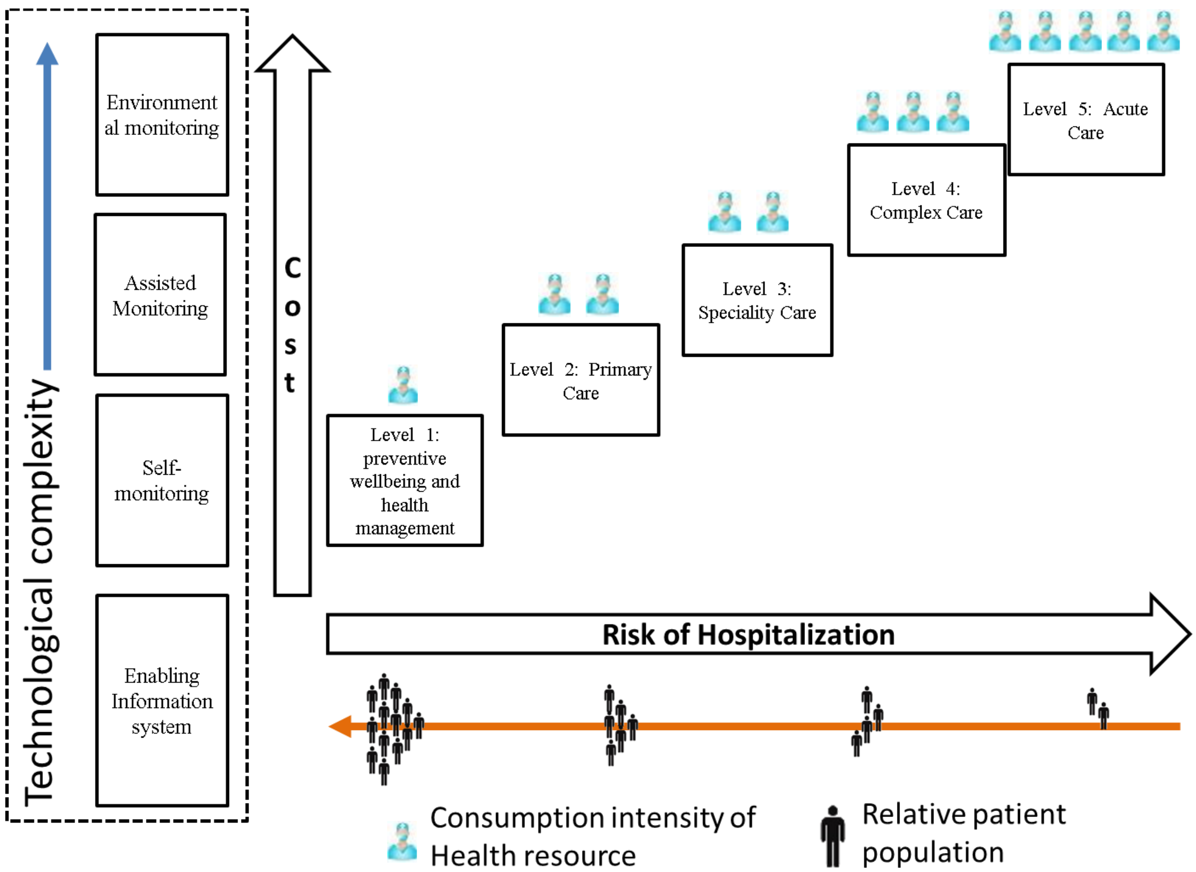

Figure 1. Correspondence between severity of patient's condition and technological complexity of system.

Figure 1 shows the relation between the severity of a patient's condition and the technological complexity of systems. As the technological complexity increases, the number of users who need access to it decreases; however, costs in terms of health operators/operations increase. Therefore, if the cost for an initial investment to introduce these systems increased progressively, by moving on the X axis, the economic benefit connected to technological complexity (shown on the left side of the chart) will be higher.

4. Holistic framework for user based RPM

The holistic framework proposed in this study aims at answering the need to align RPM systems with customer needs (both as needs of end users, and needs of health care professionals). The proposed framework is visually

represented in Figure 2. The users must be clustered to propose a different type of application for the same scope. In fact, the requirements and features must be classified based on customer (i.e. children, elders etc.). This point is crucial to avoid one of the barriers to adoption. In fact, if final users are not encouraged in the systems employment, paying attention to customer segmentation needs, even if system works well, the development effort made by IT specialist would be nullified.
In this phase, the clusters of customers can be done with the aid of LSS tool, based on the transformation from VOC to Functional Requirements and Design Parameters (i.e. QFD and Axiomatic Design (Cavallini et al., 2013; Giorgetti et al., 2016; Giorgetti et al., 2017)). The effective versatility of Axiomatic Design and its principles have been proven also by other specific applications not only in health care contexts, but also to optimize processes (Arcidiacono et al., 2015a), products (Arcidiacono et al., 2015b) and the education system (Arcidiacono et al., 2016c), by satisfying their related Functional Requirements.

This entails that, as is shown in Figure 1, focus must be put on the level of technological complexity and on the risk of hospitalization. In fact, as these two parameters increase, more attention must be paid on the involvement of health care specialists, who are indeed the actual final customers in this case. In fact, the relative patient population will decrease, in these conditions. Vice versa, if the technological complexity decreases together with the risk of hospitalization, more attention must be paid on patients, who will be the real final users of this other case scenario.

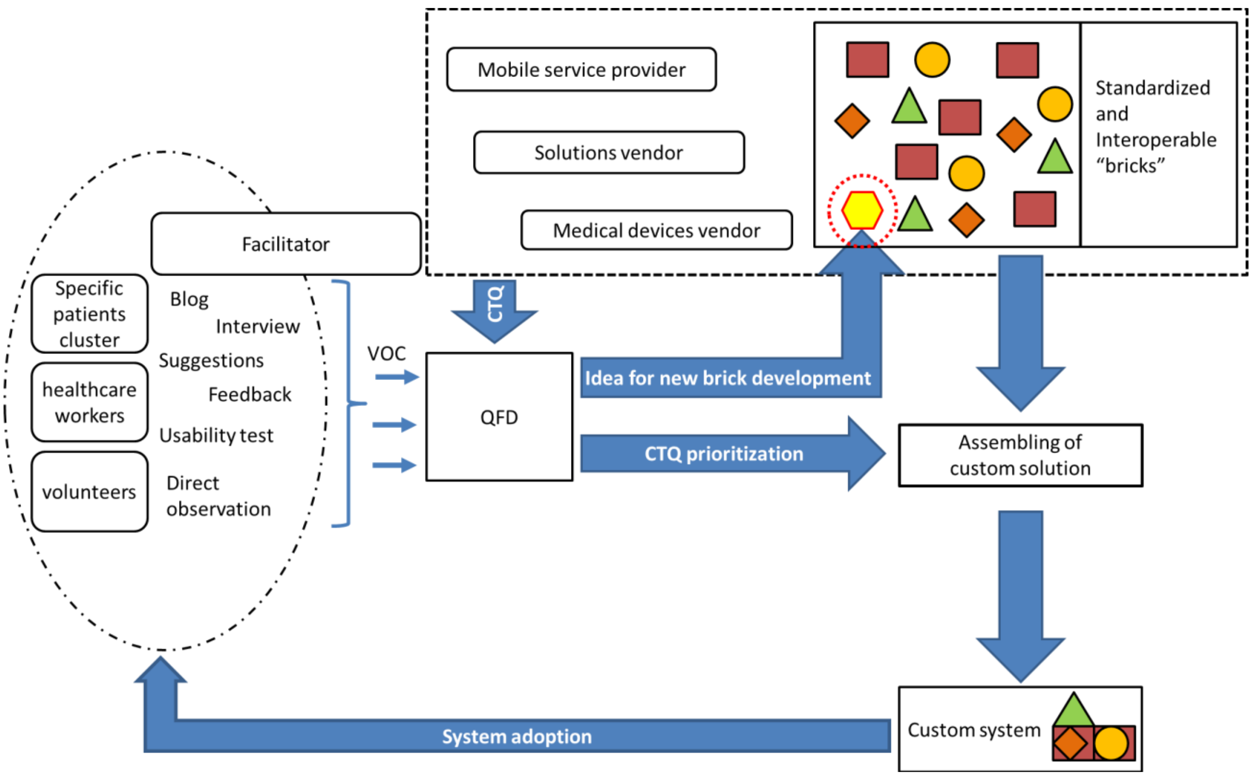

Figure 2. Holistic Framework for user based RPM.

Now, analyzing Figure 2 first, on the left side of the scheme, customer requirements are generated across a continuous exchange of information with the intervention of health workers. This happens to decrease risk of late involvement of health specialists; introducing eHealth technologies into the health care system requires careful coordination and communication among health care professionals, patients, informal caregivers, end users, and others (Dansky et al., 2006). The technical information, or output, of the device must be requested by the health care operator and must be the same, independently of the provenience of user's cluster. At the same time, end users should be satisfied with a specified interface based on various factors (age, computer friendliness, etc.). These requirements are successively transformed in a specified assembly of standard "bricks" that the IT operators will develop. On the right side, in fact, there are developers arranging "bricks" in a customer requirements vision, but these components must be standardized before, to supply to the continuous evolution of IT services, technologies, customer's needs. These "bricks", constituted by standard components, (i.e. sensors devices, software etc.) together with IT expertise, generate the applications or systems with interoperable elements, which can be assembled in multiple ways for future apps.

5. Conclusions

The convergence of communication technologies and devices in the health sector, and between health and social care, creates important opportunities for the development of RPM systems. This is why the market shows a considerable ferment of ideas and proposals from the major players who traditionally occupy the solutions connected to health care. Despite all of this, however, most of users' needs are not yet confronted with an adequate response, and this is highlighted in particular re the customization of the solutions according to the specific groups of users. The most relevant restriction so far is the lack of truly interoperable tools that allow a horizontal integration between the various medical/specialized tools and various utilities that improve the quality of life of people belonging to clusters of users with specific needs. In addition, because the medical field is constantly changing, also the mobile health solutions should have a quick change, to meet the new needs of both health care professionals and end-users. For this reason, the proposed model could be useful to ensure that the development of new solutions could be already partly guaranteed, and that it such development goes hand in hand with the evolution of medicine and people's habits.

References

Arcidiacono G., Bucciarelli L., 2016a, TRIZ: Engineering Methodologies to Improve the Process Reliability, *Quality and Reliability Engineering International Journal*, vol. 32, no. 7, pp. 2537-2547, 2016.

Arcidiacono G., Costantino N., 2016b, Yang K., The AMSE Lean Six Sigma Governance Model, *International Journal of Lean Six Sigma*, vol. 7, no. 3, pp. 233-266, 2016.

Arcidiacono G., Giorgetti A., Pugliese M., 2015a, Axiomatic Design to improve PRM airport assistance, *Proceedings of ICAD2015, 9th International Conference on Axiomatic Design*, vol. 34, pp. 106-111, 2015.

Arcidiacono G., Placidoli P., 2015b, Reality and illusion in Virtual Studios: Axiomatic Design applied to television recording, *Proceedings of ICAD2015, 9th International Conference on Axiomatic Design*, vol. 34, pp. 137-142, 2015.

Arcidiacono G., Wang J., Yang K., 2015c, Operating room adjusted utilization study, *International Journal of Lean Six Sigma*, vol. 6, no. 2, pp.111-137, 2015.

Arcidiacono G., Yang K., Trewn J., Bucciarelli L., 2016c, Application of Axiomatic Design for Project-Based Learning Methodology, *Proceedings of ICAD2016, 10th International Conference on Axiomatic Design*, vol. 53, pp. 166-172, 2016.

Atienza A.A., Hesse B.W., Gustafson D.H., Croyle R.T., E-health research and patient-centered care examining theory, methods, and application, *American Journal of Preventive Medicine*, vol. 38, no.1, pp. 85-88, 2010.

Black AD., Car J., Pagliari C., Anandan C., Cresswell K., Bokun T., et al., The impact of eHealth on the quality and safety of health care: a systematic overview, *PLoS Medicine*, vol. 8, no. 1, 2011.

Cavallini C., Giorgetti, A., Citti, P., Nicolaie F., Integral aided method for material selection based on quality function deployment and comprehensive VIKOR algorithm, *Materials and Design*, vol. 47, pp. 27-34, 2013.

Chan C.V., Kaufman D.R., A Framework for Characterizing eHealth Literacy Demands and Barriers, *Journal of Medical Internet Research*, vol.13, no.4, 2011.

Chaudhry S.I., Phillips C.O., Stewart S.S., Riegel B., Mattera J.A., Jerant A.F., et al., Telemonitoring for patients with chronic heart failure: a systematic review, *Journal of Cardiac Failure*, vol. 13, no.1, pp.56-62, 2007.

Currie W.L., Seddon J.J.M. A cross-national analysis of eHealth in the European Union: Some policy and research directions Information & Management vol. 51, pp. 783–797, 2014

Dansky K., Thompson D., Sanner T., A framework for evaluating eHealth research. *Evaluation and Program Planning*, vol. 29, no.4, 2006.

De Vito L., Postolache O., and Rapuano S., Measurements and Sensors for Motion Tracking in. Motor Rehabilitation, *IEEE Instrumentation & Measurement Magazine*, vol. 17, no. 3, 2014.

Di Carlo C., Santarelli E., ICT nella Sanità in Italia, Ministero dello Sviluppo Economico, 2012.

Ernst & young LLP, Connecting patient with providers A Pan-Canadian Study on Remote Patient Monitoring, Canada Help infoway, 2014.

Gheorghiu B., Ratchford F., Scaling Up the Use of Remote Patient Monitoring in Canada, *Proceedings of the International Conference Global Telehealth 2015: Integrating Technology and Information for Better Healthcare*, pp. 23-26, 2015.

Giorgetti A., Girgenti A., Citti P., Delogu M., A Novel Approach for Axiomatic-Based Design for the Environment. *Axiomatic Design in Large Systems*, Chapter 5, pp. 131-148, 2016.

Giorgetti A., Cavallini C., Ciappi A., Arcidiacono G. and Citti P., A holistic model for the proactive reduction of non-conformities within new industrial technologies, *International Conference on Mechanical Engineering and Electrical Systems - MATEC Web of Conferences*, in press, 2017.

Hicks C., McGovern T., Prior G., Smith I., Applying lean principles to the design of healthcare facilities, *International Journal of Production Economics*, vol. 170, part B, pp. 677–686, 2015.

Morgan M.W., Zamora N.E., Hindmarsh M.F., An inconvenient truth: a sustainable healthcare system requires chronic disease prevention and management transformation. Healthcare Papers vol.7, pp.6-23, 2007.

PWC report, Socio-Economic Impact of mHealth, an assessment report for European union, *PWC report*, 2013.

Vavilis S., Petković M., Zannone N., Impact of ICT on Home Healthcare, *International Conference on Human Choice and Computers*, 2012.

Wijma J., Trip A., Does R.J.M.M., Bisgaard S., Quality Quandaries: Efficiency Improvement in a Nursing Department, Quality Engineering, vol. 21, pp. 222–228, 2009.

World Health Organization report, Medical Devices: Managing the Mismatch: An Outcome of the Priority Medical Devices Project, 2010.

World Health Organization report, mHealth - New horizons for health through mobile technologies, 2011

Biography

Beniamino Pacifici is currently a PhD student at Guglielmo Marconi University, he is working in GE Oil & Gas for his research projects. He graduated in Energy Engineering M.S at University of Florence, Italy. He has published journal and conference papers. Dr. Pacifici has completed research projects with GE Oil & Gas, his research interests include mechanical, thermal and process engineering, energy management, industrial plants optimization with studies on design and off-design configurations, Axiomatic Design and lean six sigma.

Chiara Parretti Chiara Parretti, currently an adjunct professor at Guglielmo Marconi University. She graduated from the University of Pisa. He has participated in many research projects with the University of Florence, and with the Guglielmo Marconi. University. His research interests include process optimization, Lean Six Sigma, communication tools, adult education, health and security.

Andrea Girgenti is a PhD Candidate in Physic Science and Engineering of Industrial Innovation at Guglielmo Marconi University, Italy. He has been involved in several R&D projects both in the mechanical and the oil & gas fields. He received his Master Degree in Mechanical Engineering (2012) from the University of Florence.

Alessandro Giorgetti is currently a Researcher at Guglielmo Marconi University. He earned M.S Mechanical Engineering and PhD in Machine Design from University of Florence, Italy. He has published journal, book and conference papers. Dr. Giorgetti has completed research projects with Ferrari Spa, FIAT research center, GE Oil & Gas and Hospital "Piccole Figlie" Parma. Author of more than 40 scientific papers, his research interests include process optimization, Axiomatic Design, end on line quality control, material selection algorithm, damage evolution model, process optimization, functional coating and Lean Six Sigma.

Gabriele Arcidiacono is Head of Department of Innovation & Information Engineering (DIIE) and Associate Professor at G. Marconi University (Rome, Italy). Visiting Professor (1998) and Guest Researcher (2000) at MIT (Boston, US). He implemented and developed the first Six Sigma program in Italy (General Electric, 1996).
Author of more than 100 scientific papers and 10 books, including "Six Sigma: Handbook for Green Belt", the most widely used book in Italy (over 13,000 copies) by industry experts, and "Lean Six Sigma in Healthcare" presented with the Italian Minister of Health Care.