

*Pisa takes a stand for responsibility in healthcare and medical technology
6th Annual HCTM Conference -HOF- Scuola Superiore Sant'Anna
3-5 October 2007, Pisa, Italy*

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Towards responsibility and compliance in the innovation and
management of healthcare technologies:
international perspectives and comparative experiences

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Implementation and results with macroprocess management in a public hospital

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Abstract: Due to the dynamic and turbulent environment in which a public hospital is inserted, people and process management are important factors to improve quality in service operations. This paper aims to address the question of how can be implemented an operations service strategy in the healthcare field. An action research approach was employed for the adoption of process management and development of operations service strategy in a big-sized clinic of a public general hospital in Brazil. Some of the tools adopted were: 1) a macroprocess map, 2) a behavioral metaphor for working in teams, 3) a formal systematic to periodically review the system, critically analyze results obtained and to plan new corrective and preventive actions. The results after seven years of research show that goals based on data have been reached, hospital resources have been translated in practical terms (not only in financial resources), more patients have been treated, the occurrences of no-show have decreased and the patients evaluate positively the quality of the service.

Keywords: implementation of service operations in hospital, quality in public sector health services, action research

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ESTAV: a new approach for innovation in the public health service

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Abstract: The Tuscany local government has established the ESTAV organization, as a consequence of the necessity to contain administrative costs in the Public Health Service. Scope of the project is to aggregate together 16 local Health Local Authorities, settled into

Tuscany region, into a single body, the ESTAV (Area Vasta technical-administrative services supply body). This is the first example of a centralizing management project into the Public Health Service. The operation context for ESTAV project is the historical environment of Italian Public Health System, whereas the performed activities are not exactly the "core" ones (see for instance the distribution operations):

A fragmented situation, strongly localized, with poor professional tools and facilities, where the traditional lack of investment generates huge economical loss and, somewhere, situations close to the safety limits. The present situation, after the completion of the integration project, shows a re-organized local system with the following features:

- concentration of operation into a unique qualified body (ESTAV);
- know how transfer from private Company;
- business logics fitting, 'investing today, saving tomorrow';
- strong development of warehouses logistics, automation and informatization;
- solid economies of scale, useful for important cost reduction.

This new subject, very autonomous regarding the strategy building perspective, follow two main streams:

- * programming activities and gain efficiency;
- * rationalize goods and services expenses, maintaining or improving the quality of the supplied services.

The improving intervention for ESTAV issue required a certain effort under every perspective, unexpected without a straight collaboration with private Company and primary University, both important supplier of technical support and knowledge. The organizational change has been driven with the following development lines:

- Competencies re-thinking

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- Core competencies
- Atypical competencies
- Roles re-definition
- Structures composition
- Performances indexes re-thinking
- Using of the concept of “outsourcing” for process management

In the field of “Facilities innovation” the ESTAV plant adopts the latest Knapp automatic sorting line which manages all the phases of the automatic picking.

The latter operation is the core activity of pharmaceutical distribution and it requires high level of performance and quality: this targets can be achieved only by efficiently applying automatic solution. The Knapp solution permits to achieve a performance level extremely high and definitely not comparable with handly managed processes and a productivity improvement over the best benchmark. From the perspective of “Logic innovation” we can mention the change management process that has driven a modification in the basic management attitude: from the logic “item – service” replied many times, to the logic “item – system – service” only once. For the economic issue, that was considered the primary one of the whole project – as focus of the new management committee, the activities centralization and a careful use of outsourcing for the so called “atypical competencies” has obtained various examples of economies of scale and a sensible reduction of fixed costs. The strong synergy with a primary pharmaceutical wholesaling Private Company permitted huge savings through the co design of a routing system that ended in the result to diminish the number of trucks to use for the transport issue. Finally, for “Social innovation” perspective, ESTAV focuses on the development of its “core competencies” with the aim to transfer them, through economies of scope, to other public bodies that are involved in the health sector, thus to minimize further the level of risk related to materials handling and shipping in the Country. In order to boast its competence and its performance level under every perspective, ESTAV wants to perform a Quality Management logic inspired by the most important standard such as ISO 9001:2000 pattern. Furthermore, after the Quality certification target, the approved Management system will be integrated with all the additional requirements as for Ethic Management System – whereas the target certification model will be the SA 8000 standard.

The role of medical professional regulatory board in health technology assessment

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Abstract: The health technology assessment (HTA) following the NHS definition is “an internationally recognised term that covers any method used by those working in health services to promote health, prevent and treat disease and improve rehabilitation and long-term care. "Technologies" in this context are not confined to new drugs or pieces of sophisticated equipment”. The HTA programme addresses the questions that patients and the public health system need the answers, providing the scientific evidence to inform appropriateness choices.

If ‘Technology’ includes all interventions used to promote health, therefore the medical doctors are and have to be involved not only in the introduction phase but also in the subsequent evaluation, during the process of care as the main users, to verify the safety and effectiveness of the technology in everyday practice.

Furthermore after the introduction of new technology the education process have to be changed both for the undergraduate and postgraduate directly influencing the thresholds to assess fitness to practice. The introduction of new technology thus implies a new set of standards that a medical doctor has to follow to guarantee the efficacy and safety of the care outside the research phase. These new standards could be used in assessing the fitness to practice process but more frequently they are used by expert witness malpractice litigation. This means that the medical regulation have a strong connection with HTA and setting in EU a new and modern role of medical regulation board could fulfill the quality and safety requirements of European citizens.

Telematic integration of health data: the INTESA project

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Abstract: Following an approach based on the methods of basic research, the INTESA project has developed a complete architecture of health information system, capable to guarantee a smart and safe storing of the essential information, an effective and personalized retrieval of data, and some innovative models to compare the results of clinical and medical activities of all the “actors” of the health care process. Together with other metropolitan repositories based on HL7 messages and applications able to examine the data stored, the developed archive will contribute to keep a check on every citizen’s health history, clinical examinations and cure therapies, but, above all, it will allow to verify the efficacy and efficiency of the health care processes related to particular pathologies.

Keywords: electronic health record; data storing and integration; data warehousing; data mining.

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Tracking implantable devices through software integration: the 'event-type' model

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Abstract: Tracing the path of implantable devices (such as hip prostheses, pacemakers, cardiac valves, breast implants etc.) is a crucial issue from several points of view: internal process control, patients' safety, quality management, external evaluation. We propose a highly feasible and largely transferable conceptual and operational model, especially aimed to fulfil common requirements on traceability, also providing usable and homogeneous information to different regional institutions committed to healthcare planning and research. The keypoints of our model are: a) identifying key data and information flows; b) selecting information and communication (ICT) technology procedures; c) adopting computerized Operating Theatre Registries (OTR) and store procedures; d) adopting a 'service interface' method (WebService) to transmit events of interest to different stakeholders. By ensuring operational interaction and transparency, WebService Technology (WST) can improve internal and external connections through an 'event-type' transmission. The case of hip replacement provides a good example for a wider implementation of the proposed model, covering the whole field of implantable devices.

Keywords: traceability, implantable devices, medical devices, webservice, event-type system,

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Stefania Rodella is Coordinator of the Quality Unit at the Regional Agency for Healthcare in Tuscany. She is Medical Doctor, earned her MSc in Epidemiology and Biostatistics from the McGill University of Montreal (Canada), her Specialty in Gastroenterology and her PhD in Cancer Pathology from the University of Verona (Italy). She worked more than 10 years as hospital physician and general practitioner; since 1991 she became involved in epidemiological research, mostly in the field of cancer. She works in Quality of Healthcare Services since 1995, her major fields of interest are evaluation research, quality and performance indicators, clinical guidelines and clinical governance.

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Organizational innovations in Catalan hospitals. The case of telemedicine

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Abstract: Nowadays, healthcare is focused on patient satisfaction. Thus, one of the most important challenges for hospitals is to be more efficient, improving the quality of care. Technological and organizational innovations play a key role in achieving this aim and ICT related innovations are leading major organizational changes in healthcare organizations. In this framework telemedicine is seen as one of the most relevant innovations. The aim of our paper is to analyse the case of telemedicine as organizational innovation. Telemedicine is introduced by adopting the existing technologies, but is the responsibility of the hospitals to manage it appropriately. Our work is based on a research carried out in 16 hospitals of Catalonia, a region located in the north-east of Spain. Regional governments in Spain are responsible of the budget and management of the regional health system.

Keywords: Telemedicine, organizational innovations, healthcare management, efficiency.

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Quality for Medical Technology[®]: a new paradigm based on ISO 9001

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Abstract: Quality for Medical Technology (QMT[®]) is a model developed by TNO Quality of Life to support hospitals in building, implementing and maintaining a structured framework for quality management of medical technology. It is based on the standard ISO 9001 and modified into a model that suits hospital organizations. QMT[®] is a model for self certification with external reference with an external certification. This paper presents the vision on improving safety and describes in detail the QMT[®]-model and hospital experiences. Some of the specific components are the orientation on (technology) processes throughout the organization, focus on specific technology aspects and risks, explicit risk analysis, a hospital-wide quality committee for medical technology, and one person responsible for work processes regarding the specific technology. Dutch hospitals that implemented QMT[®] are very positive, since more risk reduction is possible, work processes are more efficient, and high quality is visible through a QMT[®]-certificate.

Keywords: risk management, risk reduction, patient safety, medical technology, medical technology process, technology management, quality management, PDCA, quality in health care, self certification.

Biographical notes: Robert A. Bezemer is a researcher and consultant for development, production and practical application of medical technology at the Netherlands Organization for Applied Scientific Research TNO and has 10 years experience in this field. He concentrates on quality and patient safety aspects in design & development of advanced medical devices (e.g. fulfilling CE-requirements, validating production processes) and in daily use of these devices, especially in the hospital. He assists organizations in realizing risk and quality management approaches that fit the specific organization needs and routines. He helped many hospitals to implement risk and quality management systems, often based on QMT[®]. He received his M.Sc. degree in experimental physics from Leiden University (the Netherlands) and his MTD (Master of Technological Design) degree from Eindhoven University of Technology (the Netherlands).

Adrie C.M. Dumay is a research director for innovation in health care at the Netherlands Organization for Applied Scientific Research TNO and manages the TNO department Technology in Health care. He has over 20 years research and management experience at research organizations. He received his B.Sc., M.Sc. and Ph.D. degrees from the Delft University of Technology (the Netherlands) and MBA (*cum laude*) from the Teesside University (United Kingdom). Dr. Dumay is board member of various research councils and foundations to stimulate innovation in health care.

From the Clinical Outcome to the surgical device: how a J&J product is born

Federico Bilotti

European Co-Invention Team, Ethicon Endo-Surgery, Johnson & Johnson Med. SpA.

Abstract: The European Commission's December 4, 2006 report titled the "Global Innovation Scoreboard (GIS) Report" shows Finland at the top of the Global Innovation Leaders' list in front of US and Japan, and Italy in the Innovation Follower's group together with the Russian Federation and Hong Kong. 21 different indicators are used to determine the Innovation score of each of the EU countries. The European Commission also states that since 2002, the Innovation gap between US and EU25 has shrunk thanks to increased EU tertiary education, early-stage venture capital and EPO patents to list only some of the improvements. J&J, WW leader in Health care, has contributed to reducing the innovation gap between US and EU by investing a considerable portion of the \$7.1 Bil Research expense in 2006, on EU innovation. In his Innovator's Solution book, Christensen describes the Innovation path going from nebulous chaos to pattern definition and to rule based, only in those organizations willing to disrupt themselves. In surgery, the innovation for the control of unwanted blood flow, started in 1909 in Bulgaria with Dr. Hultl who described the mechanical application of silver staples for a gastrectomy procedure. But it was the WWII aftermath that stimulated Russians in 1954 to produce large numbers of mechanical surgical staplers to standardize surgical techniques and enable large numbers of non-experts to treat pathologies that could only be treated by few experts. In 1967, Dr. Ravich brought the Russian technology to US, starting an escalation of innovation that brought us to today's standards of stapling. J&J has learned from Dr. Ravich and successfully adapted mechanical stapling to Hemorrhoid pathology, Rectocele, Rectal tumor treatment, all innovations that started in Europe from ideas of European surgeons. The European Co-Invention Team based in Rome, Italy has developed an innovation process that takes in consideration the "Outcome" of a surgical procedure as the objective of sustainable innovation. As described by Anthony Ulwick in his book "Turn Customer Input into Innovation" HBR 2002, the EU Co-Invention Team works with customers (Physicians, Patients, Payors, Providers) to identify the most opportune Clinical Outcome for the innovation to address. Examples are given of J&J products based on Clinical Outcomes identified by customers and addressed by solutions that leverage EU innovation to "Transform the life of the surgical patient".

Which Intranet for the healthcare firms? First results from a case-based research

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paper

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Abstract: This article is based on evidence from the empirical research conducted by the Observatory of Intranet during 2006. Results refer to 19 case studies carried out in the Italian healthcare sector through direct interviews with the management. The article focuses on the following questions: (1) what are the Intranet models (functionalities, services, processes and performance)? and (2) what are the evolution paths towards those models? That is: what barriers and levers.

Keywords: Intranet model, healthcare in Italy, retrospective case studies

Biographical notes: Mariano Corso, PhD is full professor of Organization at the Polytechnic of Milano where he chairs the course of Management Engineering at the Cremona site. He is director of the Master in "Management and Organisation Development" and of the Observatory on Intranet applications and Enterprise 2.0. He promoted and coordinated national and international researches on Knowledge Management. He is author of more than 70 publications at the international level.

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Matteo Boddi is a managerial engineer who worked at the Observatory on Intranet. He is now purchasing manager at Piaggio SpA.

The laboratory reorganization and Laboratory Information System

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Abstract: During 2005 we implemented an Unique Computer System in the laboratories of the Department of Laboratory Medicine of the Autonomous Province of Trento. Following the approach of the Project Management, the "Project LIS 2005" has been formalized. The group of job servant for this purpose, implemented, within 9 months, the unique computer system in the 9 laboratories of the Department of Laboratory Medicine and in the two laboratories of the Department of Transfusional Medicine. The implementation of the unique Laboratory Information System (LIS) has brought to a critical revision and to the redefinition of the whole activity in the laboratories. We conformed and standardized the procedures of acceptance, collection, transport and maintenance of samples. Each laboratory test is expressed with the same units of measure and the same reference intervals in all the laboratories. The report and the transmission of the results have been standardized in the hospital departments using the web technology.

Keywords: reorganization; department; LIS.

Biographical notes: Patrizio Caciagli MD, is the Director of Department of Laboratory Medicine APSS. and is professor of Programming and Organization of Health-Care at the School of Hygiene of the University of Siena and professor of Laboratory Proteinic Alteration at the School of Haematology of the University of Parma. His research areas include biochemistry, microbiology and electron microscopy. He published in the Italian Journal of Public Health, Microbiology Medicine, Medicine Laboratory, Infection Control Hospital Epidemiology.

Nello Bergamo PhD is the manager of the Departmental LIS of APSS and professor of Laboratory Organization at the School for Laboratory Technician of the University of Verona. His areas of interest are Clinical Chemistry and Computers and Laboratory Information.

Leonardo Sartori CIO Manager of the APSS 's information system (Azienda Provinciale per i Servizi Sanitari) of the autonomous province of Trento with qualified experiences in: Architecture and management of complex technological infrastutture; Organizer and speaker in national congress about problems of the medical information system; Manager of important project of telemedicine, Netlink: European health card and activation and bancarization of the magnetic health card of the autonomous province of Trento.

Ettore Turra Director of Innovation & PMO Executive Azienda Provinciale per i Servizi Sanitari (APSS) Provincia Autonoma di Trento (Italy); CEO's office in the definition, planning and control of the major organization and information systems development programs. Most recent publications and articles are in the field of Project Management, Healthcare Technology Assessment and eHealth. is a certified Senior Project Manager (cSPM, IPMA lev.B) in Austria. He received a university degree in Business Administration at the "Università Luigi Bocconi" in Milan.

Cost Accounting in teaching hospitals: an application in a surgery unit

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Abstract: Nowadays the Italian Healthcare National System is involved in a deep process of change aimed at diffusing managerial techniques used in private sector to public administrations. In this context, a wide literature on healthcare Planning and Control Systems (PCSs) is growing. PCSs are characterized by a complex architecture made by three elements: the process infrastructure, the organizational infrastructure, the technical infrastructure. In this paper we focus on technical infrastructure and, in particular, on the logic of cost accounting in teaching hospitals. The paper presents a specific application related to the design of the cost accounting system at the teaching hospital "Azienda Ospedaliera Universitaria Federico II". The case study was devoted to identify allocation criteria for costs sustained in a surgery unit. In addition to the allocation model the paper offers some observations derived from the case study and concerning the importance of integration among the infrastructures of PCS.

Keywords: Planning and Control System, Cost Accounting System, Teaching Hospitals, Surgery Unit.

Biographical notes: Lorella Cannavacciuolo, Phd in Economic and Managerial Engineering, carries out her research activity with Department of Business and Managerial Engineering at the University of Naples Federico II. One of her research interests is the Planning and Control Systems with a particular attention towards design and implementation of Planning and Control Systems in healthcare public institutions, such as hospitals and local healthcare delivery structures. Since 2001, she takes part in several projects about Planning and Control Systems in healthcare public structures and now she is working on the Management Accounting System of the teaching hospital "Azienda Ospedaliera Universitaria Federico II".

Roberto Delfino is, since 2006, a Phd student in Health Management at the teaching hospital of the University of Naples Federico II. His phd dissertation

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will be devoted to explore the issues related to the implementation of Planning and Control Systems in teaching hospitals. In 2004, after his degree in Economics at University Bocconi, he worked as accounting manager at Niguarda Hospital of Milan and at Santobono Hospital of Naples as project leader.

Cristina Ponsiglione, Phd, is a research fellow of the Department of Business and Managerial Engineering at the University of Naples Federico II. She is also assistant professor in Management Accounting at the School of Engineering at the University of Naples Federico II. Since 2001 she is involved in several projects concerning the designing and the implementation of Planning and Control Systems in healthcare public structures and now she is working on the Management Accounting System of the teaching hospital "Azienda Ospedaliera Universitaria Federico II". Her research interests concern the designing and the implementation of Planning and Control Systems in healthcare public institutions, such as hospitals and local healthcare delivery structures.

Consequences of Electronic Health Records on the doctor's liability: a comparative view

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Abstract: The Electronic Health Records (EHR) trend appears to have taken hold within the medical field globally, motivated by, on one hand, the need to improve continuity and interoperability in the quality of health care and, on the other hand, the wish to improve the economic efficiency of the health care sector. The focus of this article is to show that States who prepare a health reform with a view to a nationwide EHR system need to be aware of the necessity to conserve the trust of the patient but also the acceptance of the new system by the health professionals. The choice of the system will give, more or less, rights to the patient and consequently change the position of the doctor with an effect on his liability. It appears interesting to focus on a State which is in the first stages of implementing e-Health, like Ireland, as opposed to France, where the balancing nature of the reform is clear and which illustrates the delicate choices which have to be made.

Keywords: electronic health records; doctor's liability; patient; personal data concerning health.

Biographical notes: Keiva Carr graduated with a B.A. in Legal Studies and Social and Political Science in 2005 and an LL.B in 2006 from the National University of Ireland, Galway. After Graduation she worked there as a tutor of Sociology of Law and Equity. In March 2007 she obtained a research scholarship at the Lider-Lab of Scuola Superiore Sant'Anna in Pisa. Her research areas of interest include tort law, in particular, medical negligence and damages in a comparative perspective.

Violette Peigné graduated with a Master in Civil law at the University of Rennes in France (2006). After an Erasmus period at the University of Pisa, she obtained a research scholarship of Italian Ministry of Foreign Affairs to make a research and study period at the Lider-lab of Scuola Superiore Sant'Anna in Pisa (October 2006-June 2007). Her research areas of interest include data protection, electronic health records and liability in a comparative perspective. After a training period with the Italian Privacy Commission, she will begin a consultation for this Authority regarding privacy and e-health from September 2007.

Digital Hospital: management of impact of Mobile Electronic Medical Record on processes

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Abstract: This paper is aimed at analyse the impact of changing from paperbased medical records to Mobile Electronic Medical Records process on a healthcare centre dedicated to rehabilitation medicine. This project fulfils the operators' need of information availability at patients' bed. In fact, processes have been studied and re-engineered in order to guarantee that all the information contained in the clinical case history will be always available, independently from the area where they may be inside the hospital. Considering the potential impact of such a process on the organizational work as well as on the whole staff performance, the description of the main steps defined in order to introduce this technology with the highest probability of success, have been included.

Keywords: Digital Hospital; Mobile Electronic Medical Record; Electronic Mobile Case History; Information Communication Technology.

Innovative applications of surgical gesture analysis in laparoscopic surgery

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Abstract: The paper describes how relevant can be the integration of competencies from different research areas, such as robotics, computer science, engineering, to address challenging issues in several medical fields, in particular in surgery. The selected field of application is Minimally Invasive Surgery (MIS), that can be considered a key example of the innovations in the medical and healthcare sectors, achieved thanks to cutting-edge technologies and novel multidisciplinary approaches to solve complex problems. A brief overview of the limitations posed by the current approaches to a wide diffusion of the stated above technologies will be presented, together with the description of novel concepts, methods and instruments. The goal is to provide complete and effective solutions for the definition of objective metrics to evaluate surgical performance, for the development of new surgical instruments and for the robotic automation of surgical procedures. Finally, conclusions and future work will be illustrated.

Keywords: Minimally Invasive Surgery (MIS), Laparoscopy, Surgical performance, Automation of surgical procedures, New surgical instruments, Ergonomics, Gesture Analysis, Machine learning, Biomechanics.

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Biographical notes: Filippo Cavallo received the Master Degree in Electronic Engineering from the University Of Pisa, Italy, in 2003. In the same years he joined the ARTS Lab, Scuola Superiore Sant'Anna, Pisa, as Research Fellow, working in pedestrian navigation. From 2004 to 2007 he defended his Ph.D. degree in bioengineering at CRIM Lab, Scuola Superiore Sant'Anna, Pisa. Since 2006 he has also joined the EndoCAS – Center of Excellence, Pisa, working in computer assisted surgery. His field of research is focused on computer-assisted surgery, analysis of surgical gesture, biomechanical analysis, wearable sensor systems, sensor networking, localization and navigation system and biomedical signal processing.

Stefano Sinigaglia was born in 1976 in Livorno (Italy). He received the master degree in Physics from the University of Pisa on 2003. In the same year he joined to the Computer Assisted Surgery Group of the CRIM Lab of the Scuola Superiore Sant'Anna. He received Ph.D. degree in Electronic Engineering and Computer Science from the University of Genova in 2007. His research interests are in the fields of machine learning theory focused on gesture analysis, surgical simulators and training, robot learning and robot control.

Giuseppe Megali was born in 1972 in Reggio Calabria (Italy). He received the Laurea degree in Computer Science from the University of Pisa in 1998, and in the same year he joined to the MiTech Lab (now CRIM Lab) of the Scuola Superiore Sant'Anna in Pisa. He received his Ph.D. degree in Robotics from the University of Genova in 2002. From 2002 to 2004 he had a Post-Doctoral fellowship in Bioengineering at the Scuola Superiore Sant'Anna in Pisa. Since 2004 he is assistant professor of Biomedical Robotics at the Scuola Superiore Sant'Anna. His main research interests are in the field of biomedical robotics, computer-assisted surgery and analysis of surgical gesture. His research is carried out in the context of National and European projects in the field of biomedical engineering.

Since October 1998, Anna Eisinberg has been involved in research activities at the CRIM Lab, in the Micromanipulation Group. She acquired research skills in the following areas: Design and control of sensorized instrumentation for micromanipulation; Microassembly of mechanical components; Manipulation and characterization of mini and micro biological samples; Haptic interfaces; Adhesion forces in micromanipulation; Robotics for physiology; Micromanipulation in medicine. Since July, 1st 2004, Assistant Professor of Biomedical Engineering at the Scuola Superiore di Studi e Perfezionamento Sant'Anna, Pisa, Italy.

Andrea Pietrabissa was born in 1959 in Pisa. He graduated with honors in Medicine and Surgery at the University of Pisa and he specialized in General Surgery. From 1986 to 1988 he was Research Fellow in Hepatic Transplantation at the University of Chicago, and from the 1992 to the 1993 he was Senior Registrar at the Ninewells Hospital in Dundee (Scotland) and Lecturer in Surgery at the University of Dundee. Since 1999 he is Associate Professor of General Surgery at the University of Pisa. He is responsible of the Minimally Invasive Section of the Department of General Surgery and Transplantation at the University of Pisa, and, until now, he performed over than 3000 surgical interventions. He is member of several scientific societies (EAES European Association of Endoscopic Surgeons, SAGES Society of American Gastrointestinal Surgeons), and he is in the international Editorial Board of the Surgical Endoscopy journal. He was involved in a lot of research projects at national and international level and co-inventor of some patents.

Paolo Dario received the Dr. Eng. Degree in mechanical engineering from the University of Pisa, Pisa, Italy, in 1977. He is currently a Professor of

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Biomedical Robotics at the Scuola Superiore Sant'Anna, Pisa, Italy. He also teaches courses at the School of Engineering of the University of Pisa, and at the Campus Biomedico University, Rome, Italy. He has been a Visiting Professor at Brown University, Providence, RI, at the Ecole Polytechnique Federale de Lausanne (EPFL), Lausanne, Switzerland, and at Waseda University, Tokyo, Japan. He was the founder of the Advanced Robotics Technologies and Systems (ARTS) Laboratory and is currently the co-ordinator of the Center for Research in Microengineering (CRIM) Laboratory of the Scuola Superiore Sant'Anna, where he supervises a team of about 70 researchers and Ph.D. students. He is also the Director of the Polo Sant'Anna Valdera and a Vice-Director of the Scuola Superiore Sant'Anna. Prof. Dario served as President of the IEEE Robotics and Automation Society during 2002–2003, and he is currently Co-Chair of the Technical Committees on Bi-robotics and of Robo-ethics of the same society.

Cost measurement in laparoscopic surgery: results from an activity-based costing application

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Abstract Activity Based Costing (ABC) techniques are designed to support advanced cost analysis in different organizations. Centred on organization activities and processes, it provides more accurate cost information on cost objects using appropriate cost drivers and constitutes a powerful costing model to improve efficiency and effectiveness in delivering products and services.

ABC can be successfully applied also in Health Care organizations, where the patient is the main “object” of the activities performed. In addition, it can be fruitfully used in costing the resource consumption of new medical technology devices or surgery processes to assess their economic impact on health care costs. The purpose of this paper is to describe an Activity based costing model designed to measure and control resources consumption and cost when a new technology is applied in health care processes. An ABC model has been defined in relation to laparoscopic technologies applied to surgical cases, designing a health care “activity hierarchy” based on the processes of a specific local unit organization. The output of the application has been a full cost of laparoscopic surgery to be compared with the correspondent DRG current value.

As a further result, the paper shows how the ABC model is able to generate different cost figures referred to activity levels or aggregations able to support decision making especially when the introduction of a new surgical technology has to be economically assessed. Propositions are finally made to generate discussion about the effectiveness of the existing cost accounting systems in the health care organizations and on the need for the wider diffusion of ABC techniques in this service sector.

Key words: Activity-Based Costing, Economic assessment of surgery techniques

Biographical notes: Lino Cinquini is professor in Management Accounting and Business Administration at the Scuola Superiore Sant'Anna of Pisa. His main research areas are Cost management, Strategic Management Accounting and Performance measurement. He is involved in projects on Health Care management of the Management and Health Laboratory (Mes Lab) of the Scuola Superiore Sant'Anna

Paola Miolo Vitali is professor in Management Accounting and Business Administration at the University of Pisa. Her main research areas are Management and Cost Accounting and Performance measurement in private and public sector.

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Patient mobility, Health Records portability and medical “accountability”: in search of a better system to protect citizens health and medical professionals

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Abstract: Modern rich societies are experiencing increasing mobility as regards its citizens, both within and outside national or regional borders. At the same time, it is possible to note the mobility of medical professionals across nations either for short, (e.g. for the performance of surgical operations in hospitals globally) or longer stays (e.g. nurses or medical doctors permanently migrating to other countries). Against this bedrock, there is a striking difference among different countries regarding the regulation each legal system offers when it comes to several issues relevant when considering the circulation of either patients or medical professionals. Among the relevant regulated topics are certainly, but not exhaustively: medical malpractice standards, data protection and circulation, health records management, medical accountability and medical boards responsibilities, electronic records management; proficiency levels monitoring. The aim of this paper is to sketch the main problematic issues arising from this new trend of circulation within the European Union borders, in order to envisage a possible model of (electronic) data recording which could integrate with different regulatory frameworks (e.g. tort law for malpractice; data processing for privacy protection; the relationship between professional accountability and the relevant regulating medical board; electronic documents and signatures for data security; liability and first party insurance). This comprehensive, flexible, regulatory framework should permit, at least, better monitoring of health care delivery, more safe citizen circulation, a reduction of the tension among players in national health care systems, a possible link between risk management and compensation costs awarding systems.

Keywords: Patient mobility, Health Records; “accountability”; health; medical professions; privacy, fundamental rights

Biographical notes: Prof. Dr. LLM Giovanni Comandé is a full Professor of Private Comparative Law, Scuola Superiore Sant'Anna, Pisa, Italy. He is also the Director of the Lider-Lab, an international and comparative law research laboratory (www.lider-lab.eu). Alongside this, he is a Visiting Professor of Private Comparative Law and Comparative Electronic Business Law at several American Universities. He holds membership of the Italian State Bar in Pisa and is also an Attorney at Law, Member of New York State Bar. Presently, he acts as Professor (by contract) of Private Comparative Law at the University of Pisa School of Law (1999-to present). His other activities include, member of the European Group on Tort Law for drafting Principles of European Tort Law (PETL), and member of the European center for Law and Insurance (www.ectil.org, Wien). Among his fields of interest are comparative law, tort law (mainly medical malpractice, personal injury damages, products liability), European private law, insurance law, information society law (mainly privacy and e-commerce), health law, and fundamental rights protection.

Changes in the Hospital Care Following European Working Time Directive

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Abstract: The European Working Time Directive (EWTD) became EU law in 1993 but certain groups were excluded (doctors in training, workers in road, air, sea, rail and inland waterways). The EWTD was revised in August 2000 to include these previously exempt worker groups. As far as doctors are concerned the EWTD mandates that by 2009 no doctor in training will be allowed to work more than 48 hours/ week. This has major implications and challenges to the training of doctors as future specialists and to healthcare delivery in EU member states. Thus in the UK, where statistical data are available, the revised EWTD has reduced surgical training from 30,000 man hours of clinical training over a 5 year period to 6000 man hours over the same period (80% reduction). Within EU member states, specialist training based exclusively on the clinical apprenticeship system is no longer sustainable and the nature/ delivery of healthcare is being subjected to significant changes imposed by the revised legislation. Thus national healthcare systems would need to recruit some several thousand extra middle grade doctors (double or treble this work force) while simultaneously maintaining current levels of service provision and retaining similar working practices. Several measures are actively being considered to address these problems: (i) training senior grade nurses as specialist nurse practitioners to perform tasks previously done by doctors, (ii) creation of non-doctor roles such as doctors' assistants to reduce doctors' workload by reduction of 'non-medical tasks' of doctors, (iii) recruitment of pharmacy technicians to manage patient medicines to free up doctor time and (iv) the establishment of multi-specialty skills training laboratories to complement the clinical apprenticeship system and to train healthcare workers in communication, leadership and team skills. The health economic aspects of these and other measures would also need to be addressed.

Keywords: working time, training, EU Directive.

Biographical notes: Alfred Cuschieri is Professor of surgery at the Scuola Superiore Sant'Anna and has been recently appointed Research Director and Chief Scientific Advisor to the Institute Of Medical Science and Technology, a joint initiative between the Universities of Dundee and St Andrews in Scotland. He was formerly Professor of Surgery and Head of the Department of Surgery and Molecular Oncology at the University of Dundee. Professor Cuschieri has received numerous international awards for his contributions to the development, practice and training in minimally invasive surgery including the International Society of Surgery/ Société Internationale de Chirurgie, 1993 Prize of the Society for "pioneering work in minimal access surgery", Ernest Miles medal, 1996, Sir John Marnock Medal – University of Aberdeen, 1997, Royal College of Surgeons of Edinburgh, Gold Medal, 1997, Knight Bachelor -

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Her Majesty Queen Elizabeth II, 1998, Fellow of the Academy of Science, 1998, Fellow of the Royal Society in 1998, Queen's award for higher and continued education in 1999, Excel Award of the Society of Laparoendoscopic Surgeons 'for outstanding contributions to laparoscopy, endoscopy and minimally invasive surgery in 2000, the SAGES outstanding achievement award in 2001, The Nissen Prize – German Surgical Association in 2001, Gimbernet's prize – Catalonian Surgical Society in 2001, Life time achievement award Indian Association of Endoscopic Surgeons in 2004, Hon Fellowship of the American College of Surgeons in 2005 for 'outstanding contributions to the science and practice of surgery', Hon Member American Surgical Association in 2006 'for seminal contributions to surgical science'. He has been conferred with Hon Degrees from 6 European Universities and has been visiting Professor to 24 Universities in Europe, North America and China. He is the Editor in Chief of Surgical Endoscopy and serves on the Editorial Board of 6 other major peer-review journals. He has served as President or council member of 15 surgical national and international societies. He has 452 original publications in major peer review journals and is the author of 23 books.

Giuseppe Turchetti received his Laurea Degree in *Economics and Management* from the University of Pisa. He received his PhD in *Economics and Management* from the Scuola Superiore Sant'Anna in Pisa, where he is associate professor of *Economics and Management*. He spent several years for research in USA as Visiting Scholar at The Wharton School of the University of Pennsylvania. He is Co-Founder of the Research Centre on Technologies and Services for the Support of Longevity (EZ-Lab) and of the Research Laboratory on Management and Innovation (MAIN Lab), and the Director of the Research Centre on European Transplantation Management (ETXMAN Centre) of the Scuola Superiore Sant'Anna, Pisa. His main research interests are in the fields of the organisation, financing and evaluation of healthcare services and health technologies. He is working on several national and international projects in the area of healthcare technologies and management. He is author of several books and scholarly papers, and he is Associate Editor of the *International Journal of Biomedical Engineering and Technology* (IJBET) published by InderScience.

High Resolution Read-out Circuit for DNA Label-Free Detection System

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paper

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Abstract: This paper presents novel read-out electronic systems for a fast DNA label-less detection. The capacitive shift due to the hybridization effect is monitored by means of a charge sensitive amplifier and a differential stage. The systems provide an A/D conversion and an evaluation of the capacitive shift amount with a resolution of 11 bit. The read-out solutions demonstrate the ability to identify a 0.01% variation on the capacitive value of the sensor. The investigated techniques are suitable for monolithic systems or for a micro-fabricated array of sensors.

Keywords: DNA biosensor read-out. Charge sensitive front-end, differential read-out system.

Biographical notes: *Daniela De Venuto* graduated in Electronic Engineering at the Politecnico di Bari, Italy, in 1989 where received the PhD degree in 1992. In 1993 Dr. De Venuto took a post-doctoral position at the Politecnico di Bari and since 1993 she is member of (National Institute of Nuclear Physics) INFN working on silicon drift detector design (DSI Project) and in design and test of radiation hardened analogue front-ends for pixel-detector (ALICE project) developing part of research activity at CERN, Geneva, Switzerland. She became assistant professor in 1994 at the University of Lecce, Italy and then in Bari in 1999. In 2000 Dr. De Venuto was on sabbatical leave at the Laboratoire d'Electronique Generale as Fountioner Scientifique at the Ecole Fédéral de Lausanne (EPFL), Switzerland. During this stay she worked in the area of Hall sensor interface design in FD SOI technology. Since 2002 she is Visiting Scholar at the University of Washington, Seattle (USA) and Visiting Professor at the Lancaster University (UK). Since 2003 she is Associate Professor at the Politecnico di Bari teaching courses in Analog Electronics and Design of Integrated Circuits and System. Prof. De Venuto is co-author of more than 100 papers on major international Journals and Conferences Proceedings and of a patent on a fully digital technique to test Sigma-Delta ADC in collaboration with the Politecnico di Torino. Her research interests include the design and test of analogue Ics, design for testability for analogue and mixed-signal circuits as well as characterisation of sensors.

Bruno Riccò was born in Parma (Italy) on February 8, 1947. In 1971 he graduated in electrical engineering at the University of Bologna (Italy) and in 1975 received a Ph.D. from the University of Cambridge (U.K.) where he worked at the Cavendish Laboratory. In 1980 he became Full Professor of Applied Electronics at the University of Bologna. He has been Visiting Professor at the University of Stanford, at the IBM Thomas J. Watson Research Center (Yorktown Heights) and at the University of Washington. From 1986 to 1996 he has been European Editor of the IEEE Transaction on Electron Devices. Senior Member of the IEEE in 1991, in 1995 he received the G.

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Marconi Award by the Italian Association of Electrical and Electronics Engineers (AEI), for his research in electronics. In 1996 he became President of the Group of Electron Devices, Technologies and Circuits of AEI and in 1998 became President of the Italian Group of Electronics Engineers. In 1999 he was appointed European representative for the International Electron Device Meeting (IEDM). In 2002 he has been elected Chairman of the IEEE North Italy Section. Starting January 2003 he has been elected Fellow of the IEEE. In 1999 he founded the first university spin-off in Italy active in the field of advanced digital systems. From 2001 to 2005 he was in charge of the policy for technology transfer and spin-off creation of the University of Bologna. Since 2005 he is leading the program PIU, a cooperation between the University of Bologna and the Chamber of Commerce of Bologna, aimed at supporting research in Small/Medium Enterprises. Since 2005 he is leading T3Lab, a structure established by the University of Bologna and Confindustria Bologna for technology transfer from the academic world to industries. Since 2003 is the President of I Tech-Off, a consortium (between the University of Bologna, Aster and Fondazione Alma Mater), for the creation of knowledge-based enterprises in the field of ICT. Prof. Riccò has been consulting for major semiconductor companies and for the Commission of the European Union in the definition, evaluation and review of research projects. From a scientific point of view, Prof. Riccò has worked in the field of microelectronics and is (co-) author of over 300 publications on major international Journals, of three books and of 6 patents in the field of Non-Volatile memories.

Healthcare Risk Management: an Advanced Decision Support System for risk assessment and patient safety

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paper

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Abstract: The presence of high risk activities, dangerous and harmful for patients, increases the intrinsic complexity of healthcare organizations, bringing out the need of identifying innovative practices for risk management. The aim of this paper is to create a Healthcare Risk Management Map by which it will be possible to clearly and accurately identify high risk healthcare units depending on their inner processes and associated risks. The map will be created by developing a unique conceptual framework based on the assumption that each clinical process can be divided into five macro-areas - i.e. Documental, Reception/Anamnesis, Diagnosis, Cure, Post Cure - and analyzed from four main points of view: Software (working rules and procedures), Hardware (tools, equipments, technologies), Environment (workplace, social and politics backgrounds), and Liveware (human and relationship factors), This Map will allow to calculate indexes and parameters necessary to evaluate risks as well as to create a communication channel between inside and outside actors (end-users, suppliers, insurance, and maintenance companies).

Keywords: Healthcare Risk Management, Risk Map, Quality of Care, Healthcare Process Analysis

Biographical notes: Giuseppe Digregorio got the master degree in Management Engineering in 2001 and the Ph.D. in Advanced Production Systems at the Polytechnic of Bari (Italy) in 2006. He is currently professor of Project Management at Polytechnic of Bari. His research activities are related essentially to two interconnected topics. The first one concerns the healthcare services localization and, in particular, the developing of a decision support system for Hub and Spoke healthcare network, the second concerns the risk management models for healthcare organizations.

Claudio Garavelli is Full Professor at the Polytechnic University of Bari. He has obtained his Ph.D. in Engineering Management and he has been Assistant Professor at the University of Basilicata, Italy, since 1994. Visiting scholar in 1996 at the University of South Florida (Tampa, USA), he was formerly Associate Professor at the University of Lecce. His main teaching and research areas concern operations management, decision support systems, organisation clusters. He is involved in many national and international research projects and he is author of more than 80 papers published on national and international journals and conference proceedings.

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Fulvio Iavernaro got a Ph.D. in Operations Management at the Economic and Technology Department of University of the Republic of San Marino. He is involved in the research activities of the Knowledge Management Lab at the Mechanical and Management Engineering Department of Polytechnic of Bari where he also supports teaching activities of the graduate courses such as Economics Applied to Engineering, Management, and Management Control System. His research activity is mainly focused on two interrelated topics: new product development and process analyses.

Models of Information Systems devoted to Medical Imaging Labs: an experience in the CNR Clinical Physiology Institute

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paper

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Abstract: At the end of the 1990's, the SPERIGEST project, supported by the Italian Health Ministry, and fully developed at the Institute of Clinical Physiology in Pisa, established an operative integrated clinical and healthcare information system. From that first implementation, a continuous evolution aims to realize and optimize procedures and protocols, by solving problems of: harmonization of instrumentation of different brands; management of multimedial data provided by different medical imaging labs; satisfaction of both clinical and research needs as well as legal and economical requirements; user-friendship of the provided tools. A ten years experience shows that the positive approach by medical and healthcare operators guarantees coordinated activity, higher efficiency, simplified procedures which imply a major concentration onto the medical decision-making issues.

Keywords: information systems; healthcare management; medical imaging.

Biographical notes: Ezio M. Ferdeghini is Senior Technologist at the C.N.R. Institute of Clinical Physiology, Pisa, Italy. Graduated in Physics from the University of Pisa. His main research areas of interest include biomedical imaging, medical information systems, telecommunications. He has contributed to various journals and participated to conferences both for presentations and as invited chairman.

Alberto Macerata is Associate Professor of Bioengineering and Informatics at the Department of Human Physiology of the University of Pisa. Graduated in Electrical Engineering at the University of Pisa (1975). Chief of the Unit of Bioengineering and Medical Informatics of the C.N.R. Institute of Clinical Physiology. His research area includes biomedical signal analysis, healthcare information systems and standardization in medical communications.

Antonio Benassi is Research Director at the CNR Institute of Clinical Physiology, Pisa, Italy. Graduated in Informatics at the University of Pisa. Chief of the Department of Tecnosciences for the Bio-Medicine of the C.N.R. Institute of Clinical Physiology. His research areas include biomedical engineering, biomedical electronics, telecommunications. He has provided a large contribution to many important journals, and he holds many national and international copyrights on tools and technologies supporting medical research and clinic.

Improving daily clinical practice with 3D patient-specific anatomical models: limits, methodologies and our experience

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Abstract: In today clinical practice radiologists and surgeons make diagnosis and establish therapies on the basis of a “mental model” of the specific anatomy of the patient that they create starting from the information given by

pre-operative exams (consisting in volumetric data examined as sequences of 2D images) and their anatomical knowledge. Current technologies give the possibility to visualize volumetric medical dataset, such as computer tomography (CT) and magnetic resonance (MRI), with 3D virtual models of anatomical structures. This kind of visualization permits an easy and natural understanding of anatomical structures described by the images, avoids interpretation error of the exams, and allows a clear communication between the radiological and the therapeutic departments. Further, the introduction of this 3D virtual representation of the patient anatomy inside the operative room, will lead to a revolution of the surgical scenario due to the development of image-guided and robotic systems. Visualization of 3D patient specific anatomical models offers great benefits for the physicians, in terms of improved diagnosis, surgical planning and surgical intervention, for the patients, in terms of safety and reduced invasiveness, and for the sanitary system in terms of efficiency and financial resource (due to less errors and reduced intervention time). In the paper we describe our experience in the adoption of these techniques in the treatment of abdominal organs and we provide an overview of solutions and of the methodological approach we followed in the development of a navigation system for laparoscopic surgery in the abdominal district.

Keywords: medical imaging, segmentation, registration.

Biographical notes: Vincenzo Ferrari was born in 1976 in Italy. He received the master degree in computer science engineering from the University of Pisa in 2001. In 2002 he worked at ISTC-CNR (National Research Council) on motion modeling and surface deformation for a 3D talking face. From 2003 to 2005 he worked for a private company on machine vision, voice interactive systems, animatronics and 3D avatars, and he received a master in energetics. In January 2006 he joined to the EndoCAS Center as PhD Student in Health Technologies at the University of Pisa where he works on segmentation and registration of medical images.

Giuseppe Megali was born in 1972 in Reggio Calabria (Italy). He received the Laurea degree in Computer Science from the University of Pisa in 1998, and in the same year he joined to the MiTech Lab (now CRIM Lab) of the Scuola Superiore Sant'Anna in Pisa. He received his Ph.D. degree in Robotics from the University of Genova in 2002. From 2002 to 2004 he had a Post-Doctoral fellowship in Bioengineering at the Scuola Superiore Sant'Anna in Pisa. Since 2004 he is assistant professor of Biomedical Robotics at the Scuola Superiore Sant'Anna and coordinator of the EndoCAS Center. His main research interests are in the field of biomedical robotics, computer-assisted surgery and analysis of surgical gesture. His research is carried out in the context of National and European projects in the field of biomedical engineering.

Carla Cappelli was born in 1974 in Pisa. In 2000 she graduated with honors in Medicine and Surgery at the University of Pisa and she specialized in Radiology in 2004. In 2005 she was Research Fellow at the Diagnostic and Interventional Radiology of the Department of Oncology, Transplants and Advanced Technologies in Medicine of the University of Pisa. Since 2006 she is PhD Student in Health Technologies at the University of Pisa, working in the Diagnostic and Interventional Radiology; she also collaborates with the EndoCAS Centre of the University of Pisa. Her main research interests are in the field of abdominal multidetector CT, particularly on its application to pancreatic diseases.

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Elena Troia was born in 1978 in Terlizzi (Bari, Italy). She received the master degree in Mechanical Engineering from the Politecnico of Bari in 2005 discussing a thesis about "Setting up of models (numerical and experimental) of lumbar spine for the study of spinal painful pathology". In 2006 she has worked as research fellow at the EndoCAS Centre of the University of Pisa where she designed mechanical tools for optical purposes. Since January 2007 she is Ph.D. student in Health Technologies at the University of Pisa. Her main research interests are in the field of biomedical robotics, computer-assisted surgery and analysis of surgical gesture. Her research is carried out in the context of National and European projects. Since July 2007 she's a student member of European Society of Biomechanics.

Filippo Cavallo received the Master Degree in Electronic Engineering from the University Of Pisa, Italy, in 2003. In the same years he joined the ARTS Lab, Scuola Superiore Sant'Anna, Pisa, as Research Fellow, working in pedestrian navigation. From 2004 to 2007 he defended his Ph.D. degree in bioengineering at CRIM Lab, Scuola Superiore Sant'Anna, Pisa. Since 2006 he has also joined the EndoCAS – Center of Excellence, Pisa, working in computer assisted surgery. His field of research is focused on computer-assisted surgery, analysis of surgical gesture, biomechanical analysis, wearable sensor systems, sensor networking, localization and navigation system and biomedical signal processing.

Andrea Pietrabissa was born in 1959 in Pisa. He graduated with honors in Medicine and Surgery at the University of Pisa and he specialized in General Surgery. From 1986 to 1988 he was Research Fellow in Hepatic Transplantation at the University of Chicago, and from the 1992 to the 1993 he was Senior Registrar at the Ninewells Hospital in Dundee (Scotland) and Lecturer in Surgery at the University of Dundee. Since 1999 he is Associate Professor of General Surgery at the University of Pisa. He is responsible of the Minimally Invasive Section of the Department of General Surgery and Transplantation at the University of Pisa, and, until now, he performed over than 3000 surgical interventions. He is member of several scientific societies (EAES European Association of Endoscopic Surgeons, SAGES Society of American Gastrointestinal Surgeons), and he is in the international Editorial Board of the Surgical Endoscopy journal. He was involved in a lot of research projects at national and international level and co-inventor of some patents.

The transformation of ConvaTec, a Bristol-Myers Squibb Division into a real customer-oriented company: considering CRM as an organizational strategy

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paper

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Abstract: The Italian affiliate of ConvaTec, a Bristol-Myers Squibb Division, engaged in a transformation process from product focused commodity provider to patient and customer oriented healthcare player. Actually, the great opportunity for ConvaTec in Italy was to become a true Customer Relationship Management Company in the ostomy business. Reacting on the needs of in-calling patients, the organization set up a service center and different information services for patients in parallel to their conventional sales force structure. The call center started with out-bound calls to reach more patients. Finally the different customer channels (call center counselors and sales representatives) were integrated, the sales approach transformed into a consultative approach targeting the main customers, mainly nurses, as well as individual patients. The customer and patient centric approach had direct positive effects on ConvaTec's market position in Italy.

Keywords: customer relationship management; CRM; customer centric; customer oriented; customization; service; ostomy; medical devices

Biographical notes: Ferruccio Fiordispini is Managing Director at SIAF, International School of Advanced Education in Management and Technology, located in Volterra, Tuscany. After his university degree in economics he served as an officer (lieutenant) of Guardia di Finanza, Italian national police corps. After receiving his master's degree in marketing and communication, he started his business career in Nestlé, the world leading food manufacturer, where he developed as a marketer, working in Italy and Germany and managing several strategic brands (Nescafé, Kit Kat, Smarties, Baci Perugina). Then he was in Coors, a major US brewer, as a Country Manager for Italy. Later he has been working for Bristol-Myers Squibb, a major pharmaceutical multinational corporation, where he has held several positions in Italy, Germany and the UK. His last responsibility was Marketing Director for Europe. He is a member of Italian Society of Marketing and has served as lecturer and teacher of marketing at several universities and training centers, including the Scuola Superiore Sant'Anna of Pisa.

A Sub Rosa World: Medicare and the Cost of New Technology

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paper

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Abstract: Medicare, the United States program that provides health care coverage to the elderly and disabled, is not allowed to consider cost when making coverage decisions about new medical technologies. The cost concerns are still present, however. The current focus on evidence-based medicine, which purports to encourage more rational and useful coverage decisions, presents a series of problems in the context of these unspoken cost concerns. This article examines how cost and the principles of evidence-based medicine as used by CMS and device manufacturers can lead to distorted decision-making throughout the United States health care system.

Key Words: medicare, coverage, evidence-based medicine, cost-benefit

Biographical notes: Jacqueline R. Fox, J.D., LL.M., is an assistant professor of health law and bioethics at the University of South Carolina School of Law. Fox received her J.D. and LL.M. at Georgetown University Law Center, was a post-doctoral Greenwall Fellow in health policy and bioethics at Johns Hopkins University, and a Yale University Donaghue Visiting Scholar of Research Ethics.

Medicine, science, and the law. From risk management to insurance changing mechanisms

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Abstract: This paper analyses the relationship between new scientific paradigms (both medical and not medical) and the parameters of risk assessment in insurance contracts. Insurance itself presents a new model: the traditional scientific paradigm in insurance uses a mathematical description of the risk and an assessment based on (a large amount of) historical data. One of the main effects of this paradigm is that many problems are studied and analysed only after the production of errors and damages. The shift towards the new dynamic paradigm in insurance (which involves a link between insurance and risk management) could have good applications in the field of medical malpractice, especially if combined with – and analysed with parallel attention to – the rise of the new standards of care in medical liability law. Thus, liability rules and risk assessment parameters in insurance contracts could both combine, and give more scientific importance to usually ignored risk features.

Keywords: scientific paradigm; insurance contract law; risk assessment parameters; risk features; risk management, medical malpractice, healthcare.

Biographical notes: Maria Gagliardi is Researcher of Comparative Private Law in the Scuola Superiore Sant'Anna, Pisa. She earned her PhD in Comparative Law from the University of Firenze. She teaches as professor assistant undergraduate and graduate courses in Comparative Private Law and Insurance Contract Law; she is a teacher in many advanced courses at the Scuola Superiore Sant'Anna. Her research areas of interest include comparative private law, insurance contract law, tort law, privacy, and information and communication technologies law. She has published law journals articles, and chapters in edited books. She has been an invited speaker at both national and international conferences.

Mass medication distribution for disease outbreak – comparison of PDA vs. paper-based decision support

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Abstract: In a disease outbreak medication must be rapidly yet safely distributed to a population. Are there significant differences in efficiency (time) and error rates in drug dissemination to a population using algorithm-driven paper vs. PDA methodology? In this study, conducted at the University of Hawaii, mock citizens were sent through points of dispensing with volunteer clerks processing them during two sessions (alternating modes for session two). No significant differences were found in time or number of errors with PDA vs. paper. However, mode and order of testing affected time. Clerks doing the paper method second were slower than those doing paper first (significant at $p < .0001$ level). The PDA was consistent in time whether clerks used it first or second. This may indicate the presence of a fatigue factor from using the paper method and may indicate that during an outbreak, when clerks are tired, using an algorithm-driven PDA may help to sustain efficiency.

Keywords: PDA, mass medication distribution, algorithm, errors, efficiency, disease outbreak

Biographical notes: Victoria Garshnek received her P.D. from the University of Oregon in Physiology and applied her interests at the Naval Aerospace Medical Institute, Pensacola Florida, as an Aerospace Physiologist. She became a Research Analyst with NASA Headquarters, Washington, DC. and held an Assistant Research Professorship at the George Washington University Elliott School of International Affairs, Center for International Science and Technology Policy, conducting research on satellite use for disaster relief and telemedicine. After moving to Hawaii she joined the Pacific E-Health Innovation Center, Tripler Army Medical Center, to manage the Telemedicine Evaluation Initiative, and later became Telemedicine Research Director. Currently she is the Telemedicine Research Coordinator at the Telehealth Research Institute, University of Hawaii School of Medicine.

Lawrence Burgess is a graduate of the US Military Academy and the John A. Burns School of Medicine, University of Hawaii (UH). He is a Board Certified Otolaryngologist Head and Neck Surgeon, who recently completed a

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distinguished career in the Army, where he served as Chief of Surgical Services at Tripler Army Medical Center. He also served as the Consultant to the Surgeon General of the Army for Otolaryngology. As the Director of the Telehealth Research Institute at UH, he continues to work with the Department of Defense in developing telehealth and advanced medical technologies (including virtual reality and simulation), while assisting Hawaii and Pacific Rim organisations to improve their telemedicine capabilities. Currently he is also Associate Dean for Government Affairs and Professor of Surgery at UH.

Dr. Deborah Birkmire-Peters received her Ph.D. from the University of Delaware in Newark in the area of Cognition. From 1979 – 1987 she served as a Research Psychologist with the US Army Human Engineering laboratory, Aberdeen Proving Ground, MD. From 1987 – 1993 she continued there as the Team leader in Visual Performance . She relocated to Hawaii in 1995 as a Researcher at Tripler Army Medical Center, Hawaii, and became Director of Telemedicine Research in the Department of Surgery at Tripler in 1997. In 2002 she accepted the position of Research Manager, Telehealth Research Institute, John A. Burns School of Medicine, University of Hawaii, where she continues with Telehealth research, notably the Diabetes Care and Treatment Program, a Joslin Telemedicine Initiative. Its major goals are the establishment of a telemedicine system for comprehensive diabetes management and assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care.

Christoph Aschwanden received his doctorate in Computer Science from the University of Hawaii. He has a Master's in Electrical Engineering from the Federal Institute of Technology in Switzerland. Christoph Aschwanden is currently working as Program Manager for the Telehealth Research Institute, John A. Burns School of Medicine. He is a leading researcher for haptic interfaces and surgical simulation. He is also involved in research projects with the Institute for Triple Helix Innovation and Tripler Army Medical Center.

Danny Horne graduated from the University of Texas, and received his masters degree in personnel management from Central Michigan University. He recently retired from US Air Force Reserves as Intelligence Officer and the U.S. Army, Pacific (USARPAC) Deputy Chief of Staff for Medical (DCSMED), where he served as a medical planner. He was the administrator for the Asia-Pacific Military Medicine Conference conducted annually by USARPAC under the Theater Security Cooperation Program (TSCP). He was also in charge of medical planning for operational and contingency plans and coordinated peacetime and wartime health service support with USPACOM, service components, major subordinate commands, and MEDCOM. He also assisted with coordination for force health protection issues and military medical engagements in support of the TSCP. Currently he is Project Administrator for ICU Multipoint Military Pacific Consultation Using Telehealth (IMMPACT) at the Telehealth Research Institute, University of Hawaii School of Medicine.

Brooke Burgess is a graduate of Creighton University, Omaha, Nebraska, and served as a research assistant for this study. She was instrumental in data collection and analysis.

RD Clyde is a Senior Solutions Developer for CTA, Inc., Honolulu, HI. He is a Microsoft Certified Professional as well as an A+ Certified Computer Technician. His skills include database design, application architecture/development, computer instruction, project management, and Sharepoint development. His major projects include web-based intranet

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applications for use by CINCPACFLT. He has also worked with Tripler Army Medical Center to build computer applications to record a patient's medical readings and assist physicians in determining a course of treatment. His work with PDA technologies is noteworthy in both the Nurse's PDA project (PDA configured for use by in-home medical care providers to record/track patient medical conditions) and also the Patient's Medical Assistant project (a configured PDA for diabetic patients to record/track their readings such as blood glucose, then uploaded to web server using GPRS cellular phone uplink built into the PDA).

Michael R. Meyer graduated from the University of Hawaii Hilo and received a Masters degree in history from the University of Hawaii Manoa. He has spent over thirty years in electronic media implementing new technologies for the cable television industry. While with Time Warner Cable he oversaw the implementation of many new media services including the launch of Road Runner High Speed Internet service. Since 1999 he has been the president of Wave Internet, a software development and computer consulting company. He is also on the faculty of the University of Hawaii system having taught History, Computer Science, and Business Technology.

A proposal of a management framework to optimize waiting queue in healthcare organizations

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Abstract: The internal dynamics of a hospital represent a complex non-linear structure. To plan and manage day-to-day running of a hospital requires a thorough understanding of the system together with detailed information for decision-making. The main objective of a hospital is to offer services of good quality to their patients utilizing their medical expertises with the support of their specialized and expensive infrastructures: personnel, intensive care units, surgical operations units, specialized laboratories besides beds for in-patient stay, ambulances for emergency transfers, pharmacy for the required medicines and the other logistic infrastructures like restaurant for preparing food and the laundry service. To maintain high quality standards these resources have to be coordinated in order to eliminate “slack” at various resources centres and the inefficiencies caused by discharge delays, late-start surgeries and slow laboratory turnaround. For this reason we can say that hospitals need a planning and control system to plan patients’ processes and required capacity. Poor capacity, resources utilization and the more and more high waiting times are among the strategic issues that continue to plague hospital planners. The question is ‘how do we give patients the right services at the right times?’ The following paper presents a tool to manage, plane and coordinate the resources in a hospital in order to reduce the waiting queue and increase the resources utilization. The study applies the integration concepts of ERP systems, widely used in manufacturing environments, to the healthcare organizations. Referring to DRG (Diagnostic-Related Group) and considering the hospital resources linked to the patient treatment (medical staff, nurse, surgery theatres, support departments, etc), a planning and control system is developed. It looks at the patient like the customer who needs the services offered by hospitals and at the treatment like the instrument to define the necessary resources and materials besides the lead times to provide the suitable service. Following the ERP system logic, it processes data (patients and available resources) and planes the resources utilizations according to the real patients needs, highlighting, if there are, overloads and problems. The system considers also difference between inpatient, out-patient, and emergency and integrates the resources of the different departments.

Keywords: healthcare systems; MRP system; hospital resources planning.

Biographical notes: Raffaele Iannone graduated cum laude in Mechanical Engineering in 2000. After a collaboration with Department of Mechanical Engineering (DIMEC) in 2001 he earned his Phd, in Advanced Manufacturing System Engineering, in 2005 with a dissertation on Supply Network Management. Currently he works at University of Salerno as assistant professor in Operations Management. His research areas of interests include Supply Chain Management, Production Planning, Simulation, Operations Management, ERP and Just-In-Time Systems. He has about fifteen publications in national and international conference proceedings and international journals.

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Claudia Pepe graduated in Mechanical Engineering in March 2005. Currently she is a Phd student in Mechanical Engineering at University of Salerno. She spent about seven month at the Concordia University in Montreal (Canada) to collaborate for a research on Healthcare Systems. Her research areas of interests include Production Planning and Scheduling, Simulation, Operations Management, ERP and Hospital Planning. She has publications in national and international conference proceedings.

Stefano Riemma graduated cum laude in Mechanical Engineering in 1988. He's worked in a aeronautical company for about five years as a responsible for start up and management of new advanced manufacturing systems. In 1997 he obtained his Phd in Industrial Plant Management with a dissertation on Advanced tools for design and management of Flexible Manufacturing Systems. He became associate professor at Department of Mechanical Engineering at University of Salerno. Since 2002 he is a full professor in Operation Management at the same University. His research areas of interests include Supply Chain Management, Automation of Manufacturing System, Production Planning, Manufacturing Information Systems, ERP Systems. He published works on international journals like *International Journal of Production Research*, *International Journal of Flexible Manufacturing Systems*, *International Journal of Computer Integrated Manufacturing* as well as international and national conference proceedings. He is member of APICS, POMS and INFORM.

The management of innovative change in a public organisation: a methodological framework

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paper

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Abstract: Best care is not necessarily the most expensive, but the most appropriate, and prevention is the most powerful tool to promote health. A novel approach might envision the reduction of hospital admittance (thus meeting a requirement from long term condition patients: they would rather not being hospitalized!) and the enforcement of peripheral (both on the territory and at home) assistance. In this direction, experiences of redesigning new service deliveries towards an integrated disease management, namely clinical pathways, can be observed in Europe and in different parts of the world. Aim of this paper is to present a methodological guideline to help management in planning clinical pathways, outlining main barriers limiting this process. In particular, we present the results of planning of a clinical pathway at the Center for Hypertension of the teaching hospital "Azienda Ospedaliera Universitaria Federico II".

Keywords: business process reengineering, clinical pathway, healthcare management, hypertension, social responsibility, sustainability.

Biographical notes: Maddalena Illario, MD, PhD, is researcher at the Federico II DBPCM. She is endocrinologist, and during her PhD in Molecular and Cellular Biology and Pathology she worked as Research Associate at Duke University Medical Center for over 3 years. She is an auditor for Quality Management Systems, for Environmental Management Systems, and supervises Economical and Management Engineering thesis applied to healthcare. Her research interests include the development of management instruments to improve the quality of healthcare in public systems.

Lorella Cannavacciuolo, PhD in Economic and Managerial Engineering, carries out her research activity with the Department of Business and Managerial Engineering at the Federico II University of Naples. One of her research interests is Planning and Control Systems, with a particular attention towards design and implementation of Planning and Control Systems in healthcare public institutions, such as hospitals and local healthcare delivery structures. Since 2001, she has been taking part in a number of projects dealing with Planning and Control Systems in healthcare public structures. She is currently working on the Management Accounting System of the Naples' teaching hospital "Azienda Ospedaliera Universitaria Federico II".

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The challenge of collecting data in healthcare settings: experiences from clinical case research

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Abstract: This paper gives advice on how to gain access to data in healthcare organizations. The paper is based on clinical research in Swedish healthcare organizations, where the concern was both with generating new knowledge and contributing to the practical concerns of the organization. In conducting the research, we experienced difficulties in gaining access to appropriate data and needed to develop practices to gain access. Among these practices were the manner in which the research project was introduced, the building of rapport and the way data were collected.

Keywords: case study methodology, clinical research, data collection

Biographical notes: Torbjörn Jacobsson holds a M.Sc. in Mechanical Engineering and is currently a PhD Student at the division of Operations Management, Chalmers University of Technology. His research focuses on the adoption of process flow improvements in health care.

Biographical notes: Pär Åhlström is Professor of Operations Management at Chalmers. His research interests are in the areas of innovation management, operations strategy and service operations management.

The impact of diverse computerized and automated dispensation and distribution integration levels on hospital responsibility

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Abstract: The paper compares the impact of diverse computerized and automated prescription, dispensation and distribution integration levels on hospital responsibility. 24/7 real-time integrated process sliced by phase of the day transfers responsibility upward into industrial, political and scientific communities. Properly managed – commitments added, not expelled – it may thereby increase quality and decrease costs. Case come from integrated logistic process tested in the postal world with distributed network of remote-controlled automated vaults real-time opened and traced from shared central database.

In France, with recent regulation – ‘contrat de bon usage’– hospitals must prove any drug administered. Lifting responsibility then requires perfect tracking, impacts three knowledge integration levels discussed: A) ‘Divisional’ local unit primary responsible to define, prepare and administer prescriptions, even when using both ‘best practice’ norms and centralized support resources. B) Hospital integrated prescription iatrogeny control, drug preparation and dispensation (supply-chain functional). C) Further integration of hospital teams with scientific, technological and pharmaceuticals knowledge communities.

Keywords: responsibility, iatrogeny, automated dispensation, healthcare delivery technologies, multidisciplinary, knowledge management.

Biographical notes: Philippe P. Journeau is Director and Associate at E-BOX Paris, in charge of International, Marketing and Economic studies. He earned his PhD in Industrial Economics at Polytechnique, Paris. A part of his career has since then concentrated on creating and developing a micro-economical and financial simulations software company in Europe and in the US. Another part has been devoted to research and teaching around knowledge management issues, from theoretical questioning, namely epistemological, to the practical, managerial rising problems of IP, innovation and high-tech development valuation, financing and measurement. He has published in journals such as Bank Strategy, Risques, Gérer & Comprendre, American Institute of Physics.

Creating an arena for use-centred development of medical and health care technology

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paper

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Abstract: The development of medical and healthcare technology can be approached from different perspectives. A user (or use) perspective implies an understanding of users and use. Prerequisites are communication and collaboration between developers and users, i.e., the involvement of users in e.g. product evaluation. The purpose of the project has been to develop a process through which users, staff and patients, can be involved in field evaluations of medical and healthcare technology. Interviews with different stakeholders (nursing staff, developers, purchasers) and the experiences from four case studies have led to the following conclusions. The process for involving users in product evaluations must be flexible and adaptable to the situation at hand. Users (nursing staff) have the potential to act as active evaluators rather than subjects or participants only. Further education and training could be necessary to release this potential. Users involvement in field evaluations must be supported by a formation of *facilitators* or door openers to the healthcare organisation, *moderators* enhancing the dialogue between developers and users, and *mentors/coaches* for the users acting as evaluators. The combination of knowledge of healthcare and use of medical devices, knowledge of methods and tools, technical knowledge and the formation of facilitators, moderators, and mentors, create an arena for use-centred development of medical and healthcare technology.

Keywords: user-centred design; user-centred product development; user involvement; product evaluation; user-developer collaboration; medical devices.

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Biographical notes: MariAnne Karlsson is Professor in Human Factors Engineering at Chalmers University of Technology. Her research addresses questions regarding methods and tools for user requirement elicitation and for design evaluation, and the prerequisites for implementing user-centred approaches in manufacturing companies.

Pontus Engelbrektsson's research is focused on user-centred product development, in particular how to enable users to communicate their requirements to developers. He holds a Ph.D. in Consumer Technology and is currently employed at Chalmers University of Technology.

Lena E. Larsson has a B.Sc. in Nursing. She is a Research Nurse, at present employed as a research assistant at University West. Her research concerns work-place improvements in healthcare organisations.

Lena Pareto holds a Ph.D. in Computer Science. She is a lecturer/researcher at University West, and Head of the Digital Media programme. Her research concerns IT Design.

Ulrika Snis holds a Ph.D. in Information Systems. She is a lecturer/researcher at University West. Her research concerns IT Design.

Lars Svensson, Ph.D., is the Director of Forum for Work-Integrated Learning at University West. His main research interests deal with IT-support for workplace learning and distance education.

Bo Berndtsson is a project coordinator, employed by University West. He has a background from education, marketing and behavioural science.

MY HEART: a multimedia program to enhance patient's care for his/her own heart

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Abstract: The cultural and linguistic gap between patients and physicians is often a serious obstacle to communication and cooperation. "My Heart / il Mio Cuore" is aimed at providing patients with an easy multimedia communication tool able to translate the "obscure" language of the cardiological discharge report into an intelligible message. Patients can interactively access and explore, in a plain but still scientifically correct manner, the nature and mechanisms of their own heart disease; look at a 3D, dynamic, virtual picture of the diseased heart; access to the instrumental findings and the clinical processes leading to the diagnosis and to the therapeutic medical decision. The project, winner of the "Internetional Pirelli Award" as the best product of multimedia communication in life sciences, forwards the idea of implementing medical informative systems based on integrating communicational tools to interface all the actors of the health system, starting from the patient.

Keywords: physician-patient communication, medical jargon, multimedia, 3D heart, ischemic heart disease.

Biographical notes: Giuseppe Andrea L'Abbate is graduated in information science. He is researcher at the Department of Medical Computer Science of the Institute of Clinical Physiology – CNR and graphics designer on the field. He operates in the setting of clinical information system working on integration and representation of cardiological data. In May 2006 he won the INTERNETional Pirelli Award 2005 in the life sciences category. He has presented his research at international meetings such as *ESC, Computers in Cardiology, NNESMED, NATO ARW "Understanding Cardiac Imaging Techniques: from basic pathology to image fusion"*, *Euroecho*.

Clara Carpeggiani is a cardiologist, a career researcher of CNR. Her research interests are mainly related to epidemiology of cardiovascular disease and computers in cardiology in particular database management and informatics in health care. She has published in journals such as *Circulation, Circulation Research, American J of Cardiology, European J of Cardiology, Int J of Bifurcation and Chaos, Computers in Cardiology*.

Antonio L'Abbate holds the chair of Internal Medicine at the Scuola Superiore Sant'Anna and is scientific Director of the CNR Institute of Clinical Physiology. His research interests are mainly related to pathophysiology and clinical management of cardiovascular diseases, in particular of ischemic heart disease, and to the technological development of cardiac imaging. He has published articles in peer-reviewed journals including the most prestigious cardiological journals as *Circulation, Circulation Research, JACC, American Heart J, American J of Cardiology, European J of Cardiology* and in journals of Internal Medicine such as *New England J of Medicine, Lancet, JAMA and Archives of Internal Medicine*.

Health Technology Assessment and Budgeting: the Quest for integration

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Abstract: The increasing pace of development of innovative healthcare technologies obliges both the healthcare regulators and the healthcare providers to be responsible for the portfolio of healthcare technologies they decide to promote or adopt to deliver healthcare services. In fact most economists and policy analysts consider innovation in health technology, along with weak cost-containment measures to be major drivers in rising healthcare costs. During the last years the health technology assessment (HTA) discipline has been receiving increasing attention as instrument for supporting decision-making. However a larger attention has been paid to the regulator's perspective, while only recently some authors have started to investigate the applicability of the HTA guidelines to the providers. In particular some authors minted the term "hospital-based HTA". The researchers dealt mainly with the understanding of the metrics to evaluate a healthcare technology.

However the problem of selecting new healthcare technologies is not a novelty for healthcare providers and budgeting copes with this issue every year. In fact the resources for new healthcare technologies are limited and the demand is endless. The interest for the HTA discipline has led a number of healthcare providers to enact new budgeting procedures for taking in some guidelines.

In this context this paper explores the integration of these two processes – budgeting and HTA – in order to understand the benefits (or shortcomings) in term of responsibility for the selection of new healthcare technologies.

The integration between budgeting and HTA have been studied through a case study approach.

This methodology was considered the most suitable to provide answer to the research questions at this early stage of knowledge.

Three cases were selected to capture the diversity in dealing and integrating budgeting and HTA. The choice was also based on the possibility to gain wide access to the hospital and the availability to share confidential information. The authors triangulated multiple sources of evidence including semi-structured interviews, direct observations and documents. At the end of the case study exercise two roundtables were organised with all people interviewed to discuss specific issues related to the integration of budgeting and HTA.

The analysis led to argue that where the integration is manifest some benefits could be achieved.

In particular it emerges that:

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- The managing board is more aware of the responsibility they have for the assessment and the selection of healthcare technologies;
- The larger accountability of the decision-making process improves the negotiation between managers and physicians;
- The full integration is related only to the high-risk and high-cost healthcare technologies because of the “cost” of the HTA process itself;
- The average quality of the proposals committed by the departments for the adoption of healthcare technologies increases because of a pre-selection performed by the physicians themselves;

Despite the previous common results, the cases show also differences in the stage of integration and in the modalities. In the full paper the factors influencing the performance of the integration will be discussed.

Flexibility as a means for short throughput time in an emergency department

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Keywords: Emergency department, flow analysis, waiting times, flexible manning, throughput time

Abstract: This paper, which is based on a case study, deals with throughput times within a pediatric emergency department. As the emergency department has a lot in common with a high technology electronic industrial process a method developed based on knowledge from that environment was used. It is important to cover the very specific system characteristics, which an emergency department has. The method used separates process times, planned and unplanned waiting times. By use of this method it is possible to evaluate the impact from both structural limits, disturbance specific and management related aspects. The results show that it is possible to get significant improvements by use of means for getting a more efficient match between the need for capacity and the varying needs. The key characteristic is the ability to build in flexibility to handle the internal resources.

Biographical notes: Jan Lindér has a Ph.D. in Industrial Management and Economics. He teaches courses in Production Management and Work Organization. As a research fellow at IMIT (Institute for Management of Innovation and Technology) his research areas comprise different aspects on Lean Production and Management of Change.

Henrik Almgren has a Ph.D. in Operations Management and Work Organization. He has had a professional career as Production Manager at Volvo Car Corporation. Since a year he is Director of Pediatric surgery and emergency health care at Sahlgrenska University Hospital.

Assessment of a telemedicine innovation in cardiology

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Abstract: Recently, in all of the national health systems, the need to keep health costs under control and to have an efficient welfare system with high quality standards shifted the attention from hospitals to primary cares, territorial structures and patient home. In this context, telemedicine represents a strong feature to satisfy the need of new clinical management approaches allowing chronically ill patients to effectively receive care in a home setting. In particular, among chronic disease, Chronic Heart Failure represents a relevant application field due to its rapid epidemiological growth in industrialized countries. The application of new telemedicine services always requires a feasibility evaluation that considers on the one hand the responsibility of healthcare manufacturers in supplying high-quality and user-friendly technologies, on the other hand the responsibility of healthcare organizations in providing cost-effective telemedicine services.

In this context, this work aims at assessing the adoption of a remote monitoring service for follow-up examinations of heart failure patients implanted with biventricular ICD (Implantable Cardioverter Defibrillator). In fact the system is designed to monitor the implanted device's performance, as well as physiological aspects of the patient's condition.

Keywords: Chronic Heart Failure; ICD; Home monitoring; Telemedicine; Health Technology Assessment.

Biographical notes: Cristina Masella is Full Professor at the Department of Management, Economics and Industrial Engineering at Polytechnic of Milano, where she teaches Economics and Business Administration and Healthcare Management. She is also President of Public Administration Engineering and Director of the School of Healthcare Management and Innovation. Her research activities, focused on innovation in management accounting and performance measurement in the past, are at present related to innovation in healthcare organisations. She works on investment evaluation, management accounting, performance measurement and benchmarking.

Paolo Zanaboni received his Laurea Degree in Management and Manufacturing Engineering from Polytechnic of Milano in 2005 and now he is a PhD Student

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at the Department of Management, Economics and Industrial Engineering of Polytechnic of Milano. His research area concerns Health Technology Assessment, in particular, telemedicine and the evaluation of home-care services. He is working on several national, regional and private projects which involve the use of some telemedicine innovations.

Web & RFID Technology: New Frontiers In Costing and Process Management For Rehabilitation Medicine

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Abstract: Radio frequency identification (RFID) has recently begun to receive increased interest from practitioners and academics. This type of technology has been widely used in Healthcare Organizations for different purposes, like to localize patients, devices and medical instruments. This paper presents the results of a study in which we used RFID technology and modern systems of cost management methodologies (Activity-Based Costing, Activity-Based Management, Process Management) in a “proof of application” aimed at defining some specific data on care needs of a person with disability, costs of the main activities performed during his/her rehabilitation process and level of performance which could be reached in order to improve the “disability management” process, from a clinical as well as a managerial perspective.

Keywords: RFID, Activity-Based Costing, Process Management, Healthcare, Rehabilitation Medicine

How the Pisa Hospital addressed stock management related issues: a case study on how an innovative industrial solution is capable of “reducing”, “monitoring” and “improving” the inventory at the ward level

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Abstract: The focus of this article is to show how the use of electronic cabinets for drug and supply management at the hospital ward level, connected with the central pharmacy, is capable of highly improving the efficiency of the stock. During the last quarter of 2006 this innovative stock management system was tested with success at the Cisanello Hospital in Pisa. The solution tested was based on a project developed by Cardinal Health, which had been selected among various suppliers as preferred partner.

Tremendous results have been achieved: around 30% reduction in the inventory with an estimated value comparable with the double of the investments for the equipment; 90% reduction in the urgent and ordinary replenishment requests; 27% average reduction in the use of medical supplies in spite of an increase in the surgery activity; 90% reduction of time spent for logistic activity at the pharmacy level and 40% reduction at the ward level.

Keywords: Inventory and stock reduction, drug and supply management at ward level, Pharmacy workflow, electronic cabinets, Automated Dispensing Machine.

Biographical notes: Filippo Michelagnoli is Business Development Manager in the Italian affiliate of Cardinal Health. He earned his Degree in Mechanical Engineering (specialising in Business Management and Production) from the University of Florence, having obtained top marks. He's currently leading a team for the implementation of complex projects such as the re-engineering of the replenishment process between Hospital Pharmacy and Wards or the introduction of Patient Data Management System (PDMS) in Hospital

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Departments. He participated as speaker in medical congresses such as: “V Update di Neonatologia”, Florence 2006; 8th Annual Meeting Tuscany Critical Care, Pisa, 2005; XXXII Giornata di Anestesia e Rianimazione in Terra di Lavoro "Nuove Tecnologie per la Gestione del Paziente in Sala Operatoria", (CE), 2004. He published the following journal articles: “La Gestione Informatizzata del Blocco Operatorio” Rivista Meridionale di Anest. e Rianim., 2004; “La gestione dei dati diagnostici nei rotabili FS-Trenitalia”, Ingegneria Ferroviaria n°12, 2002; “Design of a Drum Motor” and “Deformations in Gearbox Components”, Engineering Design and Product Development (K&P), Technical University of Denmark, 1998.

Marcello Pani is Pharmacy Director in Estav Nord Ovest, a Public Healthcare Organization in Tuscany. He earned his degree in Chemistry and Pharmaceutical Technology from the University of Pisa, specializing in Clinical Pharmacology from the University of Florence, having obtained top marks. He's currently leading a team to centralize acquisition, storage and picking of pharmaceutical products for 6 Health Local Authorities, with 18 Public Hospitals and 1.300.000 people living in the North West Area of Tuscany. He has developed a clinical management system for drugs, medical devices and diagnostics, working for 15 years in the Public University Hospital in Pisa. Author of several Medical Journal articles, he participated as speaker in a few Medical Congresses and Conferences.

Carlotta Belli is graduated in Pharmacy and specialized in “Hospital Pharmacy” at the University of Pisa; PhD in “Healthcare Technology: Evaluation and Management of healthcare innovations” at the department of Oncology in Pisa with the following thesis: “Pyxis an innovative stock management system tested for the re-engineering hospital logistic chain into the transplant block of the Cisanello Hospital in Pisa, for minimizing clinical risk and for inventory and stock reduction”; she has worked for six years in the Public University Hospital in Pisa helping with the clinical management of medical device as Pharmacist; she is currently employed at Estav Nord Ovest, Public Healthcare Organization in Tuscany, managing a centralized sourcing, storage and picking of pharmaceutical products for six Health Local Authorities. She participated as speaker in medical congresses and published several journal articles.

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HTA report and new medial device technology: Stapled Haemorrhoidopexy (PPH) compared with Milligan-Morgan Technique MM in patient in whom surgical intervention is considered appropriate for the treatment of prolapsed internal haemorrhoids in UK

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Abstract: The most common surgical procedure for the treatment of haemorrhoids is currently the Milligan-Morgan (MM) haemorrhoidectomy in UK. Improvements in the understanding of the anatomy of haemorrhoids prompted the development of new and innovative methods of treatment: Stapled Haemorrhoidopexy (PPH) known as Longo technique reduces the prolapse of haemorrhoidal tissue by excising a band of the prolapsed anal mucosa membrane above the dentate line with the use of a specific circular stapling device. The purpose of this HTA report was to determine the safety, clinical effectiveness and cost-effectiveness of PPH compared to the MM technique for treating prolapsed internal haemorrhoids from the NHS's perspective. PPH is a valuable alternative to MM in patient surgical intervention appropriated. Efficacious without compromising QoL, whilst decreasing length of stay and OR time, PPH can be considered a cost-effective procedure for prolapsed internal haemorrhoids.

Keywords: Stapled Haemorrhoidopexy, HTA, Milligan-Morgan, PPH, cost effectiveness, Longo technique

Biographical notes: Luca Morlotti is working in Ethicon Endo Surgery European headquartered in Hamburg as a Senior Health Outcome Manager. He is primarily responsible for managing the reimbursement and health economics team and supporting the surgical business pre and post launch across the EU at a strategic and operational level. Luca is coordinating and implementing the clinical and economic evidence strategy related to specific country needs. Prior to joining EES, Luca was responsible for ensuring successful reimbursement and broad market access for pharmaceuticals by providing regional and local payer/health care provider solid evidence based value arguments and data at Analytica International. The majority of his project work was focused in the Europe pricing and reimbursement practice, which has helped Luca gain a solid understanding of the evolving pricing and reimbursement environment in the EU.

Causation as a policy instrument in healthcare law

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paper

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Abstract: in this article the author attempts to prove that causation is the most common of today's instruments in case law in deciding on which interest is to be protected. In actual fact, causation is far from being an objective element in tort cases and is more concentrated on judicial discretionary power. Therefore, causation is an important policy instrument. There does not exist a unique causation notion in law, but it varies according to policy objectives. Often, judicial causal theories hide cryptotypes. This makes it necessary to verify the correspondence between orally established and actually applied rules.

Keywords: healthcare liability; comparative law; causation; concurring causes; policy; crypto-types.

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Stakeholder dynamics during process innovation implementation in healthcare: Lean thinking in a theatres department of a UK NHS hospital

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paper

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Abstract: This paper focuses on the implementation of process innovation in healthcare. In particular, it explores the role of the dynamics of stakeholder interactions in the trajectory of implementing Lean Thinking in a theatres department of a UK National Health System hospital. Drawing on Actor-Network Theory, we suggest that the success of Lean depends on stakeholder dynamics, manifested through the mobilisation of a global network of actors that resource such projects, the mobilisation of a local network of actors that implement such projects, and the imposition of the project as a single connection between these networks. We also show how different meanings for Lean were formed in each of the networks over the period of implementation, which however did not inhibit the implementation process. The global-local framework provides offers insights into the process of network formation, stabilization and maintenance over time, handling with the complex dynamics of process innovation.

Keywords: Healthcare, process innovation, Lean thinking, stakeholder dynamics, Actor-Network Theory.

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The Efficiency and the Effectiveness in the Hospital Pharmacy Supply Chain Management

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Abstract: This paper presents the early results of a research project to improve efficiency and effectiveness in the hospital pharmacy supply chain management. The author analyzes the practices proposed in literature for the management of the flows of material and information in the hospital pharmacy. These methods are essentially practices that are almost consolidated in other industries (for example, those used by manufacturing firms) with some opportune adjustments. Particular attention has been paid to the current logistic situation at Azienda Ospedaliera "Ospedale Policlinico Consorziato", Bari (Italy). Therefore, on the basis of interview responses and the literature some possible ways to have more efficiency and effectiveness in the hospital pharmacy and, obviously, in the entire supply chain are presented.

Keywords: Hospital Pharmacy Supply Chain, Logistics, Efficiency, Effectiveness.

Biographical notes: Roberta Pellegrino is PhD student (first year) in Advanced Production System in Department of Mechanical and Management Engineering at Politecnico, Bari (Italy). The topic of the thesis is under definition in the area of organizational process management (economic-management engineering). However, her research areas of interest include today also the theory of Real Option Approach to evaluate real investment projects.

Managing productivity in multi-specialty operating unit

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Abstract: In earlier studies the effects of different operations management methods on operating unit performance have been concerned. In this paper we study the challenges to manage daily productivity in a multi-specialty operating unit in an unstable environment. Results indicate that total amount of personnel resources, allocated OR time and OR utilization rate had statistically significant effect on daily productivity. Unexpected factors, such like emergent cases, personnel absence and cancellations of operations, had no effect on productivity during office hours. The results indicate that the managerial challenge is to optimize staffing in long period, allocate resources to specialties based on demand, and maximize the use of the allocated OR time. As surgical specialties have no financial or other incentives to schedule OR time efficiently it is worthwhile for them to maintain overcapacity. Reallocating OR time and personnel flexibly during the day of operation the daily output and productivity can be increased.

Keywords: productivity, operating room management, efficiency

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Impact of microfluidic systems for molecular and genomic analysis: technological and socio-economic perspectives

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Abstract: In the last few years there has been a remarkable development of microfluidic techniques and miniaturized systems, designed for applications in life-sciences, and especially for biomolecular, genomic and cellular analysis. In this work an overview of the current most common techniques for molecular analysis is provided, then, as a comparison, several examples of microtechnologies for genomics are also presented, and the major advantages and potential benefits coming from such systems are described. It will be shown that most of the solutions so far developed aim primarily at gaining a higher level of automation in the analysis procedures, thus saving costs and time, while reducing the errors that usually may occur when employing manual standard analysis methods. Some economic data and considerations are provided in order to sketch the market potential of such novel devices and a patent overview is presented. A future scenario is eventually provided, where new trends in molecular diagnostics are sketched out, thanks to the integration of such miniaturized devices in the everyday clinical practice.

Keywords: microfluidics; genomics, microdevice, lab-on-a-chip.

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Implantable drug infusion systems for cancer therapy in tricky anatomic compartments: the case of brain tumours. Technological and socio-economic implications

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paper

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Abstract: Administration of chemotherapeutic agents to the brain tissue is at present a not completely fulfilled target and cerebral tumours are still a major cause of death. The difficulty in the treatment of such kind of pathologies is due to several reasons, such as the tricky anatomic location or the presence of a group of physiological protection mechanisms, that prevent the brain tissue to be reached by any kind of substance coming from the systemic circulation out of the nutritional ones. In this paper, first a sketch of the economic burden of the pathology is provided presenting a review of the published data about costs of treating brain tumour. Then, state-of-the-art solutions for drug delivery are briefly reviewed and critically evaluated in a future perspective. Special emphasis is posed on a solution currently under development in a research project at University Campus Bio-Medico which is presented with some more detail. The technology and the architecture of such a device are briefly described, together with an overview of the possible advantages versus the alternative approaches proposed in the literature. Eventually, a technological roadmap is outlined and the related (potential) socio-economical impact is briefly discussed.

Keywords: implantable drug delivery system, brain tumour.

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Early assessment of neuro-rehabilitation technology: a case study

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paper

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Abstract: In the field of robotic devices for neuro-rehabilitation a novel platform has been developed, that measures post-stroke functional recovery through whole-body isometric force measurements. An early assessment of the prototype is presented in this paper, by using a SWOT survey submitted to all the research groups participating in the design and development of the platform. The main aim of the analysis was to identify both the main strengths and the problems to be solved in order to successfully manage the device introduction on the market. Thus, the results of the SWOT survey are presented as a simple methodological approach for performing an "in progress evaluation" of an innovative biomedical technology. The answers and suggestions collected from the questionnaires gave useful information for bringing technical adjustments to the device and, at the same time, gave indications about its market potential. An overall acceptance of the proposed approach for an early assessment in neuro-rehabilitation was shown, also if some technical limitations of the platform emerged. On the whole, the results showed that the common efforts are devoted to the definition of a standard procedure for the assessment of functional recovery after stroke, that can provide quantitative data for interpretation of patients' conditions.

Keywords: early assessment; neuro-rehabilitation; mechatronic platform.

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Bio-Medico University of Rome. She was Member of the Organizing Committee of the International Workshop on Motor Learning in Stroke Recovery, Rome 2007 (Alladin) and invited speaker at ICORR 2007 (Workshop on "Clinical Perspectives of Hybrid Bionic Systems" in Noordwijk, the Netherlands. Her research activity includes rehabilitation robotics, functional assessment in neuro-rehabilitation, human motor learning and oncology rehabilitation.

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Action research and soft systems methodology for studying problems in emergency care delivery

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paper

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Abstract: This article describes the use of action research (AR) and soft systems methodology (SSM) for studying and taking action in complex and unstructured problem situations. Drawing from AR and SSM principles, the article proposes a research methodology to study and improve problematic flows of patients in emergency departments using operations management concepts. Three examples illustrate the methodology: analysis and improvement actions in acute radiology service, the design and introduction of a central status board, and tests of an advanced triage system.

Keywords: Emergency Department, Action Research, Soft Systems Methodology, Operations Management

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Organizational Management Developing Individual Job Capabilities: Job cognition, organizational learning and organizational performance

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paper

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Abstract: Organizational performance is improved by developing individual job proficiency in an appropriate process of knowledge management, such as recursive learning process in organization based on systemic thinking. The purposes of this paper are to present organizational learning type by strategic work unit in industry and to compare organizational performances, such as team coherency, performance reliability, fairness between two groups, the higher and the lower groups in the appreciation of organizational environment, and to identify multiple causality among the predictors and the criteria representing the emergence of meaningful, innovative action in industry and healthcare sector. The formation of organizational learning type was dependent upon the work allotted in terms of organizational goals and business strategy. Organizational performances which were shared by and meaningful for the participants differed among three types of organizational learning, and also organizational performance was significantly different between two groups, higher and lower degrees of appreciation on work environment. The results suggest that organizational learning type is formed by the unit of business strategy and in the logical level of management, and that recursive organizational learning plays a role of leverage for the participants who have a stake in the process and the results of their effort.

Key words: Job cognition, Appreciation on work environment, Organizational learning, Organizational performance, Organizational management

Biographical notes: Murako Saito is representative of HCTM Research Center in Tokyo, and Research Adviser in Institute of Future Healthcare Policy in Waseda University. She had been Professor in Graduate and Undergraduate Courses in Industrial and Management Systems Engineering, School of Science and Engineering, Waseda University, and also had been professor in Dept. of Health Sciences, School of Medicine, University of Ryuky. She received PhD

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degree of Health Sciences from Faculty of Medicine, University of Tokyo where she graduated. She had been a Fulbright Scholarship Grantee authorized by US Department after graduation from University of Tokyo. Dr. Saito currently serves for NPO Joint Lecture-Consultation Plans. Her major research interests are redesign and transformation into innovative organizations provided with cognition-action coupling processes or recursive learning processes for harnessing potentiality of the participants.

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Inventory System to Healthcare & Medical Institutions

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paper

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Abstract: This paper proposes an inventory management system suitable to Healthcare & Medical Institutions where the service level is so important that cost factors lose importance. Minimum service levels are allocated to families of items based on the shortage impact of these items in the operation. This minimum service levels are passed on to all items belonging to each family. After that, the procedure determines the best inventory model for each item as well as their respective optimal parameters, given the minimum holding and purchase costs objectives and minimum service level constraint. If the necessary total inventory investment is either unfeasible or undesirable, the manager changes one or more minimum service levels of each family and repeats the procedure to find a satisfactory total inventory investment. The procedure produces high-quality and computational feasible solution and considers trade-offs between service levels and total inventory investment.

Keywords: inventory, simulation, search methods

Biographical notes: Miguel Cezar Santoro is Associate Professor of Operations and Logistics Management in the Polytechnic School, University of São Paulo. He earned his PhD in Industrial Engineering from the University of São Paulo. He teaches undergraduate and graduate courses in Operations and Logistics Management. His research areas of interest include production scheduling, inventory and distribution.

Where is the patient's voice in research and health care?

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paper

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Abstract: Clinical trials cannot be carried out without patients and the purpose of conducting a trial is to benefit patients. This should mean that patients should be at the very centre of the whole research process and that the provision for health service should be done with patients (consumers, users, citizens, whichever terms resounds best) and not to them. But this rarely happens. Too often patients are forgotten.

A huge body of evidence suggests that benefit from their participation outweighs the drawbacks both in research, as patients possess unique expertise, even if they are not necessarily the experts on the science of their treatment, and in health-care, as they are an incredibly under-used resource in how the system actually works for, or sometimes against, them. A patient-centred-health care, addressing the needs and preference of patients, may also be a fair and most cost-effective way to improve health outcomes.

Since 1978 WHO stated that the people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

The challenge is now for the medical profession to receive this message accepting patients as equal partners in taking responsibility, improving treatment and ensuring better quality of care. To achieve this it seems crucial to overcome both the self-referentiality of the technical knowledge and the paternalism inborn in the doctor-patient clinical relationship by public education, empowering consumers to active involvement, participation , and information.

Biographical notes: Silvana Simi is a senior researcher working in the field of Genetics at the Italian National Research Council, Pisa (see PubMed). Since 1999 she has initiated a voluntary work joining the Cochrane Collaboration, as her personal war on multiple sclerosis. She has become an editor and the consumer representative of the Cochrane MS Group. Since 2002 she has been a member of the Governing Board of the Cochrane Consumer Network and also served as a member of the Cochrane Collaboration Steering Group (2000-2003).

Since 2005 she has been involved as champion in the WHO " Patients for Patient Safety" action, aimed to identify and implement programs to improve safety in healthcare.

In these capacities she is working for disseminating and advocating evidence-based communication and participation in health under the firm belief that only an "informed" patient will become the leading actor of whole health system.

Bringing Biomedical Innovation to Patients - The VECTOR Project case study

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Abstract: This paper reports about some innovation issues in the field of Healthcare and Medical Technology, that are strongly related to the patient care worldwide, following the example of the VECTOR Project. VECTOR is the acronym for “Versatile Endoscopic Capsule for gastrointestinal TumOr Recognition and therapy”: the VECTOR project aims at developing a miniaturized robotic pill, to be used for advanced diagnostics and therapy in the human digestive tract. As most of projects supported by the European Union within the Framework Programs, this project was funded for promoting strong integration and cooperation among the best skills and competencies available in Europe. The scientific and technological aspects are of paramount importance, but the attention to final users are becoming more and more important, especially in the fields related to Medicine and Healthcare. This study argues for a re-examination of the established ways of understanding technology-based innovation in Healthcare, and suggests new methods for involving patients in the entire innovation process.

Keywords: dissemination, patient involvement, healthcare innovation.

Biographical notes: Enza Spadoni is a PhD Student in Health Technology and Innovation Assessment&Management at the University of Pisa. She received the Laurea degree in Industrial Engineering from the University of Palermo in 1998. In 2002 she has been joining the CRIM (Center for Research In Microengineering) Lab of the Scuola Superiore Sant'Anna as Research Fellow. Her main research topics are innovation and development policy, exploitation of research results, new methodologies for the evaluation of research outputs and technology transfer in the field of Biomedical Engineering and Healthcare.

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Paolo Dario is Full Professor of Biomedical Robotics at the Scuola Superiore Sant'Anna in Pisa. He teaches courses at the School of Engineering of the University of Pisa and at the "Campus Biomedico", University in Rome. He has been Visiting Professor at Brown University, Providence, RI, USA, at the École Polytechnique Fédérale de Lausanne (EPFL), Lausanne, Switzerland, and at Waseda University, Tokyo, Japan. He is the Coordinator of the CRIM Lab and the Director of the Polo Sant'Anna Valdera. His main research interests are in the fields of medical robotics, bio-robotics, mechatronics, micro/nano engineering, robotics for rehabilitation. He is the coordinator of many international and European projects, the editor of books and the author of more than 200 scientific papers (90 on ISI journals). He is Editor-in-Chief, Associate Editor and member of the Editorial Board of many international journals. He has been a plenary invited speaker in many international conferences. He is an IEEE Fellow, a Fellow of the European Society on Medical and Biological Engineering, and a recipient of many honors and awards, such as the Joseph Engelberger Award.

BabyMobile: mobilising virtual baby visit at neonatal wards

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paper

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Abstract: Applications of Information Technologies (ITs) are increasing in the healthcare domain. Recent developments in ITs towards a digital hospital address medical practitioners and patients within the walls of the hospital. Little attention has been given to crossing these walls, for example, supporting relatives of hospitalized patients. BabyMobile crosses traditional boundaries of the hospital by the use of standard ITs. It explores the potential benefit brought by applications in the connecting area of Health Informatics / Health Care Technology Management. With healthcare moving towards a much more patient-orientated approach, relatively simple and low cost ITs can contribute to the well-being of patients and there relatives.

Keywords: Mobile phone, Video streaming, Healthcare.

Biographical notes: Ronald Spanjers is currently CFO/CIO of the Catharina Hospital (www.catharina-ziekenhuis.nl), Eindhoven, The Netherlands. In addition he writes his Ph.D. on Virtual Visits in healthcare at Tilburg University (www.uvt.nl), Department for Information Systems and Management. Besides his work, since 2005, he is Treasurer of the Supervisory Board of the Zonnebloem (www.zonnebloem.nl), the largest volunteers (33.000) organization in the Netherlands, helping people that due to a disease, handicap of age have physical limitations and face social isolation.

Anne.-F. Rutkowski is Associate Professor of Information Systems at Tilburg University (www.uvt.nl). She received her Ph.D. in Cognitive and Social Psychology. Since 1994, she has been involved in education and research activities in fundamental psychology and Information Communication Technology. Her research interests and publications are oriented toward topics such as group decision making, virtual teams, e-learning and IT in health care.

Medical tourism, technological developments, trade and the consequences for the USA

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Abstract: For centuries companies have traded their goods with companies and customers in other countries. Recently a new type of trade has occurred; the trade in health care services. The research presented in this paper focuses on three questions. The first question is: what is medical tourism. The second question is: how much medical tourism is occurring? The last question is: if the current trends in medical tourism continue, what will be the consequences for the US economy? It is concluded that the consequences for the US health care industry are negative since customers, instead of buying their service in the US end up spending their money in other countries which leads to an outflow of capital. However, a potential side-effect is a more competitive US manufacturing sector which would have a positive effect on the US economy.

Keywords: medical tourism, trade, outsourcing.

Biographical notes: Harm-Jan Steenhuis is an Associate Professor of Operations Management and Chair of the Department of Management at Eastern Washington University. He received an MSc. In Industrial Engineering and Management and a Ph.D. in International Technology Transfer from the University of Twente in The Netherlands. His research interests include international technology transfer, industry-university technology transfer, international operations, the aircraft industry, regional development and medical tourism. He has published in journals such as: *International Journal of Technology Transfer and Commercialization*, *International Journal of Technology Management*, *International Journal of Manufacturing Technology and Management*, *Technology Analysis and Strategic Management*, *Technology in Society*, *Journal of Manufacturing Technology Management*, *Production Planning and Control*, and *Scientometrics*.

Mary Ann Keogh Hoss is an associate professor and Program Director in Health Services Administration at Eastern Washington University. She has a MS from Eastern Washington University and a PhD from Gonzaga University in Spokane, Washington. She is a Spokane native. She is a Fellow in the American College of Healthcare Executives (FACHE) and certified nationally as a recreation therapist (CTRS) and a fellow in this clinical discipline. Her research interest include healthcare costs and delivery systems, ethics, mental health services, healthcare reimbursement, outcomes in therapeutic recreation, female healthcare leadership and medical travel/tourism. She is published in *Advancing Women in Leadership* and *Annual in Therapeutic Recreation*.

A Web-based system to manage elective waiting lists: efficiency and equity issues

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paper

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Abstract: Waiting lists for elective surgery are a topical issue in many publicly funded health systems. Decision makers should therefore state rule to prioritise access in order to attain both efficiency and equity. Efficiency requires that resources should be allocated to satisfy maximum social benefit. Equity means that everyone should receive healthcare at the right moment, i.e. before his conditions worsen (*horizontal equity*, depending on “urgency”), and that different needs should receive different answers (*vertical equity*). In Italian National Health System since 2002 guidelines suggest classifying elective surgery referrals into categories (Urgency-Related-Groups, URGs), associated to a maximum waiting time within which the patient should receive treatment. The "Surgical Waiting List Info System" (SWALIS) program is geared at setting and testing an experimental Web-based Informative System for prioritising elective surgery admissions belonging to different URGs and producing reports about the performance of waiting lists in terms of efficiency and equity indexes.

Keywords: Waiting lists, Prioritisation, Efficiency and equity evaluation, ICT impact

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Elena Tanfani is a Research Assistant in the Department of Economics and Quantitative Methods at the University of Genova, Italy. She completed her PhD in Transport Economics in 2004 with a specialisation in Operation Research. Her current research interest include mathematical modelling and

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object-oriented simulation applied to maritime transport and hospital organisation and management.

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Abstract: The Department of Medical Law is one of pedagogical section of Slovak Medical University and was established in 2000. The objectives of the Department include expanding and reinforcement of knowledge about the valid law in health care in the SR, influencing legal awareness of health care workers, increasing the modes of application of the law in the work of health care professionals, performing pedagogical and scientific - research activities as well as participation in continuous education.

Innovation in rehabilitation technology: technological opportunities and socio-economic implications

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Abstract: Innovation in rehabilitation technology is discussed for stroke that, basing on published epidemiological and economic data, represents an urgent case to deal with from multidisciplinary perspective. A theoretical model is proposed for assessing social and economic benefits of new rehabilitation technologies. A traditional approach – “trial and error strategy” is compared to the innovative one – “in progress evaluation”, considering the diagnostic and rehabilitative steps of the patient’s assistive route. The new technology allow a precise initial assessment of both the severity of stroke and the level of lost functionality, as long as an evaluation of the expected return from different potential therapy. Moreover, supposing that higher severity of stroke implies higher level of disabilities and social costs, and that the negative impact increases as the level of disability increases, the use of innovative rehabilitation technologies would be more “effective” in the case of patients with severe and very severe stroke.

Keywords: Innovation in rehabilitation technology, stroke, disability, costs, economic evaluation.

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Stefania Bellelli received the Degree in Statistics and Actuarial Sciences from the University of Florence, Italy, in 2003. She currently works at the European Transplantation Management Centre (ETXMAN Centre) and at the Management & Innovation (MAIN) Laboratory of the Scuola Superiore Sant'Anna in Pisa, Italy, as a research assistant. Her research interests include epidemiological and economic evaluations in the field of healthcare system.

Sara Cannizzo received the Degree in Economics from the University of Pisa, in 2004. She has a Master in Auditing and Internal Control of financial intermediaries. In 2004 she joined the European Transplantation Management Centre (ETXMAN Centre) and the Management & Innovation (MAIN) Laboratory at the Scuola Superiore Sant'Anna in Pisa, Italy. At the moment she works as a research assistant on the economic aspects of the healthcare system.

Ilaria Palla is graduated in Philosophy at the University of Pisa, in 1997. She received the MS Degree in Healthcare Management from the Bocconi University in Milan, in 2005. She works at the European Transplantation Management Centre (ETXMAN Centre) and at the Management & Innovation (MAIN) Laboratory of the Scuola Superiore Sant'Anna in Pisa, Italy, as a research assistant. Her research interests include the socio-economic aspects of the healthcare system.

Stefano Mazzoleni received the Degree in Computer Engineering from the University of Pisa, in 2002, and the Ph.D. in Robotics from the University of Genoa, in 2007. In 2002 he joined the Advanced Robotics Technology and Systems (ARTS) Laboratory at Scuola Superiore Sant'Anna in Pisa, Italy. In 2005 he received the "Student Travel Award" at the IEEE 9th International Conference on Rehabilitation Robotics (ICORR) in Chicago, Illinois, USA. He is currently a post-doc fellow at the ARTS Lab. His current research interests include rehabilitation robotics, functional assessment in neuro-rehabilitation, human motor control, human motor learning and human-machine interfaces.

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Bio-Medico University of Rome. She was Member of the Organizing Committee of the International Workshop on Motor Learning in Stroke Recovery, Rome 2007 (Alladin) and invited speaker at ICORR 2007 (Workshop on "Clinical Perspectives of Hybrid Bionic Systems" in Noordwijk, the Netherlands. Her research activity includes rehabilitation robotics, functional assessment in neuro-rehabilitation, human motor learning and oncology rehabilitation.

Eugenio Guglielmelli received the Laurea degree in Electronics Engineering and the PhD in Biomedical Robotics from the University of Pisa, Italy, in 1991 and in 1995, respectively. He is currently Associate Professor of Bioengineering at Campus Bio-Medico University in Rome, Italy, where he teaches the courses of Bio-Mechatronics and of Rehabilitation Bioengineering, and he is the Head of the Research Unit on *Biomedical Robotics and Biomicrosystems*. From 1991 to 2004, he has been working in the field of biomedical robotics at Scuola Superiore Sant'Anna where he also served from 2002 to 2004 as the Head of the Advanced Robotics Technology & Systems Laboratory (ARTS Lab, founded in 1991 by prof. Paolo Dario). His main current research interests are in the fields of novel theoretical and experimental approaches to human-centered robotics, to biomechatronic design and to biomorphic control of mechatronic systems, and in their application to robot-mediated motor therapy, assistive robotics, neuro-robotics and neuro-developmental engineering. He is author/co-author of more than 150 papers appeared on international journals, books and conference proceedings. He is co-author of two international patents in the field of assistive robotics. He served (2002-03) as Secretary of the IEEE Robotics & Automation Society (RAS) and he is co-founder and Co-chair of the IEEE RAS Technical Committee on Rehabilitation Robotics. He is member of the Editorial Board of the Int. J. on Applied Bionics and Biomechanics, and he served as Guest Co-Editor of the Special Issue on "Rehabilitation Robotics" of the Int. J. Autonomous Robots (2005/6) and of the Special Issue on "Robotic Platforms for Research in Neuroscience" of the Int. J. Advanced Robotics (2007/8). He also served in the Organizing Committee of several International Conferences, such as ICRA, IROS, ICAR, SYROCO and others, and he was the Program Chair of the 2007 IARP/IEEE-RAS/EURON 5th Workshop on "Technical Challenges for Dependable Robots in Human Environments".

New techniques for computer-based simulation in surgical training

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Abstract: In the recent decades robotics and computer science have been gaining more and more relevance in all aspects of our lives. In surgery, for example, they gave birth to procedures, impossible to perform otherwise, like the tele-surgery or the nano-surgery. On this regard, these applied sciences already play an important role in assisting the surgeon both in the operative room and, as a support, in the education of young surgeons, but much work has still to be done.

In fact in these last years we have seen an extreme change in the traditional training in surgery and the computer-based simulation is one of the main reason of this shift. The spread of Minimally Invasive Surgery (MIS) has brought major improvements in the quality of healthcare, but it has also increased the complexity of the surgical procedures requiring advanced and highly specialized training systems. Moreover these training procedures need to be reiterated during the operational life of surgeons. Therefore, considering the limited availability of cadavers and the public concern with the non-ethical treatment of animals, the traditional approaches to surgical training are drastically limited encouraging the use of surgical simulators based on virtual environments.

Healthcare industries and the scientific community in medicine agree indicating

the disruptive potential of the application of Virtual Reality (VR) to the training in the medical field. Therefore the next step is the development of surgical simulators with an high level of realism in order to practice complex procedures in a safe environment. Moreover it is decisive that this evolution is done integrating advanced medical imaging and processing, allowing surgeons to practice simulated interventions on patient specific dataset.

The increasing importance of MIS techniques will cause a drastic change in pre-operation planning and basic surgical training. In fact, the features of this kind of surgical approach (the workspace limitation, the 2D vision through a laparoscopic camera and the indirect physical interaction with the patient body) make it possible to use a surgical simulator to train, plan or simulate an intervention, reproducing the visual and tactile feedback of the real surgical procedure on a real patient.

This paper presents some research and applicative results on Computer Assisted Surgery (CAS) achieved in the framework of EndoCAS, a newly founded Center of Excellence in Pisa. The research has involved: the development of segmentation algorithms for volumetric datasets, the simulation of bone drilling procedures, the modeling of deformable object cuts and deformations and the simulation of rope interactions during a suture procedure in MIS. All these projects were been developed using a new open source library to support the implementation of techniques for simulating deformable objects. Our purpose is to enhance the surgical training with new improved techniques applied both to the medical imaging and to the computer-based simulation in order to carry the surgical training to a next level of realism.

Keywords: surgical simulation; computer aided surgery.

Biographical notes: Giuseppe Turini was born in 1975 in Pescia (Pistoia, Italy). He received the master degree in Computer Science from the University of Pisa in 2004, and in the same year he joined to the Visual Computing Lab of the CNR-ISTI in Pisa. Since 2005 he is a research fellow at the EndoCAS Centre, and his main research interests are in the field of computer graphics visualization and physical simulation. At the present time his research is carried out in the context of computer-assisted surgery.

Nico Pietroni was born in 1978 in Siena (Italy). He received the Laurea degree in Computer Science from the University of Pisa in 2004, and in the same year he joined to the Visual Computing Lab of the National Research Council in Pisa. He start his Ph.D. activity in 2005. His main research interests are in the field of Computer graphics, deformable models simulation and interaction.

Giuseppe Megali was born in 1972 in Reggio Calabria (Italy). He received the Laurea degree in Computer Science from the University of Pisa in 1998, and in the same year he joined to the MiTech Lab (now CRIM Lab) of the Scuola Superiore Sant'Anna in Pisa. He received his Ph.D. degree in Robotics from the University of Genova in 2002. From 2002 to 2004 he had a Post-Doctoral fellowship in Bioengineering at the Scuola Superiore Sant'Anna in Pisa. Since 2004 he is assistant professor of Biomedical Robotics at the Scuola Superiore Sant'Anna and coordinator of EndoCAS. His main research interests are in the field of biomedical robotics, computer-assisted surgery and analysis of surgical gesture. His research is carried out in the context of National and European projects in the field of biomedical engineering.

Andrea Pietrabissa was born in 1959 in Pisa. He graduated with honors in Medicine and Surgery at the University of Pisa and he specialized in General Surgery. From 1986 to 1988 he was Research Fellow in Hepatic Transplantation at the University of Chicago, and from the 1992 to the 1993 he

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was Senior Registrar at the Ninewells Hospital in Dundee (Scotland) and Lecturer in Surgery at the University of Dundee. Since 1999 he is Associate Professor of General Surgery at the University of Pisa. He is responsible of the Minimally Invasive Section of the Department of General Surgery and Transplantation at the University of Pisa, and, until now, he performed over than 3000 surgical interventions. He is member of several scientific societies (EAES European Association of Endoscopic Surgeons, SAGES Society of American Gastrointestinal Surgeons), and he is in the international Editorial Board of the Surgical Endoscopy journal. He was involved in a lot of research projects at national and international level and co-inventor of some patents.

Practical approach to Risk Management in the Azienda Ospedaliero Universitaria Pisana (AOUP)

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Abstract: AOUP instituted a Hospital Patient Safety and Litigation Management Group (UGIRCC) in 2004, aimed to prevent adverse events, detect and manage risk and to minimize malpractice lawsuits, through a multi-faceted approach. Several pre-existing administrative datasets were collected in a single database while setting up an Incident Reporting System based on voluntary reporting by healthcare workers, mainly associated to detect near miss events. The event resulting from the reports were analyzed using root cause analysis and failure mode and effect analysis. Training and continuous education of HCWs was the main elements implemented in order to overpass the defensive approach which is still dominant in Healthcare organization following the occurrence of adverse event. To this aim a training toolkit was set up.

Key word: Healthcare Risk Management, Learning Organization, Incident Reporting, Facilitator, Patient Safety Training.

Biographical notes: Cecilia Ugatti: Medical Doctor, Specialization School in Hygiene and Preventive Medicine, University Hospital, Pisa, Italy.

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Selection criteria for Organic-Iodinate Contrast Media and for MRI Contrast Media: A Research and Development project carried out by an interdisciplinary Working Team of the Provincial Health Authority of Trento, Italy

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Abstract: As part of a series of new strategies, the provincial Health Authority of Trento (Italy) issued guidelines in 2006 aimed at improving the selection and purchase processes of hospital drugs. To that end, a special project was set up to involve key personnel in the selection stage, whose mission was to obtain the best possible financial conditions from drug companies. A total of 646 invitations to tender for the supply of drugs for a total expenditure of over €25 million were prepared. Two of the invitations to tender were based on quality/cost score for the supply of equivalent contrast media. New X-ray imaging and cardio-vascular imaging technologies were introduced in the last few years due to fast technological development (digital angiography, multi-slice CT, magnetic resonance). Pharmaceutical research, through the improvement of the organic-iodinate contrast media and those for MR, produced drugs with an improved safety profile to minimize adverse effects like contrast-induced nephropathy. A team with 4 Radiologists, 1 Cardiologist, 4 Clinical Pharmacists, 1 Nephrologist was appointed. The main objective was to make a systematic review of contrast media utilisation, and how the selection criteria had been arrived at while bearing in mind diagnostic technology requirements and patients' needs. The benefits in terms of financial gain and cultural implications are no doubt relevant.

Keywords: technology assessment, contrast media, magnetic resonance imaging, computerised tomography.

Biographical notes: Luisa Ventura has been working with the Radiology Department of the Hospital in Rovereto as a radiologist since December 2003 (Consultant: Dr. P. Peterlongo). Prior to that, she worked with the Radiology Department of the Ospedale del Distretto Alto Garda e Ledro (Consultant: Dr. Sergio Benussi) and the Radiology Department of the Ospedale di Tione di Trento (Consultant: Dr. Giorgio Nicolodi). Since 2004, Luisa Ventura has taught "Imaging Diagnostics of the digestive and the urogenital systems" and "Contrast media" as part of the MRI techniques and radiotherapy course at the

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University of Verona. Scientific meetings and courses – contributions: “An update on gastrointestinal stromal tumours (GIST) and gastric lymphoma” - a meeting held in Rovereto, 2004. “Breathing issues: nasal obstructions in children” - a meeting held in Villa Lagarina, Trento, 2007. “The choice of contrast media” - a course for radiologists and radiology technicians held in Negrar, Verona, 2006. Scientific papers and publications: 41st SIRM national congress, Palermo, 2004: “Spontaneous rupture of an aneurism of the splenic artery: a case study” by M. Sessa, F. Caruso, L. Ventura, F. Tilotta, M. Recla, P. Peterlongo; “Isolated pancreas laceration in closed abdominal trauma: a case study” by M. Sessa, L. Ventura, A. Ascanio, G. Misiani, M. Recla, P. Peterlongo; “Clear cell carcinoma (glycogen accumulation) of the breast: a case study” by O. De Vita, L. Ventura, M. Sessa, M. Recla, P. Peterlongo.

Functional Role of a Risk Management Nucleus in Healthcare System: Experimental Research of ISBEM, CNR-IFC and UNIPI

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Abstract: Aim of the study is to find out the proper allocation of the Risk Management Nucleus (RMN) within the functional organization of an Healthcare Firm. Specifically, it is extremely important to assess if the two branches of RMN - the legal and the medical one - are different aspects of the same operative unit or, rather, are to be considered fully separated entities. This research issue is highly relevant considering that, in Italy, most of Healthcare Firms are just in the first phase of this practical implementation. The present study stems from a needs analysis of the Operative Unit and not by the type of functions to be performed. Previous studies have documented that the functional allocation of a new Operative Unit in the administrative organization of an Healthcare Firm is of fundamental importance for respecting the time schedule of results and for the quality of the same results. We speculate that a functional allocation of this new Operative Unit might be one of the following: a) Burocratic Office (for the legal, economical and insurance aspects); b) Forensic Medical Office (for the fallout of medical errors), as a staff function to the Medical Direction to properly manage the full gamut of related problems in the field as well as the implications for the Healthcare Firm itself.

A critical aspect would be the interrelationship of the time schedule versus the operativity of the RMN, when fully operational. A working hypothesis is to undertake the needs analysis at the same time with the operational aspects. In particular, the analysis will deal with the timeline and the contents of the answers given by the Operative Units, interviewed by the RMN. So far, the operational timeline and the resulting fallout in the Italian Administration, in general, are rather low, if compared worldwide. The capacity of a RMN on the management of professional risks will greatly impact the results expected to make Healthcare Firm efficient as well as cost effective. Two targets may be hit with the described approach: reduction of errors and reduction of relative costs.

Keywords: Risk Management Nucleus; Healthcare System; Allocation of Resource.

Notes on ISBEM: The Euro Mediterranean Scientific and Biomedical Institute is a non profit consortium that operates in the Cittadella della Ricerca (Scientific Park) of Brindisi. The founding Partners were the Universities of Pisa and Lecce, Monte dei Paschi di Siena Bank, ASL BR and the Scientific Park of Brindisi. The mission that ISBEM is to carry out projects aimed to the creation of a excellence and reference Southern node in the biomedical and health sector, through the integrated collaboration of Healthcare, Research and Enterprises systems, World, as well as the Banking Foundations and local

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Communities. ISBEM intends to be a catalyst element for those interested in promoting and enhance performing health and biomedical research in Southern Italy and Mediterranean Area.

Biographical notes: Enrico Viola, lawyer, manager of a healthcare and public system, is the scientific project coordinator of the Risk Management Nucleus for ISBEM and CNR-IFC Lecce.

Elena D'Alò and Marco Benvenuto are PhD Students in Health Technology Assessment for ISBEM and Pisa University.

Prof. Alessandro Distante is the scientific director of ISBEM and CNR-IFC Lecce.

The Redesign Practices and Capabilities of NHS Trusts in England: A Snapshot study

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**Paul Walley, Juliet Rayment and Matthew
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Abstract: The ability of any healthcare system to improve outcomes for patients through the use of IT or through process improvement depends very much on the implementation of process redesign methodologies. In this paper the redesign capabilities of 29 UK NHS Trusts are assessed, to gain an insight into the current situation within the NHS as a whole. It was found that very few individual organisations possessed internal capability to redesign processes effectively. Furthermore, in many organisations there was little integration of redesign and improvement strategy with the strategy of the organisation as a whole. Those organisations that were successful had probably developed a capability over many years. Some Trusts had performance levels poor enough to require emergency measures to remedy the situation. These sites had actively recruited people with skills to introduce a redesign capability. The paper discusses the barriers to the development of a redesign capability.

Keywords: Healthcare, process redesign, clinical systems improvement

Biographical notes: Paul Walley is Associate Professor in Operations Management at Warwick Business School. His research interests focus on the application of private sector management methodologies to public sector. His work has focused on the healthcare sector for over 10 years, where he has been involved in a series of collaborative improvement programmes at a national level.

Juliet Rayment is a PhD candidate in the Department of Sociology, University of Warwick. Her research focuses on midwives' strategies for managing disagreement and distress in the workplace, in the light of current resource and workforce restrictions within UK maternity care. She was previously Research Associate in Service Improvement at Warwick Medical School.

Matthew Cooke is Professor of Emergency Medicine at Warwick Medical School. His research interests and publications relate to access to and systems design in emergency care, including prioritisation systems both in A&E and the ambulance service. Until recently, he was the Emergency Medicine Advisor at the Government Department of Health. Matthew also continues his clinical commitment at Heart of England NHS Foundation Trust as an emergency medicine consultant.

Information asymmetry in the German public health care market: a stakeholder analysis

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Abstract: Technological development in health care leads to new processes and products aiming at improving diagnoses and therapies of diseases. Whether these are successfully introduced depends on aspects such as effectiveness and costs of the new processes and products, the way institutions support or hinder introductions and the processes of integration into health care systems.

Over 90 percent of the German population are compulsory members of the public health insurance system. Here, contributions to the system are income-based and patients receive benefits-in-kind from the catalogue of services. The remaining 10 percent receive medical services unlimited by a catalogue and are entitled to a reimbursement of their medical bills. Their contributions are based age, gender and medical history.

In this paper we show that switching from the benefits-in-kind principle to the cost reimbursement principle would lessen information asymmetry and therefore contribute to solving some of the associated problems. A switch to a cost reimbursement system would increase cost transparency and patients' choices, thereby facilitating the adoption of innovations. We also highlight the political reasoning that prevents this switch from actually happening.

Keywords: information asymmetry; German health care market; stakeholder; cost reimbursement; public insurance.

Biographical notes: Ursula Weisenfeld, PhD, Dr. habil, Dpl-Kffr. holds the chair in Marketing and Technology Management, University of Lueneburg. Her research interests include innovation management and health care markets.

Constanze Sörensen, Dpl-Kffr., Research Assistant, Marketing and Technology Management, University of Lueneburg. Her main research interest concerns health care markets.

Christian Scherer has a PhD in medicine as well as in business administration. He works as a physician and lectures at the University of Lueneburg.

Facilitating Superior Chronic Disease Management through a Knowledge-based systems development model

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Abstract: To date the adoption and diffusion of technology enabled solutions to deliver better healthcare has been slow. There are many reasons for this. One of the most significant is that existing methodologies that are normally used in general for ICT implementations tend to be less successful in a healthcare context. This paper describes a knowledge-based adaptive mapping to realization methodology that provides a means to traverse from idea to realization rapidly and yet without compromising rigor so that success ensues. It is discussed in connection with trying to implement superior ICT enabled approaches for facilitating superior chronic disease management.

Key words: chronic disease management, diabetes, ICT, healthcare knowledge-based methodology

Biographical notes: Nilmini Wickramasinghe, PhD MBA researches and teaches in several areas within Information Systems. In addition, Dr Wickramasinghe specializes in the impacts of technologies on the healthcare industry and various aspects of medical informatics. She is well published in all these areas having written several books, over 50 refereed scholarly papers and encyclopaedia entries. Dr Wickramasinghe regularly presents her work throughout North America as well as in Europe and Australasia. Currently, Dr Wickramasinghe is the US representative of the Health Care Technology Management Association (HCTM), the co- director of the Center for Management Medical Technology (CMMT) at Illinois Institute of Technology and holds an associate professor position at the Stuart School of Business, Illinois Institute of Technology. She is also the editor-in-chief of the international journal of networking and virtual organizations (IJNVO) and the inaugural editor-in-chief of the international journal of biomedical engineering and technology (IJBET) both published by InderScience.

Mr. Steve Goldberg, founded INET International Inc, a technology management consulting firm in 1988. Today, he is the President of INET, overseeing INET online data collection services for global market research studies, and delivery of INET mobile e-health projects. He also produces an annual INET mini-conference as an executive forum for wireless healthcare.

A comedy of errors? Tort, contract and compensation schemes as remedies for medical malpractice

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Abstract: The article is aimed at pointing out the differences between the contractual and the tortious approach to medical negligence and how both of them, generally, bring about similar results. At the same time alternative compensation schemes seem to draw criticism and appear to be unsatisfactory in those countries which adopt them. The conclusion is that, perhaps, the legal framework is not so important and does not have such a significant impact on the medical sector as many academic lawyers believe.

Keywords: medical negligence; contract; tort; compensation schemes; comparative law

Biographical notes: Vincenzo Zeno-Zencovich is professor of comparative law at the University of Roma Tre. He has written extensively in the field of tort and specifically on medical negligence. A complete list of publications is on the Law Faculty's website:

<http://www.giur.uniroma3.it/materiale/docenti/zeno/index.html>