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Technology and the Creative Disruption of Health Care

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In many countries, health care is becoming increasingly dependent on technology and medical devices due to a global demand for innovative medical technology solutions as a way to provide for an increasingly ageing population. This fact may also explain why it has been recognized that one of the major drivers of the increase in costs of health care is technology (Appleby 2013).

This year, in February, the International Business to Business Forum for the Medical Devices Industry, took place in Stuttgart, Germany. The Medical Devices Meetings is a business platform dedicated to the entire value-added chain of the medical devices industry, aiming to strengthen, support and develop cooperation between stakeholders from the medical sector, such as industry developers and its representatives, research institutions and providers. This diversity of stakeholders was present in the event[1], and some of them presented different types of medical devices, several already identified with the capability to have a disruptive role in health care sector. For this reason, the aspect of disruption in health care deserves a closer look.

Acknowledging that not all disruptive technologies are indeed disruptive, Christensen proposed the theory of disruptive innovation, arguing that two conditions must be present: technological enablers and a disruptive business model (Christensen 1997). Basically, Christensen argues that a disruptive technology successfully targets a market segment that is usually overlooked, by delivering more -suitable functionality, frequently at a lower price (Christensen et al. 2015).

Many disruptive innovations result from the combination of one or more innovative technologies and their application through innovative business models (Barros et al. 2015). Therefore, health organizations that embrace innovative technologies and change the normality and standardization of organizational procedures and tasks, harness a new way of disruption, by changing how things are normally done. Aiming

for the enhancement of patient's quality of life, disruptive innovations can introduce what is, until the present moment, something uncommon in terms of medical practices, entangled with a new business model. For this reason, strategic planning of research and business and even a bit of audacity go hand-in-hand.

One can never say which path a disruptive innovation will take, meaning that they are unpredictable in nature. This is reason why, a disruptive innovation can only be labelled has such, after its introduction or adoptation.

In health care, it is possible to identify main characteristics in disruptive innovations (Barros et al. 2015) such as:

- providing improved health outcomes,
- creating new services and overcoming challenges regarding accessibility to existing or new services,
- leading to cost-effective methodologies that improve access,
- promoting person-centred health delivery,
- empowering the patient/person,
- creating disorder in the old systems,
- creating new professional roles and capacities,
- creating new sets of values for the health workforce, patients, citizens and community, and
- introducing transformative cultural change.

Disruptive innovations are innovations with the potential to promote organisational changes, including the creation of new networks by involving new stakeholders, such as patients, overlooked until recently, leading to the improvement of distribution of roles and values between them.

Some of the technologies, presented in the meeting, can be seen as a reshaping or upgrading of existing technologies in order to be more attractive or appealing to the users (clients), with a tendency to over- adding features that actually don't necessarily have a real benefit for the end-user. They can be considered to be on the spectrum of "sustaining innovations"[2]. Sustaining innovations, in general, tend to ignore what the normal, regular user is looking for in a health technology, which normally is a low-cost alternative, and also a technology that fits their needs. Other technologies presented at the meeting, already have the potential to be classified and others were already labelled as disruptive innovations. Some, were even considered to be megatrends in the context of future research policy by the OECD (OECD 2016), such as artificial intelligence, neurotechnologies, nanomaterials and addictive manufacturing[3].

Inspired by the discussion and the presentations at the meeting, I will provide two examples of disruptive innovations. The first one, addictive manufacturing which is becoming more and more dominant in medicine and health care and the other, minimally invasive surgery, with the example of surgical assisted robotics, already in a more advanced stage of research, development and implementation in hospitals.

1 Addictive Manufacturing (AM)

Products produced by addictive manufacturing can have different sources in terms of materials, such as metal, plastic, organic compounds or even human tissue, but, what they all have in common is the way they are produced: layer upon layer.

Despite its recent introduction in the field, research and applications of AM have been increasing highly in the medicine and health care field. For instance, orthopaedics and prosthetics are a growing area of AM applications. Practical examples are implants and surgical fixation plates. The reason that they have such a high acceptance in surgery practice is due to the fact that they can be produced in a personalized way. Using a proper software, initial images acquired using, for instance, Computerized Tomography (CT) or Magnetic Resonance Imaging (MRI), the information obtained in the images can be uploaded and used for AM manufacturing technology productions (Koptyug et al. 2013). Indeed, CT and MRI are considered to be the two most common imaging technologies for medically applied bioprinting (Shafiee/Atala 2016). The major disadvantage already identified in this emerging field are related to required time and costs of the techniques (Martelli et al. 2016).

Despite these disadvantages, on the one hand AM produced implant models (such as titanium-aluminium-vanadium alloy) have proven to be less expensive, less wasteful in material, less energy demanding for manufacture. On the

other hand studies have showed that it is possible to optimize the manufacturing process, and therefore to reduce the costs for implants as well as delivery times (Koptyug et al. 2013).

3D printing techniques can also be used for preoperative planning (see e.g. Wake et al. 2015), with the advantage of providing a better understanding of the complex anatomy and morphology of the organs involved, providing for the possibility of surgeons training approach to the surgery planning.

Several challenges are still putting AM to the test, namely the issue of AM compounds and its sterilization. Since some materials are not resistant to extremely high temperatures, when submitted to sterilization procedures they suffer shape distortion from the model manufactured (Koptyug et al. 2013).

Another challenge is related to the biocompatibility of implant surface coating. It is not enough that the implant presents a good osseo-integration, fitting perfectly in terms of anatomy. It is mandatory that this new strange body is accepted by its user body. In order to be biocompatible the coating of the implant has been improved over time, however due to being an emerging technology, there is not enough research yet on this topic and therefore studies on toxicology of the materials used for coating are needed.[4]

The reason of AM's success in medicine is simple: freedom of component shape, personalization and good value for money. Particularly in the case of impaired/disabled people, instead of mass-produced products, AM can provide a personalized product that targets exactly the need of the individual.[5]

Existing traditional medical implants are regulated and standardized in terms of shapes and sizes. AM implants are revolutionizing the existing standardization, towards a more efficient personalized medicine. As a consequence, existing regulations should be reviewed in light of these new technologies.

Bio-printing has also been used for drug screening and delivery (Prasad/Smyth 2016), personalized medicine, fabrication and modelling of living organs for medical applications, and printing of cells, for tissue engineering and regenerative medicine (Shafiee/Atala 2016).

In terms of practical applications, the Department of Cell and Tissue Engineering, of the Fraunhofer Institute (IGB), located in Stuttgart, Germany, is specialized in constructing human 3D tissue. At the meeting, a patented skin model (three-dimensional two-layer human skin equivalent), a vascularized artificial skin and a prosthetic heart valve were presented. This new tissue has huge potential application in the field of regenerative medicine and for pharmaceutical testing. Another important collateral effect of the development of such tissue concerns the fact of the future absence of animal experiments and testing, in the field of medicine. A practical application of tissue printing can be found in auricular research, where printers are primarily used to create tissue-engineered constructs or manufacture artificial prostheses.

2 Minimal invasive surgery

Surgical robotic systems have different applications in medicine, such as tele-surgery, surgical rehearsal and pre-surgery planning, micro and nanobots and minimal invasive surgery (in the meeting, several examples were given by Cyrill von Tiesenhausen, Business Development Manager Medical Robotic at KUKA Medical Robotics, in his presentation "Lightweight robotics in Medicine").

The introduction of assistive robotics technology for minimal invasive surgery, promoted several changes not only in the surgery procedures and its associated consequences, but also changes concerning surgeon – patient interaction, work routines, professional competences, administration and management of medical departments (e.g. recovery room, operating room, etc.).

There are several clinical evidences that promote the use of surgical robots (as discussed in the meeting by Arnulf Stenzl, Director of the Department of Urology, from the University of Tübingen, in Germany, in his presentation "Robot-assisted surgery – The future begins today") such as[6] diminish of the size of the incision, diminish of blood losses and therefore diminish need of blood transfusion, less possibility of infections, reduced post-surgery pain and due to these facts, shorter hospital stay due to reduce re-

covery times (Lanfranco et al. 2004). These new clinical aspects lead to a reduction of the need for surgical hospital beds, which in some systems was a bottleneck for expansion of the volume of surgery, and also lead to the possibility of decentralisation of post-surgery care and options for day care surgery opening space to new organisational forms such as free standing surgical centres (Barros et al. 2015).

Concerning surgeon-patient interaction, having a technology as an extension of hers/his hands, the surgeon does not interact by touch with the patient's tissue/organ anymore. The interaction is made through the surgical robot, not giving the possibility (yet) for the surgeon to have haptic feedback (sensing) (Speich/Rosen 2004).

Several transformation of work in the operating room occur due to the introduction of robotic assistive technology (Maia/Krings 2015). This new reality promotes strong changes in terms of medical competences, not only by the surgeon, but also for the rest of the surgical team. Since new and several technologies are introduced in the operating room, there is a need for new knowledge and new competences, concerning the surgical procedures and the handling of the technology. Less surgical time is proportional to standardization of procedures and right training of the surgeon as the surgical team. Others aspects to consider concern the separation of the surgical team, since the surgeon can be positioned in a different room, ergonomically seat and with her/his eyes in the stereoscopic cameras, communicating with the team via an inter-communicator.

The new approach to minimally invasive surgery, made surgery possible to patients that were inoperable due to their physical conditions, and patients whose pathology was still in the early stages. This new fact leads to the inclusion of new patients in the "market". As the technique started on this type of patients (lower end of the market) one could assist that slowly, it also disrupted the previous gold standard operations such as open chest or open abdomen surgery (Barros et al. 2015).

There are also some barriers to consider when it comes to assisted surgical robots, namely existing legislation and also the lack of reimbursement by health insurance companies in these procedures.

Indeed, minimally invasive surgery disrupted not only the surgical procedures but also organizational aspects related to it, for this reasons, minimally invasive surgery is seen as a disruption of classical open.

3 Remarks

It is difficult to exactly predict which technologies and trends will transform and shape the course of healthcare, as disruptive innovation creates a new market and reshapes the existing ones. Disruptive innovations often provide a new and different perspective on things, a perspective that tends to reduce complexity in favour of the empowerment of the citizen/patient. For this reason, the lack of citizen's/patient's engagement can be considered a possible barrier for disruptive technologies, since it is important to involve all the relevant actors in the creation and diffusion of (disruptive) innovations, in order to diminish the impact of vested interests that represent a barrier (Barros et al. 2015).

In order to ensure that all societal actors work together during the whole research and innovation process in order to better align both the process and outcomes, with the values, needs and expectations of the society in general (EC 2003), Responsible Research and Innovation (RRI) has a role to play by "including a better alignment of science (policies) with societal needs and the consideration of ethical aspects, the stimulation or implementation of inclusive and deliberative processes (stakeholder involvement and public engagement), and the sharing of responsibility for innovation processes among a wide range of stakeholders by means of early engagement and mutual learning" (Coenen 2016, p. 1). It is therefore important to involve health professionals in the process of creation and diffusion of (disruptive) innovations, as well as involving citizens/patients in the policy discussion on these issues.

Although fabricated 3D printing models are increasingly being used in surgery, aiding the surgeon to plan precisely and consider contouring aspects of the surgery, the advantages and

disadvantages of their use remain to be investigated (Martelli et al. 2016).

A major limitation of 3D printing is the time and cost needed to generate the 3D models. But as printers continue to expand their abilities, reduce cost, increase speed, and use a wider range of printable materials are expected. Printing biocompatible will change the existing approach to working with tissues at the cellular level, which will lead for potential advances in medicine.

In order to insure safety and conformity in the new products produced by AM, appropriated standards and regulations should be debated and developed.

Investigating the implications of disruptive innovation in training and education of clinicians, health care staff and other stakeholders should also be a major concern, since the technologies will be incorporated into their practice.

The implementation of any disruptive innovation, should carefully address the issues of relevance, equity (including access), quality, cost-effectiveness, person- and people centeredness, and sustainability (Barros et al. 2015).

Overall, after attending the Medical Device meeting, and having in mind that a disruptive innovation is a combination of a new business model associated with technology innovations, my impression is that the mechanism to identify technologies with the potential to become disruptive should be more deeply researched, in order to reach a more creative disruption in health care.

The industry sector needs to focus on the true needs of patients and, in a broader analysis, on wider societal needs. More disruptive innovations are needed in order to reach a more desirable health care system. Three main questions should be addressed in advance: What will users really use the technology for? And in which ways the technology developed can help improve patient's quality of life? When and how can patients be included in the process?

Technology Assessment and RRI need to play a more prominent role, not only by means of a participatory approach, by involving various stakeholders, aiming to influence regulatory practices (by assessing the impacts of technology) but also by combining this with a constructive approach (associated with a responsible research and innovations approach), addressing social issues around technology and influencing design practices (by means of a more stakeholder involvement). Questions that need to be addressed are for example:

- What are the ethical and social implications associated with the use of such technologies (e.g. unintended harm)?
- Are the needs of citizens/patients clearly identified?
- Is there a gap in regulatory requirements concerning safety and efficacy of such technologies?
- If so how can they be overcome?
- How can the different stakeholders work together during the process, and how can their different values, needs and expectations be aligned and feed back into development processes?
- What is changing in health and care professional education? Which new professions can emerge and how can their competences be assessed?

TA can play a role by identifying the innovations with the potential to be disruptive in health care and RRI can complement by attending to align research and innovation processes along the entire technology value chain, by engaging the different stakeholders in the process, and by also considering the real societal needs.

Further research on potential disruptive innovation and its impacts in healthcare is needed and must be foreseen, in order to better deal with the news challenges of tomorrow.

Notes

1) For more information concerning the event and its participants, please visit: http://www.medical-devices-meetings.com
2) Sustaining innovations are considered to be innovations that do not affect existing markets. They can be classified as continuous, if they improve a product in an existing market in ways that consumers expect, or can be discontinuous if the innovation is unexpected, but still not affecting existent markets (Barros et al. 2015).

3) The internet of things, big data analysis and synthetic biology are the other trends connected to the health care sector, identified in the OECD report.
4) Phillips and Smit Röntgen, present in the meeting their last research in additive metal manufacturing concerning tungsten 3D printing and powder developments used in medical devices.
5) Besides health technologies, other examples of personalized technologies can be found as an answer to daily bases living, such has cutlery, glasses or cups, etc.
6) Although most of the literature refers to clinical advantages, several studies also refer lack of enough clinical evidences (HIQA 2011).

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