European Commission

Report of the

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH (EXPH)

on

Disruptive Innovation

Considerations for health and health care in Europe

Health and Food Safety

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Disruptive Innovation

-

Considerations for health and health care in Europe

The EXPH adopted this opinion at the 13th plenary meeting of 29 February 2016 after public consultation

About the Expert Panel on effective ways of investing in Health (EXPH)

Sound and timely scientific advice is an essential requirement for the Commission to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multidisciplinary and independent Expert Panel which provides advice on effective ways of investing in health (Commission Decision 2012/C 198/06).

The core element of the Expert Panel's mission is to provide the Commission with sound and independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to health care modernisation, responsiveness, and sustainability. The advice does not bind the Commission.

The areas of competence of the Expert Panel include, and are not limited to, primary care, hospital care, pharmaceuticals, research and development, prevention and promotion, links with the social protection sector, cross-border issues, system financing, information systems and patient registers, health inequalities, etc.

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http://ec.europa.eu/health/expert_panel/experts/working_groups/index_en.htm

ABSTRACT

Disruptive innovation is a concept that has been developed for analysing ways to improve health outcomes and reduce costs in the US health care system. The Expert Panel on Effective ways of Investing in Health (EXPH) was requested to focus on the implications of disruptive innovation for health and health care in Europe.

The Expert Panel understands "disruptive innovation" in health care as a type of innovation that creates new networks and **new organisational cultures** involving new players, and that has the potential to improve health outcomes and the value of health care. **This innovation displaces older systems and ways of doing things**.

The Expert Panel conceptualizes disruptive innovations as complex and multi-dimensional, categorising five dimensions of disruptive innovations: typology of business model, fluency of implementation, health purposes, fields of application and pivoting values.

The Expert Panel identified five strategic areas for disruptive innovation: translational research, access to new innovative technologies, precision medicine, health and care professional education and health promotion.

The implementation of any (disruptive) innovation should carefully address the issues of relevance, equity (including access), quality, cost-effectiveness, person- and people centredness, and sustainability. Health policy should be designed to encourage enablers for developing and implementing disruptive innovations and reduce the potential barriers.

While disruptive innovation can be an important concept for policy analysis, it does not mean that other types of innovation are less desirable. Sustaining innovations can be very important even when they are continuous, as well as more discontinuous innovations that may not be classified as disruptive.

Disruptive innovations can be an important mechanism for improvement of health and health care in Europe. Disruptive innovations provide new and different perspectives that, in the long run, tend to reduce costs and complexity in favour of improved access and the empowerment of the citizen/patient. Policy makers should thus, see disruptive innovations as possible new ways of developing sustainable European health systems.

Keywords: EXPH, Expert Panel on effective ways of investing in Health, scientific opinion, disruptive innovation

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EXECUTIVE SUMMARY

Health care providers are currently faced with an extremely complex challenge characterised by rising demand, increasing cost and insufficient funding. In light of this, European health systems must consider *innovation* as a key instrument in achieving sustainable and efficient solutions, while respecting the fundamental values of universality, equity, solidarity and delivery of high quality, effective and safe health services.

Innovation can be categorised by its impact on stakeholders as *non-disruptive* (or sustaining) or *disruptive. Non-disruptive innovations* do not create new markets or value networks but rather better value by continuous improvement within an established system for reward of innovation for the different stakeholders. On the other hand, *disruptive innovations* are innovations that create new networks and organisational changes (based on a new set of values) and involve new players, leading to improvements in value as well as changes in the distribution of value between different stakeholders. In fact, disruptive innovations displace older organisational structures, workforce, processes, products, services and technologies.

A disruptive innovation can be characterised by some (or all) of the following capacities:

- Provide improved health outcomes
- Create new services and overcomes challenges regarding accessibility to existing or new services
- Lead to cost-effective methodologies that improve access
- Promote person-centred health delivery
- Empower the patient/person
- Disorder old systems
- Create new professional roles and capacities
- Create new sets of values for the health workforce, patients, citizens and community
- Introduce transformative cultural change

Currently, the areas of main focus for disruptive innovations in health care are:

1. *New models of person-centred community-based health delivery* that allow a decentralisation from traditional health care venues like hospitals to integrated care models (e.g. transfer of records to patients);

2. *New technologies* that allow early diagnostics, personalised medicine, health promotion, community-based therapy and care and the empowerment of patients/citizens, as well as potential curative technologies (e.g. regenerative medicine[1], immunotherapy for cancer);
3. *Person-oriented approaches for the treatment of patients with multiple chronic diseases*, situations of frailty and/or of loss of functionalities in a multi-cultural context;
4. *Education of the health workforce and transfer of skills and tasks* from highly trained, high cost personnel to personnel that have less specialised training and are more affordable while guaranteeing quality and safety (e.g. from specialists to generalists, from generalists to pharmacists and nurses, from nurses to health care assistants and to other care providers, and ultimately to citizens themselves.)

When considering the development and implementation of disruptive innovations in the European health care systems, decision makers should take into account the following aspects:

1. It is necessary to analyse whether current incentives favour the development of sustaining innovations (halfway technology) rather than disruptive innovations.
2. It is difficult to implement a disruptive innovation if the incentives are insufficient for its adoption and diffusion.
3. Some of the most important barriers to keep in mind are: lack of engagement of patients/people; resistance of the health workforce and organisational/institutional structures; inadequate networks and processes; economic and legal factors; lack of political support, lack of coordinated actions across agents, and lack of knowledge and evaluations.
4. 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.
5. The implementation of a disruptive innovation requires the creation of new organisational models and management plans, the presence of favourable framework conditions, and the development of new models of commissioning and financing.

[1] Gardner J et al, 2015

6. Payment systems are of particular relevance for the adoption and diffusion of disruptive innovations, since what is not paid for can usually not be done, and payments also send signals to innovators about what types of innovations are profitable to invest in. However, the use of new business/financial models should not be considered only as an element that influences the adoption and diffusion of a disruptive innovation, but also as an important area for the development of disruptive innovations.
7. A difficulty in the implementation of disruptive innovations in the European health systems is represented by the significant knowledge gaps (e.g. methods of development, frameworks for designing the necessary system changes, limited experiences in the EU systems).
8. It is important to invest in trans-disciplinary research and education at a pan-European level, supporting the development of health and social innovation labs.
9. There may not be a "one size fits all" solution for monitoring, managing and stimulating the adoption of disruptive innovations.
10. Adoption and diffusion of any potential disruptive innovation should always be based on evidence deriving from a specific in-depth evaluation that takes into consideration elements such as the potential costs and benefits of the disruptive innovation, the potential costs and benefits of transformation, the reversibility of choices, the type of barriers to be overcome, and the aspects of uncertainty.
11. Decentralising the procedures of implementation, after higher-level decision making, can allow to develop all the strategic areas of disruptive innovations in a way that is adapted to the needs and realities of each decentralised community/country.

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1. TERMS OF REFERENCE

The Expert Panel on effective ways of investing in Health is requested to focus on the following points:

1. Build a simple taxonomy of disruptive innovation, by identifying key types and categories of services and technologies, illustrated by one or two examples. Technological, organisational and social innovation can all be considered in this context.

2. Provide expert view on the evidence of disruptive innovations, on methodologies used, main challenges, and the effects on cost-effectiveness, access, quality and resilience of the health systems. This should include an analysis of knowledge gaps and, if appropriate, suggestions for applied research to address these.

3. Assess the relevance of disruptive innovation for the diverse range of European health care systems.

4. Describe the drivers that trigger and the factors that are involved in successful large-scale implementation of disruptive innovations; identify the main barriers and ways to overcome these bottlenecks.

5. Investigate the implications of disruptive innovation in training and education of clinicians, health care staff and other stakeholders

6. Identify strategic areas of focus with high potential of benefitting from disruptive innovations, accompanied with an explanation of their potential benefits and practical advice how to realise these innovations and embed them in regular practice.

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2. BACKGROUND

Health care providers are currently faced with an extremely complex challenge characterised by rising demand, increasing cost and insufficient funding. In fact, models of health care need to be continuously adapted to improve in terms of organisational structures, workforce, processes, products, services and technologies in order to cope with these challenges. Never as much as today have health care systems been interested and involved with the potential benefits deriving from innovations.

We can distinguish three different types of innovations that enable changes in health care: continuous, discontinuous and disruptive. Each of these is associated with different consequences of innovation. Even though all three types of innovation can be relevant and provide advantages, if they are not properly applied they can sometimes deliver insufficient additional changes or require disproportionally high investments and levels of expertise. For this reason, in this report we analyse disruptive innovations in health care in order to allow a better understanding of which innovations will be most critical in impacting the European health care systems in the short and long run.

As regards to disruptive innovations, Christensen coined the term as innovations that "enable a larger population of less-skilled, less-wealthy people to do things in a more convenient, lower-cost setting, which historically could only be done by specialists in less convenient settings" (Christensen CM, 1997).

The concept of "disruptive innovation" is, therefore, an academic theory used to explain certain phenomena in industry, such as the demise of the mainframe computer and chemical photography sectors in favour of personal computers, digital cameras and smart phones. Literature postulates the use of disruptive innovations in health care and suggests that the core of this type of innovation is represented by 'simplifying' technology, which, however, needs to be embedded in innovative business models and value networks (Christensen CM et al, 2008).

We draw attention to the fact that Christensen's interpretation of disruptive innovations was conceived within the American context and, therefore, cannot be simply transposed to the European health systems. On the other hand, for the European context Christensen's definition can be interpreted as a starting point, as it promises converting the current services and products to higher quality, simpler, and/or more affordable ones through novel organisational models, new models of service provision and technologies – with the aim of improving access, quality, equity and/or resilience of the systems.

There are some areas of health care that present a particularly high potential of benefitting from disruptive innovations. In this sense, the main areas of focus are:

- *New models of community focused person-centred health delivery,* which imply a shift from traditional health care venues like hospitals to integrated care models with a strong primary care[2] basis;
- *New technologies allowing early diagnostics and community-based therapy and care*, necessary in supporting the innovative person-centred models of care;
- *Person-oriented approaches in a multi-cultural context* for the treatment of patients with multiple chronic diseases, situations of frailty and/or of loss of functionalities;
- *Education of the health workforce and transfer of skills and tasks* from highly trained, high cost personnel to personnel that is less trained and more affordable (e.g. from specialists to generalists, from generalists to pharmacists and nurses, from nurses to health care assistants and to other care providers, and ultimately to citizens themselves).

As regards to technology, it has been recognised that one of the major drivers of the increase in costs of health care is technology (Appleby J, 2013). On the other hand, there are also many examples of how technological (and non-technological) innovations have played a role in reducing costs and improving outcomes.

A disruptive innovation has an unpredictable nature. It can be labelled as a disruptive innovation only after its event. Each disruptive innovation has its own fluency of implementation. The fluency of implementation describes the ease with which it is applied to the health care field (Rogers EM, 1962; Adams R et al, 2013). In fact, while there are relatively few examples of successful disruptive innovations, there is evidence that many potential disruptive innovations fail to be adopted and diffused.

One of the causes behind the difficulty in implementation of disruptive innovations in the European health care systems is represented by the significant knowledge gaps, which are still present. For example, little is known about the practical application of disruptive innovations in health care and there is a lack of proven methods for their development and of established frameworks for designing the necessary system changes (i.e. organisational structures, people skills and behaviours, processes, products, services and technologies). In fact, many of the experiences have been developed and tested in the

[2] EXPH (EXpert Panel on effective ways of investing in Health), Report on Definition of a frame of reference in relation to primary care with a special emphasis on financing systems and referral systems, 10 July 2014. Available online at: http://ec.europa.eu/health/expert_panel/opinions/docs/004_definitionprimarycare_en.pdf

American health care environment. In Europe, while there are promising pilots and several successful examples of innovation, the concept of disruptive innovation as such still remains limitedly applied in health systems.

The successful implementation of a disruptive innovation greatly depends on the following elements:

- *Creation of new organisational models and management plans* that allow/promote the integration of the disruptive innovation in regular practice (e.g. political and budgetary arrangements, protocols and care pathways, human resources, etc.);
- *Engagement of all relevant actors* involved in the design, development and practical implementation of the disruptive innovation (i.e. demand and supply, public and private sectors, including: drug and device manufacturers, citizens, informal carers, third-party payers and insurers);
- *Favourable framework conditions* (patent system, health guidelines, interoperability and technical standards, market incentives to drive changes) that improve the functioning of the technology markets (eHealth systems, tele-monitoring);
- *New models of commissioning and financing* (e.g. to reduce hospitalisation by shifting care provision to primary/outpatient care, day surgeries and community services);
- *Impact of the European Reference Networks model*, which through the cooperation of experts, the promotion of knowledge sharing and the use of networking tools and IT solutions, creates a new way of addressing the needs of patients suffering from complex and rare or low prevalent diseases/conditions, and of providing a more efficient approach in cases of scarce knowledge and need of economy of scale.[3]

The implementation of a disruptive innovation can, however, be hindered by the presence of specific barriers or bottlenecks. These factors play an important role in impeding the evolution of the potential disruptive innovation from a pilot project to a standard and sustainable health service provision.

Some of the most common bottlenecks to keep in mind in disruptive innovations are:

- *The establishment of the new structure* determined by the disruptive innovation is a fundamental objective and it creates the condition necessary to eventually decommission the older structures. In this sense, it should be noted that the EU

[3] See: http://ec.europa.eu/health/ern/policy/index_en.htm

health care systems- unlike the US health care model- are mainly based on public procurement or funding;

- *The lack of clear health economic assessments* makes it difficult to estimate the costs, resource use and impact of an innovation. This type of assessment is essential in order for decision makers to commit to replacing the old structures with the innovative measures;
- *The stakeholders of the traditional structures* might have much to lose from the disruptive innovation and, therefore, have a vested interest in blocking these changes.

Along with the implementation, another relevant aspect of a disruptive innovation is its pervasiveness of application. In fact, according to the pervasiveness of application, a disruptive innovation could be considered as *systemic* or *incremental*.

This report provides an expert view on the evidence of disruptive innovations, the main areas of focus, the effects of disruptive innovation in health systems, the elements that influence their development and implementation, and the implications of disruptive innovations in research and education of health care providers.

The report reflects the opinion, expertise and experience of the members of this Expert Panel. The European Commission has also organised a literature review in support of the work brought forth by this Expert Panel.

3. OPINION

3.1. THE CONCEPT OF DISRUPTIVE INNOVATION

3.1.1. INNOVATION

3.1.1.1. Concept of innovation

Innovation is the process of translating an idea or invention into a product/service that creates value or for which customers or society or insurance will pay. To be called an innovation, an idea must be replicable and must satisfy a specific need. Innovation involves deliberate application of information, imagination and initiative in deriving greater or different values from resources, and includes all processes by which new ideas are generated and converted into useful products.

Innovation can be viewed as the application of better solutions that meet new requirements, unarticulated needs, or existing population needs. This is accomplished through more effective products, processes, services, technologies, or ideas that are readily available to governments and society. The term innovation can be defined as something original and more effective and -as a consequence- new, which "breaks into" the market or society. Innovation is synonymous with risk-taking and organisations that create revolutionary products or technologies take on the greatest risk because they create new markets.

- Innovation differs from invention in that innovation refers to the use of a better and, as a result, novel idea or method, whereas invention refers more directly to the creation of the idea or method itself.

- Innovation differs from improvement in that innovation refers to the notion of doing something different rather than doing the same thing better.

3.1.1.2. Types of innovation

Innovation can be categorised by its impact on stakeholders as *non-disruptive* (or sustaining) or *disruptive* (Table 1). A *sustaining innovation* does not create new markets or value networks but rather especially evolves existing ones with better value, allowing the firms within to compete against each other's sustaining improvements. Sustaining innovations may be either "continuous" or "discontinuous". In contrast to sustaining

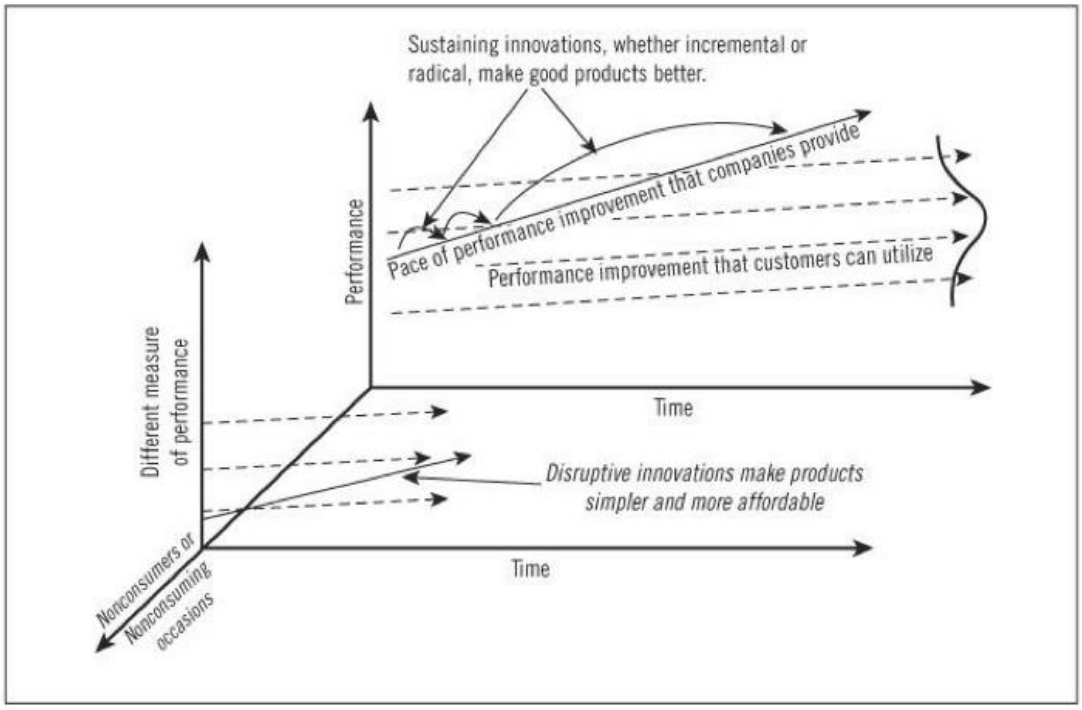
innovations, *disruptive innovations* refer to innovations that disorder old systems, create new players and serve new groups of people, or the same groups of people with new products, while marginalizing old ones, and deliver value to stakeholders who successfully implement and adapt to the innovation (Figure 1). Disruptive innovation requires a new professional culture to develop.

However, it should be noted that many disruptive innovations result from the combination of one or more sustaining innovations and their application (for example through innovative business models) to opportunities which were not originally conceptualized by the investors in and developers of the innovations.

Table 1. Types of innovation

<table>
<tr><td rowspan="3">Sustaining</td><td colspan="2">An innovation that does not affect existing markets.</td></tr>
<tr><td>Continuous</td><td>An innovation that improves a product in an existing market in ways that customers are expecting.</td></tr>
<tr><td>Discontinuous</td><td>An innovation that is unexpected, but nevertheless does not affect existing markets.</td></tr>
<tr><td>Disruptive</td><td colspan="2">An innovation that creates a new market or expands an existing market by applying a different set of values, which ultimately (and unexpectedly) overtakes an existing market.
Main features are: a) improved health outcomes
b) create new professional culture
c) serve new groups or have new products/services (“create new markets”)
d) create new players
e) disorders old systems</td></tr>
</table>

Figure 1. Model of a disruptive innovation (taken from Christensen CM et al., 2008)



3.1.2. CHRISTENSEN CONCEPT OF DISRUPTIVE INNOVATION

Disruptive means causing or tending to cause disruption; innovative or ground-breaking. However, as highlighted by Christensen in a 2015 publication, not everything that determines a situation in which an industry is shaken up and previously successful incumbents stumble, should be considered a "disruptive innovation" (Christensen CM et al., 2015).

The term disruptive technologies was coined by Bower and Christensen and introduced in the article "Disruptive Technologies: Catching the Wave" (Bower et al, 1995). In the "Innovator's Solution" (Christensen CM, 2003), Christensen replaced the term disruptive technology with disruptive innovation because he recognised that few technologies are intrinsically disruptive or sustaining in character; rather, it is the (American) business model that the technology enables that creates the disruptive impact.

Disruptive innovations are not necessarily "advanced technologies". Disruptive innovations are often novel combinations of existing off-the-shelf components, applied cleverly to a small, fledgling value network. Many disruptive innovations result from the combination of one or more innovative technologies and their application through innovative business models. The opportunities, which derive from a disruptive innovation, sometimes are not originally conceptualized by the investors and/or developers of the technological innovations.

Christensen defines a disruptive innovation as a product or service designed for a new set of customers: "Generally, disruptive innovations were technologically straightforward, consisting of off-the-shelf components put together in a product architecture that was often simpler than prior approaches. They offered less of what customers in established markets wanted and so could rarely be initially employed there. They offered a different package of attributes valued only in emerging markets remote from, and unimportant to, the mainstream."

Christensen distinguishes between "low-end disruption" which targets customers who do not need the full performance valued by customers at the high-end of the market and "new-market disruption" which targets customers who have needs that were previously un-served by existing incumbents.

Companies unwittingly open the door to "disruptive innovations" at the bottom of the market. An innovation that is disruptive allows a whole new population of consumers at the bottom of a market access to a product or service that was historically only accessible to consumers with a lot of money or a lot of skill. An innovation that has this effect is disruptive; not all disruptive innovations need to have this feature: this is a sufficient but not necessary characteristic.

"Disruptive innovations" refer indirectly to the concept of a "paradigm-shift" as described by Thomas Kuhn in his book "The structure of scientific revolutions" (Kuhn TS, 1962). The term "paradigm-shift" has also been used to describe a profound change in the fundamental model or perception of events.

Similar concepts were already described by Karl Marx as creative destruction. Although the modern term "creative destruction" is not used explicitly by Marx, it is largely derived from his analyses (Harris AL, 1942; Schumpeter JA, 1942). "Creative destruction describes the "process of industrial mutation that incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one." Capitalism destroys and reconfigures previous economic orders, but it must also ceaselessly devalue existing wealth (whether through war, dereliction, or regular and periodic economic crises) in order to clear the ground for the creation of new wealth.

While economists since long had been occupied with classification of innovations as productivity increasing and or capital or labour saving, Schumpeter (1942) invented "creative destruction" as a concept for analysis and policy. The concept was introduced first within an analysis of the business cycle, where it was used to denote an endogenous replacement of old ways of doing things with new ways, and so will destroy the capitalist structure. It was later linked to his writings on the role of the entrepreneur and large companies respectively in the process of innovation. His observation was that the most important innovations could not be described by conventional theory, and he put forward the entrepreneur as an important factor of production for what could be called "disruptive innovation". This was in his view innovations that totally transformed the way an industry or market was organised and worked. IKEA and Ingvar Kamprad could be an example of an innovation and an entrepreneur. The "flat package" was the technology enabler for disruption. It is also an innovation that was met with strong opposition from firms in the market that were challenged by the new approach to selling furniture. In later writings he

discussed the role of large companies, with resources for research and development, in the innovation process.

While disruptive innovation can be an important concept for policy analysis, it does not mean that other types of innovation are less desirable. Sustaining innovations can be very important even when they are continuous, as well as more discontinuous innovations that may not be classified as disruptive.

3.1.3. DISRUPTIVE INNOVATION IN HEALTH CARE

3.1.3.1. The applicability of disruptive innovation to health care

The evolution of societies, technologies and organisations creates different needs and offers new possibilities to solve these needs. Innovation is a key feature that organisations have to incorporate as a condition to offer sustainable and efficient solutions. But not all innovations are appropriate. If their cost is too high for the benefits obtained or if the quality and safety of the services is reduced while reducing costs, then these types of innovations are not of value for the health system. European Health Systems are based on the values of universality, equity, solidarity and access to high quality and safety services. The respect of these values is a precondition when talking of innovation.

When discussing the applicability of the concept "disruptive innovation" to health systems it seems that there are elements of this concept than can be used as valuable drivers for improvement. However, the context in which this concept arises (industrial environment, US context) makes it difficult to translate it to the health system in a European context.

For example, while the relevant dimension of the notion of disruptive innovation in the case of the US seems to be income (or wealth), as it is the main element allowing access to health care, in Europe the relevant dimension in defining access to health care is need. Many EU Member States (MS) health systems offer universal coverage, meaning that richer and poorer people are entitled to receive the same services. The concept of higher need drives access to health care. A disruptive innovation would be one that allows generalised access to a product or a service previously accessible only to the ones with a higher need or the ones not facing high barriers to access. Therefore, if one of the characteristics of a disruptive innovation is that of "allowing access to a product or service previously accessible only to the rich or skilled, lowering quality", this would seem

to be not the most relevant aspect for most European Social Models. Another aspect of a disruptive innovation, that is its capacity of "creating new markets", could be more applicable. In this case it is possible to design new products, new services, or new ways to do things, covering health needs in a better way (higher value: higher quality and reasonable cost of relevant services). The idea that introducing new ways of doing things sometimes causes the substitution ("destruction", disinvestment, decommissioning) of the old way of doing things could be also a powerful element for enabling improvement, if properly applied.

3.1.3.2. EXPH concept of disruptive innovation in health care

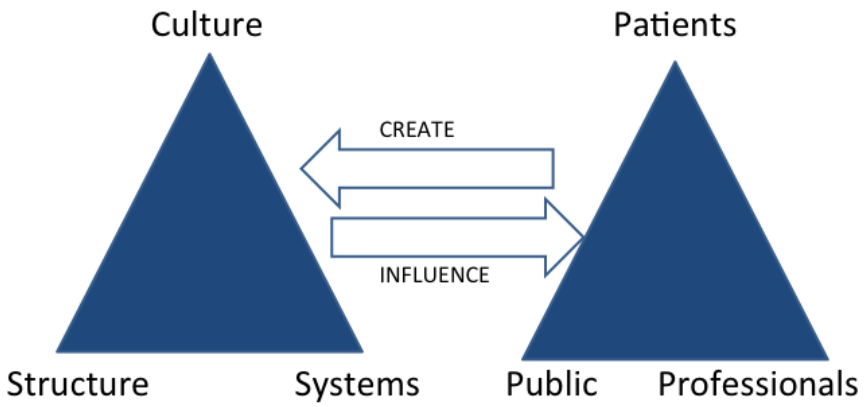
The Expert Panel understands **"disruptive innovation" in health care as a type of innovation that creates new networks and new organisations based on a new set of values, involving new players, which makes it possible to health improve outcomes and other valuable goals, such as equity and efficiency. This innovation displaces older systems and ways of doing things.**

This means that there will be uncertainty about the consequences in clinical practice, and that it may take long time to reveal these. Systematic follow up and management of the innovation may be necessary to support the adoption and diffusion and optimize the implementation of the innovation.

The concept of disruption implies that not only does an innovation take place, but that the previous "market", companies, employers or employees might change considerably.

Also in the case of disruptive innovations in health care, to increase the degree in which the decisions taken (within any health care organisation) are evidence-based, it is important to develop the appropriate *systems* and *culture*. It may also be necessary to change the *structure* of the organisation (Figure 2). Individuals and organisations need to be supported by systems that provide best knowledge currently available when and where it is required, and to exist in an evaluative culture (Gray M, 2009). The appropriate use of incentives may be necessary as well in promoting this process.

Figure 2. The three element of a healthcare organisation – structure, systems and culture



3.1.3.3. Elements that characterise disruptive innovation

It is possible to identify some main characteristics of disruptive innovations in health care. In fact, a disruptive innovation can often be characterised by some (or all) of the following elements:

- Provide improved health outcomes
- Create new services and overcomes challenges regarding accessibility to existing or new services
- Lead to cost-effective methodologies that improve access
- Promote person-centred health delivery
- Empower the patient/person
- Disorder old systems
- Create new professional roles and capacities
- Create new sets of values for the health workforce, patients, citizens and community
- Introduce transformative cultural change

Since the concept of disruptive innovation is in continuous evolution, in this analysis priority was given to the relevance of the proposed features rather than their exhaustiveness.

We can define a *necessary characteristic* as a condition without which an innovation cannot be defined as "disruptive". It is a condition that is indispensable for disruption, but that however, requires the presence of other conditions in order for disruption to take place.

On the other hand, a *sufficient characteristic* is defined as a condition which, considered alone, if present guarantees the presence of disruption.

However, it is important to underline that no characteristic of a disruptive innovation should be considered more important than the others in terms of impact on the overall health care system. Furthermore, the importance of each characteristic for the health care system does not go hand in hand with necessity and sufficiency.

High value in disruptive innovation

Some disruptive innovations could be characterized by the fact that they also present high value. In health care, high value can be defined as meeting patient expectations at the level of the individual or providing the better outcomes in the most cost-effective way in the short or long-term at the population level. Waste and value are closely related. In fact, there is a direct link. Waste, which implies the use of more resources than necessary, can be opposed to value. Where waste is high, value is low and vice versa. In this sense we can differentiate between cost and waste, where waste can be viewed as anything that does not add value (Ramsay CR et al, 2003; Gray M, 2011).

In an era in which resources often do not increase in step with increasing need and demand, when they increase at all, it is essential to promote disruptive innovations that present high value.

For this reason, the Riga roadmap (Riga Health Conference, 2015) proposes investing in innovation that is both cost-effective and valuable as an instrument to make health care systems sustainable. The declaration, underlines the need of the development of a common definition of "valuable innovation", starting from patient needs and societal needs.

Within innovations, disruptive innovations are of particular interest also for their potential in extending access to health care and improving the health of the population.

The assessment of the value of an innovation is not a novelty, yet it has gained specific interest since the formal assessments of value are increasingly used in decision-making

regarding pricing, reimbursement and funding of new medicines and other medical technologies. The issues around value are thus not only definition and encouragement, but also the necessary provision of evidence as regards to the value of an innovation.

3.2. TAXONOMY OF DISRUPTIVE INNOVATION

3.2.1. DIFFERENT OPTIONS TO CLASSIFY DISRUPTIVE INNOVATIONS

The lack of a theoretically derived and empirically developed taxonomy of disruptive innovation, conceived in terms of these perceived characteristics, continues to deter substantive research in the area. There are many options that can be taken into account in the taxonomy of disruptive innovations. We have identified a taxonomic tree with five levels of hierarchical classification of disruptive innovations: typology of business model (following the classification of Christiansen), fluency of implementation, health purposes, fields of application and pivoting values. This hierarchical classification of the taxonomy is explained in Annex 1. However, for the purposes of simplification and applicability in the health sector in the EU context, we propose the distinction of disruptive innovations based on their "fields of application" and its categories. In fact, this approach, focused on where the innovation is being applied, allows us to solve those cases where it might be initially difficult to classify an innovation.

3.2.2. THE FIELD OF APPLICATION

The field of application level describes the context in which the disruptive innovations take place. This categorisation derives from the functional application of the innovations construed in the context of health care delivery. It can be useful for decision makers in their choice of which disruptive innovation to invest in and in defining eventual regulatory aspects.

Four main categories were identified:

- technological (nontechnology, halfway technology, high technology, further described in section 3.3.2)
- organisational (models, structures, processes)
- product and services
- human resources (health workforce, patients, citizens and community).

This classification based on the field of application can be considered a theoretical categorisation since in reality a disruptive innovation generally influences more than one field of application. In fact, a disruptive innovation can have a field of application and determine a disruption also in one or more other fields: for example, we can have a new

organisational model that can disrupt a technology, making it obsolete. Otherwise, a disruptive innovation can also create new needs in another field: for example, the introduction of a new organisational model can create new needs that may require new professional figures or health workers, which in turn require specific professional training. Furthermore, we should consider that new types of business/financial models could be disruptive innovations in themselves (e.g. Managed Services).

3.2.3. EXAMPLES ILLUSTRATING THE TAXONOMY

The following are specific examples of some important disruptive innovations and their field of application.

Technological

Antibiotic development: antibiotics revolutionised medicine in the 20th century and have, together with vaccination and socio-economic development, led to the near eradication of diseases such as tuberculosis in the developed world.

Anti-ulcer drugs (section 3.5.4): they provided primary care physicians with a new, effective, low cost technology, which replaced previous technologies.

Minimal invasive surgery (section 3.5.6): disruptive of classical open surgery, it has resulted in reduced length of hospital stay and decreased morbidity and cost to the health-care system.

New and more effective treatment for HCV (section 3.5.1): these new treatments can completely change the face of Hepatitis C infection, with the potential of drastically reducing both consequences and incidence of the disease.

Organisational

Community-based mental health (section 3.5.2): an organisational innovation that disrupted the old way of looking at, and treating, people affected by mental disorders.

Population based accountable organisations (section 3.5.3): organisations that maximise value and equity by focusing not on institutions, specialties or technologies, but on populations.

Integrated care: a new organisational arrangement which focuses on more coordinated and integrated forms of care provision as opposed to the previous fragmented delivery of health and social services.

Product and services

Development of palliative care: it shifted the paradigm from cure to care and improved life-expectancy and quality of life in patients with life-limiting conditions.

Patient-centred care (section 3.5.7): this innovation has determined a complete reversal of the traditional vision in which the health service was at the centre.

Human resources

Diabetic patient self-management (section 3.5.5): insulin has transformed the management of diabetes, giving patients responsibility for self-management with the support of health professionals, teams and services who provide the patients with knowledge, skills, confidence and support they need to manage their condition(s) effectively in the context of their everyday life. Furthermore, it created complete new areas of practice for those who lived to develop complications – (retinopathy, nephropathy, foot care etc.). Ultimately it led to chronic care.

The following Table represents a matrix that clarifies the connection between disruptive innovations and policy implications (Table 2).

Table 2. Disruptive innovation and policy implications

		DIFFICULTY OF ADOPTION		
		Easy adoption	**Average adoption**	**Difficult adoption**
EXPECTED DESIRABILITY OF INNOVATION	**Low desirability**	No policy action required	No policy action required	No policy action required
	Average desirability	Monitor adoption, stimulate adoption	Stimulate adoption, focus on main barriers	Strong stimulation of adoption, reducing/removing main barriers
	High desirability	Monitor and actively stimulate adoption	Strongly stimulate adoption, actively reducing/removing barriers	Very strong policy action required to overcome all barriers to adoption

For all policy intervention, it should be clear that costs and benefits of policy action should also be included in the decision making process. In fact, implementation costs are

often not included in Health Technology Assessments, even though they are clearly relevant in this context.

3.3. STRATEGIC AREAS FOR DISRUPTIVE INNOVATION

3.3.1. DISRUPTIVE INNOVATION AND TRANSLATIONAL RESEARCH

Innovations, including disruptive innovations, may happen in any of the "steps" in the continuum of translational research: basic discovery; proof of concept in humans; clinical development and Evidence Based Medicine; practice adoption; community assessment and care delivery; community health status; global health service" (Dzau VJ et al, 2010).

Probably the most disruptive innovation in health care in the past 10 years is the change of the position of the patient from a rather *passive actor*- undergoing procedures and trying to comply with therapeutic regimens- towards an *active participant*- formulating goals, monitoring indicators, contributing to his/her care-plan. Some examples of disruptive innovations that have occurred in translational research can be found in Table 3. This table, however, should not be interpreted as a "final conclusion" within the debate on disruptive innovations, as it in itself can give space to further debate.

Table 3. Examples of disruptive innovations in translational research

	Basic Discovery	**Proof of concept**	**Clinical development**	**Practice adoption: EBM**	**Community assessment**	**Global Health**
Sustaining	Discovery of ACE-inhibitors	Testing of new drugs	Stenting for CHD	Guidelines for chronic conditions	Task shifting between health professionals	Worldwide access to ARV
- Continuous						
- Discontinuous	Discovery of penicillin	First heart transplantation	Mobile health, patient led	First meta-analysis	Citizen/patient participation in health care	Health care as a human right
Disruptive	Insights in DNA-mRNA-Protein synthesis	Testing of general anaesthesia in humans	Shift from disease-oriented to goal-oriented care (Mold et al, 1991)	Implementation of guidelines as the basis for quality care: from experience to evidence	Intersectoral action for health equity	Eradication of smallpox
Characteristics	create new market	create new players; create new markets	disorder old systems; improved health outcomes	new professional culture	disorder old systems	improved health outcomes

An on-going project that can be a clear example of disruptive innovation in translational research is the use of smart clinical registers such as the *Swedish Rheumatology Registry-Supported Care and Learning Systems*. This registry is an early version of a new generation of "smart registries", which simplify and shorten the time necessary to input data, and present time-trend analyses with visual displays to inform patients and providers in their decisions, both at and outside the point of care.

This innovation transforms the traditional database registry in one of the most advanced registry systems in Sweden in terms of the clinical practice, patient-centredeness and patient empowerment, three elements which this registry has improved. (Øvretveit et al.)

The costs of the transition from one situation to a new one introduces a new issue: is there a difference in managing change in the case of a disruptive innovation compared to any other innovation? The focus on cultural change and transformation will point to extra costs of changing organisations, at least in a first moment of impact of adoption. It is necessary to determine the "mechanisms" that allow change to happen. In fact, while strict budgets may impede an "investment" that will determine lower costs, at the same time they need to avoid increases in spending that become permanent without leading to improved outcomes. This is the challenge to solve.

3.3.2. DISRUPTIVE INNOVATION AND TECHNOLOGY IN MEDICINE

Medicine in the 21st century is increasingly dependent on technology. While technology remains the same in the US and European health systems, the business models and value networks, may differ. Therefore, the analyses of disruptive innovation in the US context can have different relevance for each European health care system. In fact, European health care systems differ in important aspects, making some more close to the US model than others.

Technology in health care is defined as any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care (INAHTA, 2013). We can distinguish between technology (which enables the real world system), information technology (which enables information to exist and flow) and information devices (which enable humans to work with information and each other).

Even though systemic information technology innovations may not attract as much attention as "point" technology innovations (e.g. new drugs or devices), particular interest should be given to their potential.

Technological change or innovation in medicine has been described as three steps (Thomas L, 1971; Thomas L, 1978): non-technology, halfway technologies and high technology.

- *Non-technology* represents a situation where there is not very much that can be done to change the course of the disease. However, a lot can be done to help the patients through the episode of illness, and this is a technology that is both commonly used and highly appreciated. An example is supportive therapy and technical advances that facilitate the care process for the care-giver.

- *Half way technology* may be described as an innovation that makes it possible to influence the course of the disease and improve outcome. The technology is often performed in hospitals and it is usually expensive. It could be exemplified by radiotherapy and surgery for some cancers, treatment of polio victims in the iron lung, dialysis and transplantation for chronic renal failure

- *High technology* is based on a true understanding of the disease. The technology could offer prevention and cure at a low cost. An example could be the discovery of the role of helicobacter pylori as a leading cause of bleeding stomach ulcers in the 1980s that revolutionised the treatment process and have eliminated the need for surgery for ulcer disease.

  A true understanding of the disease facilitates the possibility of making the cure available to all, without wastes and determines a significant improvement in the outcome.

Thomas' model of medical progress shows strong links with Christensen's theory of disruptive innovation.

It should be noted that there are often strong incentives for developing new half way technologies that address important unmet medical needs. However, these technologies are often expensive and not particularly effective (Kumar RK, 2011). On the other hand, these new half way technologies may represent a necessary step in the understanding and development of medicine. As a consequence, the issue should reside in the optimal

balance between the investments in half way technology and high technology and in the promotion of prompt access to a new high technology when it becomes available.

3.3.3. DISRUPTIVE INNOVATION AND PRECISION MEDICINE

Precision medicine is defined as customised health care based on individualised genomic risk information (biomarkers) which is referenced against population genomic data (biobank) and used to prevent, diagnose, and treat disease (James JE, 2014).

Inherent in this definition is the goal of improving clinical outcomes for individual patients and minimising unnecessary side effects for those less likely to have a response to a particular treatment (Jameson JL et al, 2015).

Some authorities use the terms *personalised medicine* and *precision medicine* interchangeably, while others intend slightly different meanings. In *precision medicine* the focus is on identifying which approaches will be effective for which patients based on genetic, environmental, and lifestyle factors (National Research Council, 2011). However, due to concern that the word "personalised" could be misinterpreted to imply treatments and preventions being developed uniquely for each individual in this opinion we opted for "precision medicine" to "personalised medicine".

This would allow a woman to know not only that she has breast cancer, but also to know the particular sub-type of breast cancer involved. One of the benefits of this is, not only that woman could be offered treatment that is specific for that sub-type, but also that all the women who do not suffer from that particular subtype could be spared from receiving a treatment which would have no beneficial effects for them but that would determine possible harmful effects.

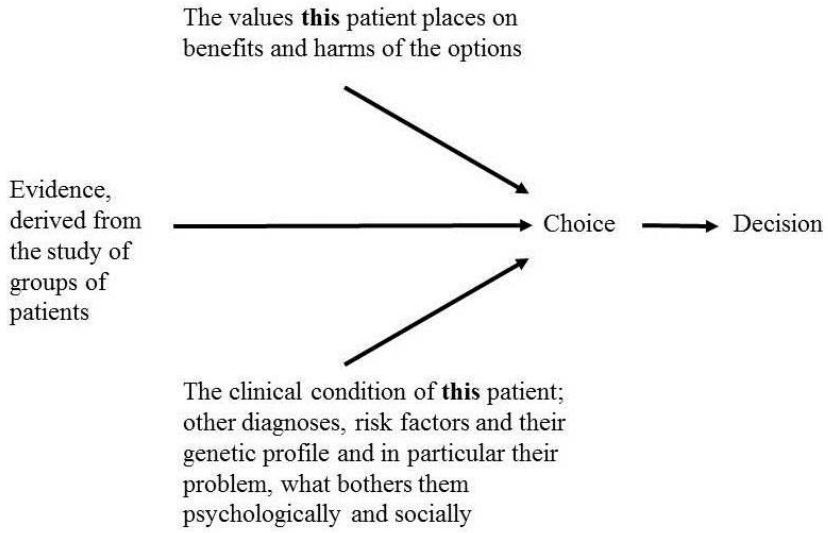
The ability to detect particular sub-groups within the population of people with raised blood pressure would allow each sub-group to be offered treatment that is related to the problem that is the cause of their high blood pressure. In fact, high blood pressure is a consequence of a number of different pathological mechanisms.

The study of drugs related to genetic sub-types is called pharmacogenomics.

It is important to emphasise, however, that personalised medicine existed before the decoding of the human genome and, in a sense, that all medical treatment should be personalised. Knee replacement surgery for example should be decided not simply on the patient's x-ray diagnosis of osteoarthritis: it should be decided based on the particular

problem that is bothering the patient and on the value that he/she gives to having an operation which is not guaranteed to be one hundred percent successful. The model for personalised decision-making, which derives from the work of the late Professor David Sackett, the creator of evidence-based medicine, is very well summarised in Figure 3. It can and should be applied to any decision such as those regarding knee replacement, genomic information, molecular diagnostics and pharmacogenomics. This model was further developed by De Maeseneer et al, with the translation of values into "goals" and the integration of the concept of "functional status" (De Maeseneer et al, 2012).

Figure 3. The model for personalised decision making



A new dawn or false promise

There was great interest in genomic medicine, and its potential to make care more precise and personalised. There are indications that "epigenomics" (i.e. all the molecules that are "around" the genome and that "stear the genome operationally") is probably more important in understanding why a person with a certain genome becomes ill, while another with an identical genome does not. However, the development of this field is not without limitations and problems. These issues will be aggravated by the increasing ability of individuals to have their human genome assessed commercially. In fact, several such services already exist. These services issue reports expressed in terms of relative percentage, which could lead to the generation of high levels of anxiety and/or demand

on the health services, that did not select the test in the first instance, as would be customary in our current approach to clinical practice. The European Union is already funding a project to explore this issue in a number of member states. It is recommended that this project be asked to report earlier on the methods that should be used to assess the cause and benefits of:

- Molecular diagnostics to identify people who might benefit from particular preventable activities;
- Molecular diagnostics to identify some groups who should receive or not a particular treatment – precision medicine;
- Identification of some groups of the people with the disease who would benefit from some particular type of treatment specific to that subgroup – personalised biomedicine.

Rigorous evaluations of efficacy, safety, and cost-effectiveness should be performed with an open mind, to determine whether and in which specific context the tools of precision medicine actually provide value (Rubin R, 2015).

This should be done in partnership with relevant private companies such as life science industry, medical technology firms, etc. In fact, these companies will have to face the challenge of developing products with the same cost but whose market could become much smaller. For example, for pharmaceutical industry, a drug which traditionally would be given to everyone who suffers from asthma, may become relevant for example to only ten percent of people with asthma.

Precision medicine is an example of disruptive innovation that requires urgent attention because it has both great potential and great risks, not at least from an equity-perspective.

3.3.4. DISRUPTIVE INNOVATION AND HEALTH AND CARE PROFESSIONAL EDUCATION

Disruptive innovations in health and care professional education can be analysed under two perspectives. The first deals with the disruptive innovations that have profoundly changed the history of health and care professional education. The second takes into consideration the role of health and care professional education as a potential enabler of disruptive innovations.

As for the importance of disruptive innovations in the history of health and care professional education, many reports document important transitions in medical education, such as in India in the 6th century BC (Filliozat J, 1964) and in China in 600 AD (Zhu Y-P, 1998). However, it was only in the 20th century, that disruptive innovations took place in Health Professional Education (Frenk J et al, 2004).

The **first generation of disruptive innovations** launched at the beginning of the 20th century, instilled more science-based curriculums for bio-medical sciences and public health related sciences, as a reaction to the wide spread of non-scientific approaches in patient care. In the new vision, modern sciences became foundational for the medical curriculum (Flexner, 1910), research was no longer viewed as an end in itself but as a step towards improved patient care and clinical training, and health and care professional education shifted from an apprenticeship-model to an academic model. This period of innovation also advocated for university-based schools of nursing. (Gies WJ et al, 1926).

After World War II, in parallel with the increasing engagement of national governments in health care, a **second generation of disruptive innovations** started both in industrialised and in developing nations. School and university development was increasingly accompanied by the expansion of tertiary hospitals and academic health centres, facilitating the integration of training, research and care provision. Postgraduate training took place in order to prepare physicians for specific specialties, and problem-based learning and interdisciplinary integrated curricula were introduced. The emphasis was on new pedagogic approaches such as student-centred learning and the use of "standardised patients" to train and assess students in practice. Focus was put on strengthening provider-patient relationships and integrating earlier student exposure to patients, who increasingly took an active role in the care processes. Health and care professional education was increasingly expanding outside the framework of hospital care to health care in communities at the primary care level. In this period, departments of primary health care and community health increasingly took the lead in the reform processes. Furthermore, attention was given to the concepts of patient-centeredness, Evidence Based Medicine/Nursing/Physiotherapy and other health care professions, and the awareness of social accountability.

Nowadays, a **third generation of disruptive innovations** in health and care professional education is required in order to face important demographic and epidemiological transitions (e.g. multi-morbidity), socio-economic challenges, increasing

social gradient in health both within and between countries, changing position in health care of the citizen (formerly known as the "patient"), scientific developments (pharmacogenomics, "health-apps", etc.) and increasing globalisation and multi-culturality.

This generation of innovations focuses on patient and population centeredness, competency-based curricula, inter-professional and team-based education, IT-empowered learning (internet data-bases for knowledge exploration, interactive e-learning for problem-solving using virtual cases/simulation (Ziv A et al, 2006), game-based learning, etc.), policy and management leadership skills.

In fact, a multitude of recent reports underpin the need for changes in health and care professional education (The Association of Faculties of Medicine of Canada, 2010; General Medical Council of the UK, 2009; Cooke et al., 2010; Hager et al., 2008) in order to address the challenges introduced by ageing, changing patient populations, cultural diversity, chronic diseases and multi-morbidity, care-seeking behaviour and heightened public expectations (WHO - Transforming and scaling up health professionals' education and training, 2013).

Emphasis should be put on quality assurance (using PDCA-cycle approaches), international accreditation-processes, increased involvement of stakeholders from outside universities in the education process (health care providers, patient organisations, local authorities, employers of health care services, etc.) and in establishing trans-disciplinary professionalism by building health workforce capacity through community-based education (Global Forum on Innovation in Health Professional Education, 2012).

Medical schools should become more socially accountable (GCSA, 2010), by orienting education, research and service activities towards priority health concerns of the community and regions the schools have a mandate to serve. Health and care professional education will have to integrate the role of the citizen/patient in its learning processes and a comprehensive assessment of the needs of the population has to define the content of the learning processes with an emphasis on training in the community context. Consideration should also be given to possible obstacles to any health profession developing new skills and tasks. For example, a greater involvement of a highly trained, skilled and underutilised workforce of pharmacists across Europe could be a disruptive innovation in health care – providing improved health outcomes, more accessible, lower cost, person-centred services empowering patients/persons to manage their health and

wellbeing. Trust and confidence between health professionals could be encouraged by early interaction and collaboration (e.g. during education, training, and practice).

An important feature of all reforms in health and care professional education is related to increasing the use of information and communication technology: e-learning takes an increasing share of the blended learning approach for health and care professional education (Al-Shorbaji N et al, 2015).

Finally, a shift from (sub)-specialty towards "new generalism" will be needed, as multi-morbidity and social inequities have to be addressed.

One can wonder if the next disruptive innovation in health and care professional education will not be in the structure of our universities, passing from a structure based on "faculties" to one based on capacity groups (e.g. "molecular mechanisms and interactions", "communication-transfer-transport", "organisation-leadership-management", "care-relationships" and "systems thinking")?

The second perspective takes into consideration the role of health and care professional education as a potential enabler of disruptive innovation in health care.

From a conceptual point of view, progress in health care delivery depends on a reform across the continuum of health care education, including graduate and post-graduate education and continuing professional development. Therefore, the "systems approach", as described in the third generation of innovations, aims at a fundamental organisational change in health service delivery by professionals, who are using tools and knowledge to manage change both in the care delivery system and in the educational environment. One of the strategies in achieving this is to establish trans-disciplinary professionalisms aimed at improving health outcomes (Cuff PA, 2014).

Currently, there is not enough evidence on the impact of health and care professional education on innovation in health care. Probably, more integrated structures of health and care professional education and service delivery are needed in order to obtain such an impact.

In his book "The Innovators Prescription. A Disruptive Solution for Health Care" (Christensen C, 2008) Christensen deals with a lot of issues that we described in the different generations of disruptive innovations. He documents the need for integration of theoretical scientific basis and practice in patient care, the importance of well-structured learning processes, involving simulated patients before working with real patients and the

need for better organised clerkship programs that use a progressive pathway of learning experiences through the rotations in the different departments. In a very challenging way, he compares the training of a health care provider with assembling a car. The generally applicable principles, for making a car are: activities, that are well defined with a clear go/no-go verification at the conclusion of every activity; connection: avoiding that a part that is not ready, is used in the next step; pathway: sequencing the steps of a series of activities; improvement, in order to achieve perfection every time and never allowing the cause of a problem to persist but change the methods whenever a faulty result occurs so that it cannot happen again. Notwithstanding the fact that Christensen has a point in challenging the efficiency of actual learning processes, one can question the similarity between assembling "cars" and "training students to become professional health care providers". Contrary to the production of "cars", the training of a provider cannot be reduced to a sequence of (for all students) identical activities, as health care requires not only the acquisition of knowledge and skills, but also of attitudes and the development of reflective capacity. Different from a car, a trainee in health profession will learn a lot from the interaction with the trainer and the patient. Christensen predicts that there will be a need for more training of primary care physicians, as increasingly technology, that actually is used in specialist care, will be available in primary care in the future. Christensen is not really using a holistic (eco-bio-psycho-social) concept of medicine, as he describes care as dealing with "disorders": that move from the intuitive toward the precision end of the spectrum of medical practice". He overlooks the complexity of the diagnostic and therapeutic process, as it has to integrate the context and the "goals" of the patient, taking into account the impact of the disorder on functioning and social participation. Paradoxically in his view the specialist doctor is focusing on "intuitive medicine", whereas the primary care doctor, will use the Internet-based decision tools bringing the diagnostic capabilities of the world's best specialist into the offices of general practitioners. Christensen overlooks the important role of primary care providers in the medical decision process, using history taking and clinical examination in order to select appropriate use of technology in a mainly healthy population and avoiding "false positive results". Where Christensen has certainly a point is in the view that much of the work of general practitioners today will be taken over by nurse practitioners physician assistants and medical technicians – suggesting that we need to train more of these and other health professionals.

3.3.5. DISRUPTIVE INNOVATION AND HEALTH PROMOTION

Health Promotion emerged as a dynamic multidisciplinary field within public health in the 1980s, representing *a paradigm change in thinking about health* (WHO, 1986). Health Promotion reframed the challenge of improving population health by seeking to address the question of where is health created and how can the greatest health gain be achieved for the greatest number of people (Kickbusch, 1996). Bringing a focus on promoting population health and well-being shifted the centre of gravity from a deficit model of illness to the health potential of everyday settings, a social model of health replaced a biomedical model, and perspectives from political, environmental and social sciences brought a fresh perspective on addressing health challenges (McQueen & Jones, 2007). This transdisciplinary approach, which embraced a socio-ecological model of health, brought new players and innovative strategies from the non-health sector into the health field. Health promotion seeks to address the broader determinants of health (the 'causes of the causes') and to place empowered citizens at the centre of their own health (WHO, 2005). To achieve a 'health for all approach', health promotion combines diverse and complementary approaches with a shift from more costly biomedical interventions to more integrated socio-environmental and systems-based approaches that can be implemented at a population wide level. These include interventions that will build healthy public policy, create supportive environments for health, strengthen community action to achieve better health, develop personal skills to enable more control over health, and reorient health services beyond clinical and curative services to the pursuit of health promotion (WHO, 1986). A new suite of less costly actions and strategies was identified for improving health. These ranged from the use of public policy mechanisms (e.g., legislation and taxation for tobacco control) to cross-sectoral engagement and organisational change (e.g., in creating health promoting environments in cities, workplaces, and schools), through to the use of new technologies (e.g. the online delivery of behaviour change and health literacy interventions) for improving health.

A successful example of a disruptive innovation for health promotion is the use of tobacco legislation to address the leading preventable causes of mortality and disease. The Minnesota litigation of the 1990s (Minnesota Tobacco Settlement, 1998) was a milestone legal settlement that imposed permanent legal restrictions on the activities of cigarette manufacturers and generated hundreds of millions of dollars annually for Minnesota's treasury to support research and promote tobacco cessation and control measures.

The Minnesota settlement, the fourth largest legal settlement globally, acted as a forerunner for the successful introduction of the first global public health treaty, the WHO Framework Convention on Tobacco Control (WHO, 2003), which was enacted into force on 27 February 2005. The treaty has 168 Signatories, including the European Community, and is one the most widely embraced treaties in UN history. As the first international legal instrument for public health, the WHO FCTC asserts the responsibility and right of governments to protect public health and the right of all people to the highest standard of health. The WHO FCTC represents a paradigm shift in developing a global regulatory framework for implementing public health measures and introduced a suite of innovative strategies for addressing tobacco control including supply, demand and harm reduction strategies (WHO, 2003).

Building on the scientific evidence for the harm caused by tobacco, the WHO FCTC addressed the global threat posed by transnational tobacco advertising, promotion and sponsorship, advocated measures to tackle illicit trade in tobacco, and supported the need for cooperative international action to address these problems. The implementation of the treaty globally has had a significant impact on the public health landscape within a relatively short time period. The treaty has been followed up with the introduction of further legislative mechanisms at local, national and regional levels, including the protection of children and workers from tobacco related harm and the introduction of standardised packaging for tobacco products. Policy measures are being implemented by national governments to support the realisation of tobacco free societies (e.g. Tobacco Free Ireland - Department of Health, 2013). Within the EU, the 2001 Tobacco Products Directives (2001/37/EC) was enacted which regulates the manufacture, sale and protection of tobacco products. A revised Tobacco Products Directive (2014/40/EU) was approved by the European Council on 14th of March 2014, which includes measures on tobacco labelling and packaging, ingredients and emissions, traceability and security features and cross border distance sales of tobacco. This new Directive must be transposed into national law by Member States by 2016.

Through exemplifying how an international regulatory framework can be implemented in response to a global public health threat, i.e., the globalisation of the tobacco epidemic, the WHO FCTC opened a new phase in global health policy and demonstrated the importance of global health governance. This approach has since been further developed through actions on health inequity and the social determinants of health (CSDH, 2008; Rio Political Declaration on Social Determinant of Health, 2011), the Political Declaration

on the Prevention and Control of Non-communicable Diseases (United Nations, 2011) and the WHO Global NCD Action Plan 2013-2020, which provided a menu of policy options and cross-sectoral actions for health equity, health gain and the reduction of premature mortality from non-communicable diseases.

With the realisation that many of the determinants of health and health inequities lie outside of the health sector, the potential health impact on population health of public policies and decisions made in all sectors and at different levels of governance has been brought to the forefront (WHO, 2014). A 'health in all policies approach' is also reflected in the EU health strategy and the WHO Health 2020 European policy framework for health and wellbeing, which call for actions across whole of government and whole of society that will "significantly improve the health and well-being of populations, reduce health inequalities, strengthen public health and ensure people-centred health systems that are universal, equitable, sustainable and of high quality" (WHO, 2012).

The introduction of these new health promotion approaches has brought a transformational change in how population health is understood and the range of mechanisms and strategies that can be used to promote health and well-being and reduce health inequities. An integrated policy approach is now integral to effective action on health promotion, entailing multisectoral action across government, civic society and international organisations. The potential application of this approach is very broad, e.g. in relation to healthy public policy on food, alcohol, housing, environment etc., and calls for the use of new entry points and innovative strategies for health promotion. However, political commitment to implementing such approaches has been lagging in many countries (Barry, 2008), the investment in health promotion typically pales in comparison to the resources and budgets allocated to health care, and further capacity development in implementing evidence-informed actions into routine everyday practice is needed for disruptive innovations in health promotion to reach their full potential (European Observatory on Health Systems and Policies, 2015).

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3.4. IMPLEMENTING DISRUPTIVE INNOVATION

3.4.1. FACTORS THAT TRIGGER DISRUPTIVE INNOVATIONS IN HEALTH SYSTEMS

Factors that trigger disruptive innovation in health care systems can be drivers, enablers or incentives.

Drivers are factors that cause a particular innovation to happen or develop and are commonly due to existing problems, difficulties or inefficiencies.

Enablers are people/things that make the innovation possible. (Table 4)

Table 4. Categories of innovation triggers: drivers and enablers

DRIVERS (implication)	**ENABLERS** (implementation)
Thinking of the health of populations rather than individuals	Using health promotion and disease prevention approaches and effective case management to improve population health and reduce illness and emergencies
Leveraging information and decision-making tools	EPRs: electronic patient records; Cultivating a shared awareness of quality guidelines and evidence-based health interventions
Building connections across a continuum of care from promotion and prevention to treatment and recovery for better chronic disease management	Engaging and incentivizing consumers to take health care out of exam room
Managing the overall cost of care, and not departmental profit and loss	Investing less money in high end technology and more in technologies that simplify common health problems
Experimenting with new models of care and funding of care	Health plan database: integration between medical and insurance databases (Vijayaraghavan et al. 2011)
Establishing a universally accessible high-quality primary health care system for all citizens	Culture: embracing experimentation and organisation-wide learning
Ensuring that everyone has a work role that fully utilises their professional preparation	Promoting systems in which the health care professionals' skill level is matched more closely to the level of the health problem (Christensen et al, 2000)
Health system flexibility to allow new players to emerge and new initiatives	Training with more interprofessional links
Allowing caregivers to focus more efforts on sicker patients (Vijayaraghavan et al, 2011)	Integration of health and social/welfare care

Incentives are factors that motivate or encourage someone to do something. Incentives are an important means of attracting, retaining, motivating, satisfying and improving the performance of health care systems. They can be applied to groups, organisations and individuals. Incentives can be positive or negative (as in disincentives), financial (e.g. research funding programs in Europe) or non-financial (e.g. setting up pilot projects), and tangible or intangible.

By their nature, incentives for disruptive innovation represent a debated policy issue (see section 3.4.4).

3.4.2. BARRIERS TO DISRUPTIVE INNOVATION IMPLEMENTATION

There have been examples of potential disruptive innovations which did not manage to be implemented. Often this can be caused by the presence of people or institutions whose livelihoods might be negatively impacted by the innovation. Disruptive innovations have in some cases been not only ignored, but also object of discrediting actions. In other cases, regulation has hindered the implementation, with the effect of maintaining the status quo. It becomes, therefore, necessary to overcome the potential inertia of regulation. (Christensen et al, 2000)

Different *barriers* have been identified (European Commission, 2011; European Commission, 2014), and are defined as obstacles or hindrances to the implementation of disruptive innovations.

1. **Workforce barriers**

- Opposition: reluctance to change or initial resistance to change (Health Territory Local Agreement, France 2011; Innova Saude, Galicia, Spain 2011); feelings about loss of ownership of the process; change in working practice, change in workload (Tele-monitoring service, Northern Ireland 2011)
- Cultural barriers: cultural identities; workforce silos; the gap between medico-social and sanitary actors (Hearing impairments and low vision regional centre, France); the delimitation of the network partners (Care pathways, Saxon State, Germany 2010); different organisational levels not used to working in collaborative network" (MECASS, Catalunya, Spain, 2013); resistance to change current practice to a proactive preventive system (CARTS, Ireland, 2013)

- Lack of training and motivation: the certainty that a significant amount of workforce development is required, awareness raising perceived as an issue (Tele care Programme, Scotland 2006-2011); lack of tools to share information (on-going support for workforce development, Aging Well programme, Wales, 2012); adaptation period for professionals to interiorize and optimize their new tasks (Integrated chronic disease management, Comunidad Valenciana, Spain)
- Communication between care providers and harmonisation of the care they provided were often inadequate (Networking for Active and Healthy Ageing, Nijmegen, the Netherlands); absence of integrated clinical guidelines (PROFITER, Emilia-Romagna, Italy); need for greater overlap between the responsibilities and roles of nurses ad other professionals (EIP-AHA Reference Site and IRES - Regione Piemonte, Italy)

2. Patients / persons barriers

- Cultural barriers: acceptance of the solution, proper engagement of users in the development of innovative solutions (Innova Saude, Galicia, Spain 2011)
- Lack of training of end-users/strategy towards health literacy
- Mobility support

3. Organisational/institutional barriers/inadequate networks and processes

- Lack of realistic business model
- Procurement process; Incentives (Supporting independent living and home care, Oulu, Finland 2008), reimbursement system (NEXES, Catalunya, Spain)
- Lack of adequate technical analysis and planning
- Lack of managerial support
- Inadequate information systems
- No strategy to decommission services: e.g. opportunity costs not realised (Tele care, Scotland 2006-2011)
- Lack of interoperability between technological solutions (Circles of care, Noord-Brabant, Netherlands, 2009); organisations working with different medical records (MECASS, Catalunya, Spain)
- Difficulty to coordinate different authorities (levels: Local, Regional, National; sectors: Health care, Social care) (Better life for the most sick elderly, Sweden)

- Organisational model of our institutions (hospitals, primary care centres, etc.) mainly based on a traditional "bureaucratic management"-principle with a comment-and-control approach (Anderson RA et al, 2000).

4. Economic and legal barriers

- Investment on infrastructure, technology and maintenance (Tele-monitoring of patients with advanced heart failure, Czech Republic 2013) (Home care technology and human help at home after hospitalisation, France 2013)
- Prices (hepatitis C treatment)
- Economic context (crisis; control costs by consuming less health care)
- Corruption and economic incentives for vested interests
- Lack of retail market
- Regulatory barriers that obstruct the emergence of new professions, products and services
- Reimbursement controls that force high-end providers to become more efficient; and use government money to subsidise the high costs of health care for targeted segments of the population. The reimbursement cuts usually try to force solution shop models with the aim of achieving efficiency without improving health care.
- Payment models: hospital payment models are focus on fee-for-service or case payment (e.g. diagnostic related groups) promoting volume with little consideration for quality of care. These payment models are creating barriers to innovation by rewarding volume, not value for the money spent. Moreover, payers promote health services contractual arrangements with single providers perpetuating the "silo effect" and enhancing fragmentation of care, inhibiting the creation of innovative care delivery models that will likely find new ways of integrate care.

5. Lack of political support

- Lack of political buy-in / leadership (Tele health, UK, Yorkshire & the Humber, 2011)

6. **Lack of evaluation**

- Lack of monitoring and evaluation techniques, tools and methodologies (Diabetological competence centre, Germany 2011) (Tele-monitoring service, Northern Ireland 2011)

3.4.3. ADOPTION AND DIFFUSION OF DISRUPTIVE INNOVATION

There is a body of literature around diffusion of innovation. While there are some general observations, for example the S-shaped diffusion curve with early and late adopters, there are important differences between how different technologies are adopted. One concept used to describe innovations that are quickly adopted is that they are compatible with existing practices. A special interest for disruptive innovation could be to look to what extent the innovation is compatible with existing "value system" or "power structures".

Christensen, analysing the US health scenario, believes that the way disruptive innovation will happen in health care, is in the form of decentralisation. Rather than just innovating diminishing returns on better and better hospital-based treatment mechanisms, innovation will consist in taking equal or even inferior versions of technology that exists in hospitals and moving it outward - to clinics, primary health care facilities and, eventually, the home. A "distributed health service delivery" is now possible due to different types of health service provision innovations (Auerswald P, 2015):

1. Tele health/Remote Medicine & Mobile Health (mHealth): the advent of Internet, personal computing, smart phones, mobile phones, and tablet computers have expanded the possibilities of health promotion and prevention, remote monitoring, diagnostics, and sometimes also treatment. (Auerswald P, 2015)
2. Medical House Calls/Home-based Primary Care: this increase in medical house calls has been determined by reengineering of the organisational process, and optimisation of the transportation. In this model, an interdisciplinary team that plans and supervises the health care activity at the patient's home (Auerswald P, 2015).

3. Health Agency Care/ Peer-to-Peer Health Service Delivery: a reorganisation and simplification of the access to medical knowledge with a new frame of information exchange and knowledge management (Auerswald P, 2015).
4. Big Data: there is a large amount of information that is being gathered, aggregated, and analysed by commonly used technological instruments. The presence of Big Data allows population-based health care (improvement) to become routine (Auerswald P, 2015).
5. Switch from a 'bureaucratic' command-and-control organisational model towards a "Complex Adaptive Systems" approach that values the fact that health care is realised by professionals with a high ethical standard and a need of "professional autonomy" (Anderson RA et al, 2000). This is an important organisational "disruptive innovation", that is a pre-condition for other disruptive innovations to be put into practice. Another advantage of decentralised approaches is the use of small “laboratory sites” to experiment with innovations, before they start to be implemented nationally. Decentralisation of care would enable to operate more efficiently and with less overhead.

More generally, a successful adoption and diffusion of disruptive innovations calls for a cooperation of all partners, organizations, human, technology and a model of partnership is needed to ensure full engagement of all parties (Trachtenberg M et al, 2014).

3.4.4. POLICY ISSUES

There is always a degree of uncertainty when introducing a disruptive innovation. In fact, only after an innovation is implemented, allowing its utilisation by a significant number of users, is it possible to realistically analyse its positive or negative impacts.

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.

Policy makers should analyse how to enhance the enablers and to address the already identified possible barriers for implementing a disruptive innovation within a health

system. It should be noted that while the technological enablers almost always emerge from the laboratories of leading institutions in the industry, this is not so true for business model innovations. In fact, the later tend to be forged by new entrants to the industry. Regulators should, therefore, beware of attempts by the leading institutions to outlaw a business model innovation (Christensen et al, 2003).

Positive disruptive innovations can be seen as interventions in priority or strategic areas. The EXPH Opinion on "Definition and Endorsement of Criteria to identify Priority Areas when Assessing the Performance of Health Systems" (EXPH 2014) highlighted the aspects that should be considered for this assessment. In fact, it is necessary to analyse on one hand, the impact of new policies on Common Values (universality, solidarity, equity, access to high quality and safety services), and the impact on Outcomes (health equity, health risk factors, responsiveness, economic impact) and on the other hand, the Costs of the intervention and the Cost-Effectiveness. (Figure 4). Although Figure 4 refers to all innovations, it can be useful also in the evaluation of disruptive innovations.

When identifying the Areas of introduction of a disruptive innovation, it is necessary to take into consideration the aspects regarding its Projected Impacts, Context and Feasibility:

1. Projected Impacts

   It is necessary to assess the impact that an innovation will have on: common values (universality, solidarity, equity, access to quality and safety services), health and on the economic situation.

   Research should be promoted in this field in order to create scientific knowledge and to continue improvement processes.

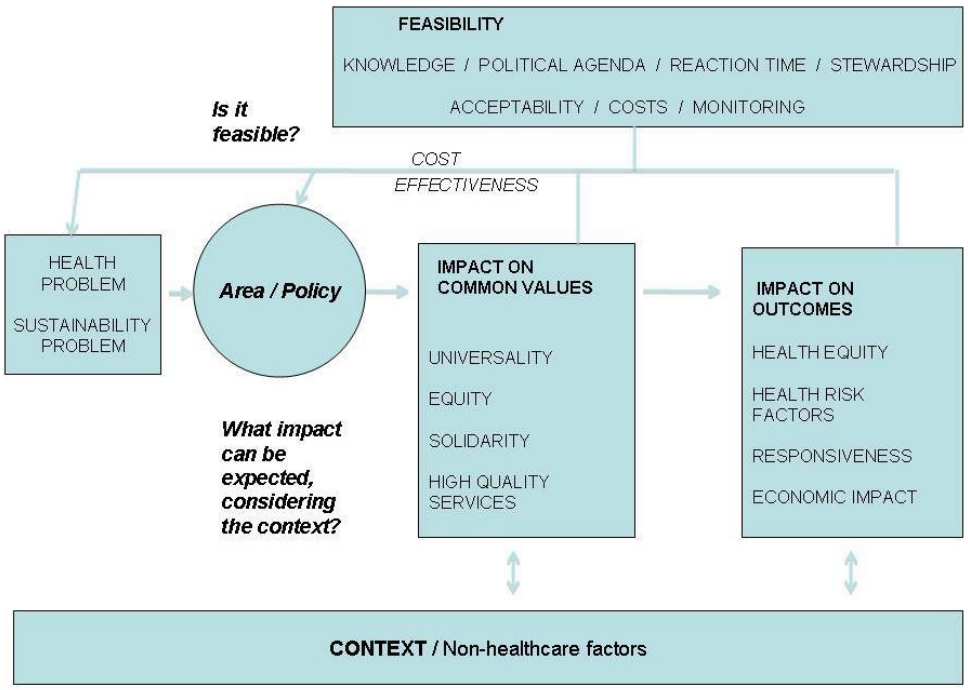
2. Context

   Every innovation takes place within a specific context (socio-economic, cultural, political factors). The context should be taken into account, since it expresses the sphere in which the innovation will act.

3. Feasibility

   To develop positive disruptive innovations, the governments have to ensure feasibility. They must, also, take into account the projected outcomes on health and on the economy. In order to do so, it could be convenient to start with pilot projects.

Figure 4. Elements for selection/prioritisation of policies/interventions



The view of some current governments is that the role of the state in spurring innovation is simply to provide the 'conditions for innovation to flourish' (BIS and HM Treasury, 2011). This is a minimalist view of the state in the field of economic policy: a far more proactive role is required. The role of the state is not only to finance fundamental research but also to develop a vision and an agenda that finances both fundamental and applied research towards this direction (Mazzuccato M, 2013).

It is worth remembering that, in many cases, it was the public and not the private sector that had the vision for strategic change, daring to think - against all odds - about the 'impossible' (i.e. creating a new technological opportunity, making the large necessary investments, and enabling a decentralised network of actors to enable the risky research, and to allow the development and commercialisation process to occur in a dynamic way) (Mazzucato M, 2013).

Two main policy issues that apply to both the public and the private sector are the above-mentioned incentives for (disruptive) innovation and adoption and diffusion of

innovations. The first policy issues involve what economists call incentives for dynamic efficiency.

How do we create incentives for development of valuable new technologies, as well as for new knowledge and new health professions? Are the current incentives in favour of sustaining innovations (especially half way technology) rather than disruptive innovation? Should more research be put into basic understanding of the disease, rather than the development of expensive half way technologies? What is the role of health policy for the direction of innovation? Do reimbursement systems favour half way technologies? What about other health policies?

Similar policy questions could be asked about adaptation and diffusion of technologies, knowledge and health professions. One potential example is issues related to personalised biomedicine; is there a need for a large scale investment in testing, or should this be left to the market for individual decisions? The literature on diffusion of innovations offers a theoretical framework for further discussions. A classic reference on the diffusion of innovations in general is offered by Rogers (1962).

If there are no incentives for adoption and diffusion of a disruptive innovation, this will not happen. Just informing about best practices seldom creates any change, as can be seen by the experience with Health Technology Assessment. The ”solution” that is preached today is to integrate ”innovation” in the daily work but unless proper incentives are put in place it will probably not happen. Furthermore, disruption rarely happens in a “piecemeal” manner, where stand-alone disruptions are plugged into the existing value network of an industry (Christensen et al, 2003).

Cultural change, training and motivation are necessary instruments in adopting an innovation. But the reality is that innovation creates winners and losers, and the losers will be resistant; thus Schumpeter’s concept of ”Creative destruction”. When you destruct someone’s livelihood, there is bound to be resistance. For this reason, it is important to involve the health professions in the process of creation and diffusion of (disruptive) innovations. It would seem that currently in many countries the health professions are still not so much involved in the policy discussion on these issues (Joint Action on Health Workforce Planning and Forecasting, 2015).

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3.5. CASE STUDIES[4]

3.5.1. NEW AND MORE EFFECTIVE TREATMENT FOR HCV

DISRUPTION	New and more effective treatment for HCV[5]
The problem	Hepatitis C is the leading cause of liver cancer and liver transplants and is associated with a variety of other conditions such as diabetes and depression. Hepatitis C currently affects a large number of people, somewhere between 7.3 and 8.8 million persons in the European Union (EASL, 2014) The previous treatments presented limitations due to the fact that many patients were ineligible, and in those eligible for the treatment, the success rate was approximately 50 percent. These treatments also presented a high percentage of drop outs due to the important side effects (depression, nausea, severe anemia, and flu-like symptoms etc.).
The innovation	The new anti-HCV medicines which have entered the market are expected to have cure rates exceeding 95 percent. Furthermore, they seem to be very effective, safe, and without adverse effects.
The disruption	These new treatments have the capacity of completely changing the face of Hepatitis C infection, with a potential to drastically reduce both consequences and incidence of the disease. However, given their elevated price, many patients who may benefit may not have access to these treatments. The disruption will consist in enabling all the people in need to access the medicine by pricing the medicines in relation to the cost (€300).
The benefit	It is expected that the sickness and the number of deaths associated with the disease will be drastically reduced. However, this requires a carefully designed and implemented plan for how treatments should be managed, with the aim to also reduce the risk of re-infection.
Triggers	Drivers: leveraging information and decision making tools. Enablers: reviewing pricing system (patent protection has to be linked to payment by cost plus a reasonable profit). Incentives: Cure for the patient and a better life expectancy.
Adverse effects	Economic and legal barriers. Lack of political support. The difficulty in access of these new drugs for high price reasons can potentially determine an increase in the inequalities of health between different countries and different socio-economic levels.
Cost	A new process of price determination seems to be needed. The price of a new product can fall anywhere between two extremes: on one side, the "average cost" price needed to cover the development costs and reward for innovation; on the other side, the "marginal cost" price that is relevant for decisions about treatment strategies aimed at creating the maximal benefit for patients and health care systems. Disruptive innovation will come when the new drugs are available and affordable for patients and health care systems.

[4] The EXPH underlines that these case studies are used as relevant examples and should be intended as such.

[5] Further readings: CESCR (2000); CESCR (2001); Chan M (2010); Declaration on the TRIPS Agreement and Public Health (Doha Declaration); EASL (2014); European Commission (2009); Hill A et al (2014); Light DW et al (2013); WHO, WTO, WIPO (2013); WTO (2001)

3.5.2. COMMUNITY-BASED MENTAL HEALTH

DISRUPTION	Community-Based Mental Health[6]
The problem	Till the sixties of the XXth Century, in the majority of countries the normal way of responding to severe mental disorders (SMD) was the institutionalisation in a psychiatric hospital (asylum, traditional large psychiatric institutions). These structures were designed as a place to protect the society from the patient, and the patient from himself/others, by way of restraining and isolating the patient (for long periods of time, or for the whole life) Mental Health Disorders are the cause of a high proportion of the Burden of Diseases, and, as a consequence, have a huge negative economic impact society.
The innovation	The community-based model of care determined an entirely new way of dealing with SMD. This new model was made possible by the introduction of psychopharmacology (chlorpromazine, haloperidol, etc.) and of psychotherapies, and the creation in EU countries of social health insurance programmes covering middle and low income population.
The disruption	The new model of care is strongly intertwined with an important cultural change. This changed witnessed a shift from a culture in which the patient and/or the family are perceived as "guilty" for having a mental disorder and as a risk for society, to a culture that considers the patient as a person with a problem that needs help, and the family as a necessary aid in solving the problem. Furthermore, this has allowed the idea that mental health disorders can be prevented and treated, permitting the recovery of autonomy and of the abilities to live a satisfactory life. In the new vision, the patient is no longer considered a person unable to decide, but a partner in the discussion of the therapeutic plan. The family participates also in the analysis of the problem and better ways to deal with it.
The benefit	Today, with proper care, most mental health problems can be cured or significantly improved; most people affected by mental health problems can regain autonomy, ability to maintain satisfactory relationships, productive work, study activities and capacity for enjoyment.
Triggers	Drivers: Building connections across continuum of care for better chronic disease management. Health System flexibility to allow new players to emerge. Enablers: Engaging and incentivizing patients to manage their processes in outpatient settings. Integration of health and social care. Social health insurance. Psychopharmacology. Incentives: Improving autonomy and capacity to live a productive and satisfactory life. Saving costs.
Adverse effects	Workforce. Economic and legal barriers. Sometimes the focus has been deinstitutionalisation as a way to save hospitalisation costs. Other times, when there have not been developed community Networks, the patients have been abandoned as homeless and many times have ended in prison. In other countries, the reforms have been reverted as a consequence of budgetary restrictions (it is necessary some investment before closing hospital beds, etc.), or resistance from the health professionals, and the old
Cost	This approach, when developed correctly, can decrease the costs that society spends in treatments and hospitalisation, is more cost-effective, and increases the contribution of these persons to the economy and the wealth of the society (Golberg, 1991).

[6] Further readings: European Commission (2005); WHO - The European Mental Health Action Plan (2013); Hang H et al (1999); Caldas de Almeida JM et al (2011); Lamata F (2014); Stubnya G et al (2010); Conway M et al (1994); Bond et al (2001); Seikkula J et al (2006); Golberg D (1991).

3.5.3. POPULATION BASED ACCOUNTABLE ORGANISATIONS

DISRUPTION	Population based accountable organisations[7]
The problem	The problem of failure to engage doctors in taking responsibility for resources has evolved as a result of medical specialisation in that there is now a very sharp distinction between generalists and specialists and increasingly a distinction between specialists and super-specialists. Except for those conditions in which a 100% of people reach the appropriate specialist service, the providers of specialist services have no idea if they are seeing the people who benefit most and very few of them even monitor variations in referral from generalists, family medicine doctors or general practitioners. There is thus no assurance that people most in need are being seen or that the knowledge of the specialists is being used to best effect. Furthermore, because of the funding arrangements in most countries the primary loyalty of specialists tends to be to their employing institution.
The innovation	To introduce population based accountable care organisations. These are organisations of interdependent components that work together to try to accomplish a specific aim, defined by a common need in a population, which may be a symptom such as depression, a condition such as arthritis, asthma or incontinence, or a common characteristics such as frailty in old age. There are about a hundred such problems and at present we have no means of addressing them systematically. By developing Population Based Accountable Systems, that are accountable to the population served as well as to the payers, clinicians start to work collaboratively and make the best use of resources. In addition, the specialists start to use their knowledge to help all those in the population that are affected and not just those who are referred.
The disruption	The disruption is to maximise value and equity by focusing not on institutions, specialties or technologies, but on populations. With a financial system, clinicians start to think of all the people in need and how that need can best be met with the available resources. In every country it is clear that articulate and wealthy people make more use of health services than inarticulate or deprived groups of the population. However, by taking a population based approach clinicians have a completely different orientation.
The benefit	Resources are used optimally but those who benefit most have been referred to the specialist service and the knowledge of specialists has been made available to all the people. By adopting a population based approach and producing annual reports to a defined population system, specification of overuse and underuse can be identified. Overuse often represents a lower value activity while underuse represents problems of inequity.
Triggers	Drivers: The scarce economic resources forced the system to adapt and build connections across continuum of care for better chronic disease management. Enablers: the main enablers are knowledge sharing tools and tools that permit to aggregate people that are far apart. Incentives: empowerment of the patient in the care process and cost saving
Adverse effects	No adverse effects have been reported from this approach.
Cost	Some costs need to be found for a clinician who will act as coordinator of the network that will deliver the population based system. The clinician should be supported by a programme manager, ideally a librarian, who can manage the knowledge. However, these costs can be met within the existing budgets.

[7] Further readings: Kohn LT (2000); Nelson et al (2007); Dennis P (2007)

3.5.4. ANTI-ULCER DRUGS

DISRUPTION	Anti-ulcer drugs[8]
The problem	The key policy issues initially were price and use outside of the indications studied in the pivotal clinical trials. Price was an issue, since it was more expensive than available, less effective medications, such as anti-acids. High price, combined with use outside studied indications, triggered a policy discussion about how to manage the use of the new drugs.
The innovation	The diagnosis and treatment of duodenal and gastric ulcers has advanced significantly from intuitive to precision medicine. From intuitive medicine where diseases are poorly understood and treatments are often trial and error (before this discovery ulcers were treated with recommendations for lifestyle change, dietary changes and occasionally hospital care and surgery), to precision medicine where it is well known that a specific treatment works well and clear rules can be written to specify appropriate care. The development came from an improved understanding of the causes and mechanisms of the disease (the discovery of the role of helicobacter pylori as a leading cause of bleeding stomach ulcers in the 1980s), combined with a thorough development process to provide evidence of effectiveness.
The disruption	They fulfil four important criteria for a disruptive technology: they replaced other technologies (hospital technologies, mainly surgical operations for stomach and duodenal ulcers); the transfer of treatment from hospital to ambulatory care and self-medication; they empower the patient; they are available at a low cost after patent expiration.
The benefit	They provided primary care physicians with an effective technology to treat a common problem, and also empowered patients to self-medicate on demand. The drugs are now available over the counter at low cost.
Triggers	Drivers: Managing overall cost of care, and not departmental profit and loss; Enablers: self-management using effective case management to reduce illness and emergencies; Incentives: reducing pain and complication as well as saving costs form hospitalisation
Adverse effects	The health care system, with the exception of the gastroenterologists, was rather unprepared for this technology. The potential to use the health care system more proactively in development of evidence was not used to any greater degree.
Cost	This innovation offers significant opportunities for cost savings, both in terms of direct health care and reduced loss of production.

[8] Further readings: Christensen CM, Grossman JH, Hwang J (2008); 53. Rapoport J et al (2011)

3.5.5. DIABETIC PATIENT SELF-MANAGEMENT

DISRUPTION	Diabetic patient self-management made possible by the introduction of technology for self-monitoring of blood sugar levels.[9]
The problem	The problem was to obtain an optimal glycaemic control in all the diabetic patients without overstressing the health care system and the patient.
The innovation	The possibility to shift to a facilitated network business model thanks to new portable equipment for monitoring and treatment such as insulin for auto injection and monitoring devices that are of very simple use. The education of the patient allowed a greater understanding of the sickness and of how to avoid its complications, such as coma and other acute episodes. Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes. The National Standards for DSME are designed to define quality diabetes self-management education and to assist diabetes educators in a variety of settings to provide evidence-based education. Because of the dynamic nature of health care and diabetes-related research, these Standards are reviewed and revised approximately every 5 years by key organisations and federal agencies within the diabetes education community.
The disruption	Shift the glycaemic control to the patient thanks to the education received, while the new portable diagnostic kit and auto inject therapy enables patients to monitor and auto-regulate the treatment without a medical intervention. The medical intervention shifted from treating the patient to monitoring the overall trend of the treatment.
The benefit	The potential benefit of reductions in long-term complications from diabetes. Reduced cost of complications for the health system, more frequent monitoring, treatment that is more precise and improved patient autonomy. The costs for the entire system are reduced as well thanks to the fact that patients do not need to see a doctor for frequent consultation. This has an economic impact on the health system but also on the labour cost of the patient and his relatives.
Triggers	Drivers: empowerment of the patient due to the knowledge transfer from the specialist to the patient. Ability to experiment new models of care and funding of care. Enablers: new portable equipment for monitoring and treatment. Incentives: better life style and a prolonged life expectancy.
Adverse effects	Hypo-educated patient can risk wrong dosage with relative acute risk for the patients. Difficulties to detect suboptimal compliance. Unequal distribution of health providers between urban and rural areas.
Cost	Significant cost savings in terms of reduced hospitalisation, ambulatory visit, first aid overload and emergency room use. On the other hand test sticks sometimes are a very costly item in the reimbursement system. Even though cost savings that derive from the better glycaemic control comes at a relatively low price, the benefits that derive from the glycaemic control are both uncertain and often far in the future.

[9] Further readings: Ahola AJ et al (2013); Lindenmeyer A et al (2010); Kousoulis AA et al (2014); Shrivastava SR et al (2013).

3.5.6. MINIMAL INVASIVE SURGERY

DISRUPTION	Minimal invasive surgery[10]
The problem	To reduce the impact of the operation and long term consequences on the patient without reducing its efficacy. Better aesthetic results after surgery. Not having the skills to perform new procedures.
The innovation	The innovation is to access the operation site through physiological routes such as the intestine (endoscopy technique) or through the vessels (vascular surgery or cardiologic operations). These types of techniques are very useful since they use a small access through which it is possible to reach an internal area of the body. The field of minimally invasive surgery (MIS) in neonates and infants is a relatively new field, which has evolved over the last 20 years. This has required the development of not only new techniques but also of new instruments. The process has resulted in a unique partnership between paediatric minimally invasive surgeons and industry, as both groups have struggled to find the right mix of need, technical viability, and economic sustainability.
The disruption	New patients were included in the "market". In fact, given the minimal impact of the surgery, these techniques made it possible to operate also patients who were inoperable due to their physical conditions, and patients whose pathology was still in the early stages. Decrease burden of treatment. The technique started on this type of patients (lower end of the market) and slowly disrupted the previous gold standard operations such as open chest or open abdomen surgery. New professional roles. Skills for those undertaking traditional open interventions were made redundant. Decentralisation of post-surgery care Shorter length of stay, and options for day care surgery, made it possible to develop new organisational forms, such as free standing surgical centres. Reduced the need for surgical hospital beds, which in some systems was a bottleneck for expansion of the volume of surgery.
The benefit	Less impact on the body of the patient with better aesthetic results; less hospital staying; faster recovery for the patient and easier process of rehabilitation; chance to reach area that were not easy to access before
Triggers	Drivers: Ability to experiment new models of care and funding of care. Enablers: New technologies and tools that derive from a completely new vision of the entire surgical procedure. Promote systems in which the health care professionals' skill level is more closely matched to the level of the medical problem. Incentives: Faster recovery for the patient and the possibility to reach areas that were not easy to access before.
Adverse effects	Surgeon learning curve and side effects related to it. Risk of a decrease of appropriateness of treatment. Limited market regulation on the new surgical devices with a possible increased risk for the patient. Quality registers were introduced to control the introduction.
Cost	High cost in the beginning (e.g. training to develop competences and skills) due to the high research cost for new materials and tools. Costs were shifted from follow-up care to surgery due to the need to initial investments in new equipment, and for training.

[10] Further readings: Banta HD, Schersten T, Jonsson E (1993); Banta HD, Vondeling H (1993); Michaelis L et al (2004); Ziegler MM (2009).

3.5.7. PATIENT-CENTRED CARE

DISRUPTION	Patient-centred care[11]
The problem	The problem that we face is great inefficiency because services are increasingly specialised and fragmented with the workforce becoming increasingly part time or shift working. As a result, the care of people (particularly people with multiple morbidity) becomes disorganised, expensive, poorly coordinated and ineffective. Numerous attempts are made to tackle this by bureaucratic integration of services and jurisdictions. The disruptive innovation is to put the patient at the centre of care.
The innovation	The innovation is to put the patient at the centre of care and to let the patient hold the records. In fact, all communications should be sent to the patient with copies to clinicians, rather than the other way around. There may be exceptions to this, for example giving very bad news such as the diagnosis of cancer but these are rare. Even patients who are suffering from frailty with Alzheimer's disease should be put at the centre and if necessary given a tablet. Very often such patients are receiving home visits from four or more professionals, none of whom know what the others are doing, and are involved with different specialist departments, that again are unaware of what is being done in the other departments.
Disruption	The disruption is a complete reversal of the current position in which the health service is at the centre of record keeping and coordination with the patient and their carers struggling to make sense of the disconnected services. An increasingly important opportunity is offered by the widespread availability of digital communication with Cloud Computing being the mainspring for this initiative.
The benefits	The principal benefit is that resourceful patients are engaged in their care process and that all the information is collected in the one place (the patient). This way, all the clinicians of the different departments, who are accustomed to seeing only a part of the whole, can now see the whole picture. There is also the possibility of dramatically reducing what has been called the burden of treatment namely the burden borne by patients and their carers because of disconnected care.
Triggers	Drivers: Leveraging information and decision-making tools, including electronic medical records. Enablers: Engaging and incentivizing consumers to take health care out of exam room. Incentives: empowerment of the patient in the care process and cost saving
Adverse effects	There has been concern expressed about data being made available on the Internet. It is true that there is a very small proportion of patients whose information is of interest to newspapers and other media. Their rights are to be protected and it is possible to do this. However, because this group has been the paradigm taken as a basis for all information technology design, this overlooks the fact that the great majority of patients and carers are suffering greatly because a number of different services are each having their own protected communications with patients, often on paper which is of course just as vulnerable as digital means of communication. For the great majority of patients therefore many risks of digitally delivered knowledge are becoming widespread and are more than offset by the benefits.
Cost	This innovation offers significant opportunities for cost saving.

[11] Further readings: Anderson R (2001); Stewart M (2001); Harlan KM (2010); Nutting PA et al (2009); Hoff T (2010).

3.5.8. THE SWEDISH REHABILITATION GUARANTEE

DISRUPTION	The Swedish Rehabilitation Guarantee[12]
The problem	Chronic diseases are major reasons behind high levels of sick listing and early retirement. Resources for rehabilitation are scarce and existing programs are not sufficient to cover the need. In addition, it is unclear what the effects and cost-effectiveness are for these programs.
The innovation	A Swedish national programme (the Rehabilitation Guarantee, SRG), provide cognitive behavioural therapy (CBT) to patients with light or moderate mental and behavioural disorders, and multimodal (team of different professions) rehabilitation (MMR) for patients with musculoskeletal-related pain in the back, neck and shoulders, or with generalised pain, for example fibromyalgia. The programme was introduced in 2008 with the purpose to prevent sickness absence and to increase return to work among patients with these diagnoses.
Disruption	The SRG provides a new way of delivering and paying for rehabilitation services. This stimulated the development of new models for delivery of patient centred and cost-effective services. In one region, the expansion of the services was combined with an extensive follow up of effects and cost-effectiveness.
The benefits	Access to rehabilitation services increased, and patients were also empowered through the opportunity to select the provider of the rehabilitation services. The continuous evaluation of the program through collection of real life data on outcome made it possible to provide evidence of improvement of outcome.
Triggers	Drivers: Government funding and evaluation. Enablers: Local responsibility for organisation of the services. Incentives: Pay for performance and data reporting
Adverse effects	One of the programs (MMR) turned out to be costly and deliver only small benefits in terms of reduce sick listing, which illustrate the problem of selecting the right programs to support and the need for collection of follow up data for evaluation.
Cost	The total program costs were considerable, but small in relation to the costs for the health care and social security system of the diseases. While no formal cost-benefit study has been undertaken, evidence supports the conclusion that the CBT program has been a cost-effective investment.

[12] Further readings: Inspektionen för Socialförsäkringen (ISF) Rehabiliteringsgarantins effecter på hälsa och sjukfrånvaro. Rapport 2014:12

3.6. CONCLUSIONS AND POLICY RECOMMENDATIONS

Disruptive innovations, as can be concluded from the entire document, can be an important instrument in European policies. Disruptive innovations often provide a new and different perspective of things, a perspective that tends to reduce complexity in favour of the empowerment of the citizen/patient. Disruptive innovations should, thus, be seen by policy makers as possible new methods of dealing with old issues.

As for sustaining innovations, beyond a certain level they are no longer perceived by the community as presenting an added value, and therefore do not determine higher levels of interest. Disruptive innovations, instead, start by catering to the lower range of the population and subsequently interest the whole population, triggering the process of disruption. As a consequence, disruptive innovations tend to be widely accepted and shared by the population.

Of course, considering the structures that are present in communities, there will be some barriers in the adaption and diffusion of these innovations. In fact, these barriers and bottlenecks (e.g. juridical, economical, financial, etc.) can prevent the positive effects of the disruptive innovation from reaching the health of all European citizens.

When analysing barriers and drivers for the adoption and diffusion of disruptive innovations some elements were identified and should be considered.

- Political support (considering the political agenda, reaction time, acceptability, etc.)
- Appropriate knowledge of the innovation
- Legislation framework
- Financial resources and appropriate incentives
- Appropriate business model, initial costs and investment
- Payment systems (what is not paid for can usually not be done; payments send signals to innovators what types of innovations that are profitable to invest in)
- Training and motivation of the involved people
- Literate and empowered patients in the prevention and self-management of chronic conditions
- Training and motivation of health professionals
- Information Systems
- Managerial support
- Monitoring

STRATEGIC AREAS FOR DISRUPTIVE INNOVATION

Each Member State is developing its own process of change, from a different background. In fact, there are different situations depending on the starting point. Some of the following strategic areas have been fully developed in some countries, but other countries could benefit from developing these strategic areas in a way that is adapted to their needs and contexts.

Therefore, 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.

To develop positive disruptive innovations, the Governments have to consider the context, ensure feasibility and anticipate probable impacts.

Throughout the Opinion, different examples have been mentioned. Although the situation of each MS is different, there are certain areas than seems to have the potential to obtain positive results if appropriately approached.

- Person-centred care
- Complex Adaptative System approach; clinical governance; leadership for high value care in clinical practice
- Tele-Health, remote medicine, mobile health
- Electronic health records (available but still not enough supported); universal computable EHR
- Big-data utilisation in the care of patients and the management of Health Systems
- Community based mental health
- Systems of pricing new medicines; affordable access to new medicines
- Population based accountable organisations; chronic disease management; systems enabling continuous care; coordination between social and health systems
- Early palliative care
- Waste reduction in clinical processes
- Tobacco control strategy
- Research on disruptive innovation:
  - MS and EU should stimulate the development of research focusing on "disruptive innovation", both in basic and applied research, and in research that focuses on health promotion and on the education of health professionals.

- MS and EU should invest more in research at the "right" spectrum of the Dzau continuum of translational research. This means implementation in the community, contribution to global health, overcoming bottlenecks and barriers.
- MS and EU should invest in trans-disciplinary education and research at a pan-European level, supporting the development of health and social innovation labs where end-users such as health professionals, managers, service users and citizens participate in the co-design of disruptive innovation development and implementation.
- MS and EU should take into account the future challenges of the demographical and epidemiological transition stimulating research in multi-morbidity and person-centred care is of utmost importance, looking for ways to put the goals of the patient at the centre of the care delivery.
- MS and EU should be informed on possibilities to improve the care working in decentralised communities, better stimulating them towards innovation
- MS and EU should support the creation of "laboratories" for innovation, that study ways to include disruptive innovations at the level of primary, secondary and tertiary care.

All of these fields and all the innovations, including disruptive innovations, should ultimately contribute to the goals of the health system and, therefore, be evaluated in this context.

Health systems should be responsive to innovations and allow promising disruptive innovations to be tested, evaluated, and implemented. This requires the presence of responsive and open-minded systems, professionals, payers, etc.

Policy makers should also consider the importance of exploring new models of commissioning and financing for health services in the context of expanding some clinical roles to certain health professionals (e.g. nurses and pharmacists) when those tasks and services are increasingly being assigned to them.

Policy makers should keep in mind that there is no one-size-fits-all solution for facilitating, monitoring, managing and stimulating the adoption of disruptive innovations. The appropriate policy actions need to be based on evidence, and not hopes. Elements such as the potential costs and benefits of the disruptive innovations, the potential costs and benefits of transformation, the reversibility of choices, the type of barriers to be overcome, and the aspects of uncertainty should guide the policy-making process. This

can also help to quantify (the main sources of) uncertainty and reduce them over time (e.g. through registries, outcome measurement, etc.). Finally, disruptiveness means that vested interests are bound to be hurt. This should be recognised and the eventual presence of a 'veto power' towards the positive change should be overcome. Policy (rigidness), which might represent the fear of losing control, can be one of these interests.

"*You cannot discover new oceans unless you have the courage to lose sight of the shore*".

4. PUBLIC CONSULTATION

A public consultation on this opinion took place via the website of the Expert Panel on Effective Ways of Investing in Health (EXPH) from 30 October to 16 December 2015. Information about the public consultation was widely communicated to national authorities, international organisations and other stakeholders.

Twenty four organisations and one individual person participated in the public consultation providing input to the opinion. Out of the 24 organisations participating in the consultation, there were 3 public authorities, 3 universities/research institutions, 8 NGOs, 4 companies and 6 other.

Each submission was carefully considered by the Working Group and the EXPH and the scientific opinion has been revised to take account of relevant comments wherever appropriate. The list of references has been updated with relevant publications submitted during the consultation.

All contributions received and the reactions of the EXPH are available at http://ec.europa.eu/health/expert_panel/consultations/docs/2016_results_disruptive_innovation_en.pdf.

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LIST OF ABBREVIATIONS

ACE inhibitor	Angiotensin-Converting-Enzyme inhibitor
ARV drugs	AntiRetroViral drugs
BIS	Ministerial department for Business, Innovation and Skills (UK)
CARTS programme	Community Assessment of Risk and Treatment Strategies programme (Ireland)
CBT	Cognitive Behavioural Therapy
CESCR	Committee on Economic, Social and Cultural Rights
CHD	Coronary Heart Disease
CSDH	Commission on Social Determinants of Health
DNA	DeoxyriboNucleic Acid
DSME	Diabetes Self-Management Education
EASL	European Association for the Study of the Liver
EHR	Electronic Health Records
EIP-AHA	European Innovation Partnership on Active and Healthy Ageing
EPR	Electronic Patient Records
EU	European Union
EXPH	Expert Panel on effective ways of investing in Health
GCSA	Global Consensus for Social Accountability
HCV	Hepatitis C Virus
HM Treasury	Economic and finance ministry (UK)
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
IRES	Istituto di Ricerche Economico Sociali del Piemonte

IT	Information Technology
MECASS project	Collaborative model between health and social care project
mHealth	Mobile health
MIS	Minimally Invasive Surgery
MMR	MultiModal Rehabilitation (Sweden)
mRNA	messenger Ribonucleic acid
MS	Member States
NCD	Non Communicable Diseases
NEXES project	Supporting Healthier and Independent Living for Chronic Patients and Elderly project
PDCA cycle	Plan–Do–Check–Act cycle
PROFITER project	Prevention of falls initiative in Emilia-Romagna project (Italy)
SMD	Severe Mental Disorders
SRG programme	Swedish Rehabilitation Guarantee programme
TRIPS agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United kingdom
UN	United Nations
US	United States
WHO	World Health Organisation
WHO FCTC	WHO Framework Convention on Tobacco Control
WTO	World Trade Organisation
WIPO	World Intellectual Property Organisation

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Further resources

- AMA comments to House Energy & Commerce on revised draft "21st Century Cures Act," May 8, 2015
- AMA comments to House Energy & Commerce on initial draft "21st Century Cures Act," February 23, 2015
- AMA statement to Energy and Commerce re: 21st Century Cures: A Modernized Framework for Innovative Diagnostic Tests, January 5, 2015
- AMA letter to Energy and Commerce in response to its request for feedback on the 21st Century Cures initiative, September 26, 2014
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GLOSSARY

APPROPRIATENESS: how the treatment corresponds to the needs of the patient (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies).

BUSINESS MODEL: an interdependent system composed of four components: the value proposition (a product or service that helps customers do more effectively, conveniently, and affordably a job they've been trying to do), processes (ways of working together to address recurrent tasks in a consistent way: training, development, manufacturing, budgeting, planning, etc.), resources (people, technology, products, facilities, equipment, brands, and cash that are required to deliver this value proposition to the targeted customers), the profit formula (assets and fixed cost structure and the margins and velocity required to cover them (Ref. Christensen CM, Grossman JH, Hwang J. 2008. The Innovator's Prescription: A Disruptive Solution for Health Care. McGraw-Hill).

CENTEREDNESS (patient-centeredness or patient responsiveness): consideration of individual patients' and society's preferences and values (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies).

DISRUPTIVE INNOVATION in health care: that creates new networks and new organisations based on a new set of values, involving new players, which makes it possible to health improve outcomes and other valuable goals, such as equity and efficiency. This innovation displaces older systems and ways of doing things (Ref. Expert Panel on effective ways of investing in Health. 2015. Disruptive Innovation. Considerations for health and health care in Europe).

EMPOWERMENT: in health promotion, empowerment is a process through which people gain greater control over decisions and actions affecting their health (Ref. The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/).

EVIDENCE-BASED MEDICINE: integration of best research evidence with clinical expertise and patient values (Ref. Sackett D et al. 2000. Evidence-Based Medicine: How to Practice and Teach EBM, 2nd edition. Churchill Livingstone, Edinburgh).

FACILITATED NETWORKS: type of business model that comprises institutions that operate systems in which customers buy and sell, and deliver and receive things from other participants (Ref. Christensen CM, Grossman JH, Hwang J. 2008. The Innovator's Prescription: A Disruptive Solution for Health Care. McGraw-Hill).

HEALTH EDUCATION: - communication activity aimed at enhancing positive health and preventing or diminishing ill-health in individuals and groups, through influencing the beliefs, attitudes, and behaviour of individuals and community. These influences comprise formal and informal education in the family, in the school and in society at large, as well as in the special context of health service activities (Ref. Downie RS, Tannahill C., Tannahill A. 1996. Health Promotion. Models and Values. 2nd edition. Oxford University Press).

HEALTH TECHNOLOGY ASSESSMENT (HTA): a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology (Ref. INAHTA - International Network of Agencies for Health Technology Assessment, HTA Resources. 2009).

INNOVATION: - In its broadest sense, innovation refers to positive change through the application of specialised knowledge in a creative manner to solve a problem (Dewar and Dutton, 1986; Dougherty, 1990; Gilmartin, 1998). Innovation is dynamic, multidimensional, time dependent and is influenced by external market conditions and organisational characteristics (Ref.Davies H.T.O., Tavakoli M., Malek M. 2001. Quality in Health Care. Strategic issues in health care management. Ashgate Publishing Ltd.).

- Research that incrementally advances an existing field. By discovery we refer to research that potentially transforms a field or conceivably establishes a new field of practice (Ref. Platt, A.C. et al. 2008. Commercialisation: a perspective. Surgery 143;157-161).

- An innovation is an idea, practice, or object that is perceived as new by an individual or other unit of adoption (Ref. Rogers, E.M. (1995). Diffusion of Innovation (Fourth edition). The Free Press).

- Ensuring that clinically and cost effective innovation in medicines and medical technologies is adopted. We will strengthen the horizon scanning process for new medicines in development, involving industry systematically to support better forward planning and develop ways to measure uptake. For new medical technologies, we will simplify the pathway by which they pass from development into wider use, and develop ways to benchmark and monitor uptake (Ref. Secretary of State for Health. 2008. High Quality Care for All. NHS Next Stage Review Final Report. CM 7432. Crown Copyright).

- Innovation is the first, practical, concrete implementation of an idea done in a way that brings broad-based, extrinsic recognition to an individual or organisation (Ref. Plsek, P.E. 1997. Creativity, Innovation, and Quality. ASQ Quality Press).

- Innovation is the successful exploitation of new ideas (Ref. Stern, N. 2007. The Economics of Climate Change, p.395).

- Innovation is the successful exploitation of new ideas. Four types of innovation in relation to technological change can be identified:

1. Continuous innovations represent the improvements of existing products, as has occurred with car engines;

2. Discontinuous innovations are new inventions that lead to a significant departure from previous production methods, such as hybrid cars;

3. Changes in the technological systems occur at the system level when a cluster or innovations impact on several branches of the economy, as would take place in a shift to a low-emission economy;

4. Changes of techno-economic paradigm occur when technology change impacts on every other branch of the economy, the internet is an example. (Freeman, 1992).

- Joseph Schumpeter identified three stages of the innovation process: invention as the first practical demonstration of an idea; innovation as the first commercial application;

and diffusion as the spreading of the technology or process throughout the market. (Schumpeter, 1942).

- The introduction of a new good – that is, one with which consumers are not yet familiar – or of a new quality of a good.

• The introduction of a new method of production, that is, one not yet tested by experience in the branch of manufacture concerned.

• The opening of a new market, that is, a market into which the particular branch of manufacture of the country in question has not previously entered, whether or not this marked has existed before.

• The conquest of a new source of supply of raw materials or half-manufactured goods, again irrespective of whether this source already exists or whether it has first to be created.

• The carrying out of the new organisation of any industry, like the creation of a monopoly position (for example through trustification) or the breaking up of a monopoly position (Ref. McCraw, T.K. 2007. Prophet of Innovation. Joseph Schumpeter and Creative Destruction. The Belknap Press of Harvard University Press, p.73).

- The process of translating ideas into useful – and used – new products, processes or services (Ref. Bessant J, Tidd J. 2007. Innovation and Entrepreneurship John Wiley & Sons Ltd, p.28).

- Invention is not the same as innovation (Ref. Brown T. 2009. Change By Design: How Design Thinking Transforms Organisations and Inspires Innovation. HarperCollins Publishers, p.164).

OUTCOME (health): A change in the health status of an individual, group or population which is attributable to a planned intervention or series of interventions, regardless of whether such an intervention was intended to change health status (Ref. The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/).

POLICY (health): A formal statement or procedure within institutions (notably government) which defines priorities and the parameters for action in response to health needs, available resources and other political pressures (Ref. The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/).

POPULATION HEALTH CARE: focuses primarily on populations defined by a common need which may be a symptom such as breathlessness, a condition such as arthritis or a common characteristic such as frailty in old age, not on institutions, or specialties or technologies. Its aim is to maximise value and equity for those populations and the individuals within them (Ref. NHS Right Care Glossary. 2015).

RELEVANCE: it refers to the optimal overall pattern and balance of services that could be achieved, taking into account the needs and wants of the population as a whole (Ref. Maxwell, R. 1992. Dimensions of quality revisited: from thought to action. Quality in Health Care, (1):171–177).

SOLUTION SHOPS: institutions structured to diagnose and recommend solutions to unstructured problems. Certain consulting firms, advertising agencies, research and development organisations, and many law practices are examples of solution shops (Ref. Christensen CM, Grossman JH, Hwang J. 2008. The Innovator's Prescription: A Disruptive Solution for Health Care. McGraw-Hill).

SYSTEM: a set of activities with a common set of objectives with an annual report. Most of health care is the opposite of a system – i.e. it is the random movement of patients, professionals, blood samples and reports, or to use a biological term: Brownian Movement (Ref. NHS Right Care Glossary. 2015).

TRANSLATIONAL RESEARCH: effective translation of the new knowledge, mechanisms, and techniques generated by advances in basic science research into new approaches for prevention, diagnosis, and treatment of disease, essential for improving health (Ref. Woolf SH. 2008. The Meaning of Translational Research and Why It Matters. JAMA. 299(2):211-213).

VALUE: value is expressed as what we gain relative to what we give up – the benefit relative to the cost (Ref. NHS Right Care Glossary. 2015).

We can distinguish three types of value:

- **ALLOCATIVE VALUE**: called allocative efficiency by economists, determined by how well the assets are distributed to different sub groups in the population.
- **TECHNICAL VALUE**: determined by how well resources are used for all the people in need in the population, measured by the relationship between outcomes and costs, and costs are not only financial they may be carbon costs, or the time of clinicians and patients.
- **PERSONALISED VALUE**: determined by how well the decisions relate to the values of each individual.

VALUE-ADDING PROCESS BUSINESSES: type of business models that transforms inputs of resources—people, materials, energy, equipment, information, and capital—into outputs of higher value (Ref. Christensen CM, Grossman JH, Hwang J. 2008. The Innovator's Prescription: A Disruptive Solution for Health Care. McGraw-Hill).

WASTE: anything that does not present an added value (Ref. Academy of Medical Royal Colleges. Protecting resources, promoting value: a doctor's guide to cutting waste in clinical care. 2014).

ANNEX 1. TAXONOMIC TREE OF DISRUPTIVE INNOVATIONS

In this opinion, in which disruptive innovations are conceptualised as complex and multi-dimensional, we have identified five levels of hierarchical classification of disruptive innovations: typology of business model, fluency of implementation, health purposes, fields of application and pivoting values (Figure A).

The hierarchical classification of the taxonomic tree is explained below.

- **The typology of business model** level indicates the characteristics of a business model, through which we can distinguish three different typologies: solution shops, value-adding process businesses and facilitated networks.

  - *Solutions Shops* are businesses that address unstructured problems in order to reach their diagnosis and/or solution. Solution shops deliver value mainly through the intuition and analytical and problem-solving skills of the employee-expert. Almost always their payments are in the form of fee for service. Example: specialist physicians' visits.

  - *Value-Adding Process Businesses* are business models that take inputs of resources – people, materials, energy, equipment, information and capital - and then transform them into outputs of higher value. Their payments are usually based on the delivery of the output and most of them even guarantee the result. Example: eye surgery centres, orthopaedic hospitals.

  - *Facilitated Networks* are enterprises that connect people together via a platform through which the same people buy and sell, and deliver and receive information/experience/objects from each other. Health care facilitated network business models can be structured to benefit from maintaining people in the best possible health status. Their payments are typically through membership or transaction-based fees. Example: internet based patient networks for behaviour-dependent chronic diseases.

  They are business models that take inputs of resources and then transform them into outputs of higher value, in the context of a Government-run health system. They may involve mandatory reference networks of providers (e.g. access to specialist only after seeing a general practitioner). Their payments are usually defined centrally, either by budget allocation, by negotiation or by internal contract to the public sector.

Human resources management, procurement rules and possibility of failure and closure differ from private sector. The European health care systems can be characterised as "facilitated networks by providing relevant contracts and reimbursement. It can also manage "solution shops" and "value adding process business" in a more efficient way.

- **The fluency of implementation** level describes the ease with which an innovation is applied to the health care field.

We can distinguish three categories of disruptive innovations: readily adopted, challenging and undercover.

- *Readily adopted* disruptive innovations are perceived as advantageous, less complex, more compatible with prevailing norms and values, with more observable results, and with greater scope for local reinvention.

- *Challenging* disruptive innovations are essentially the obverse of the 'readily-adopted' innovations. The profile implies that these innovations are more complex and require changes and accommodations to be made outside the innovating core group.

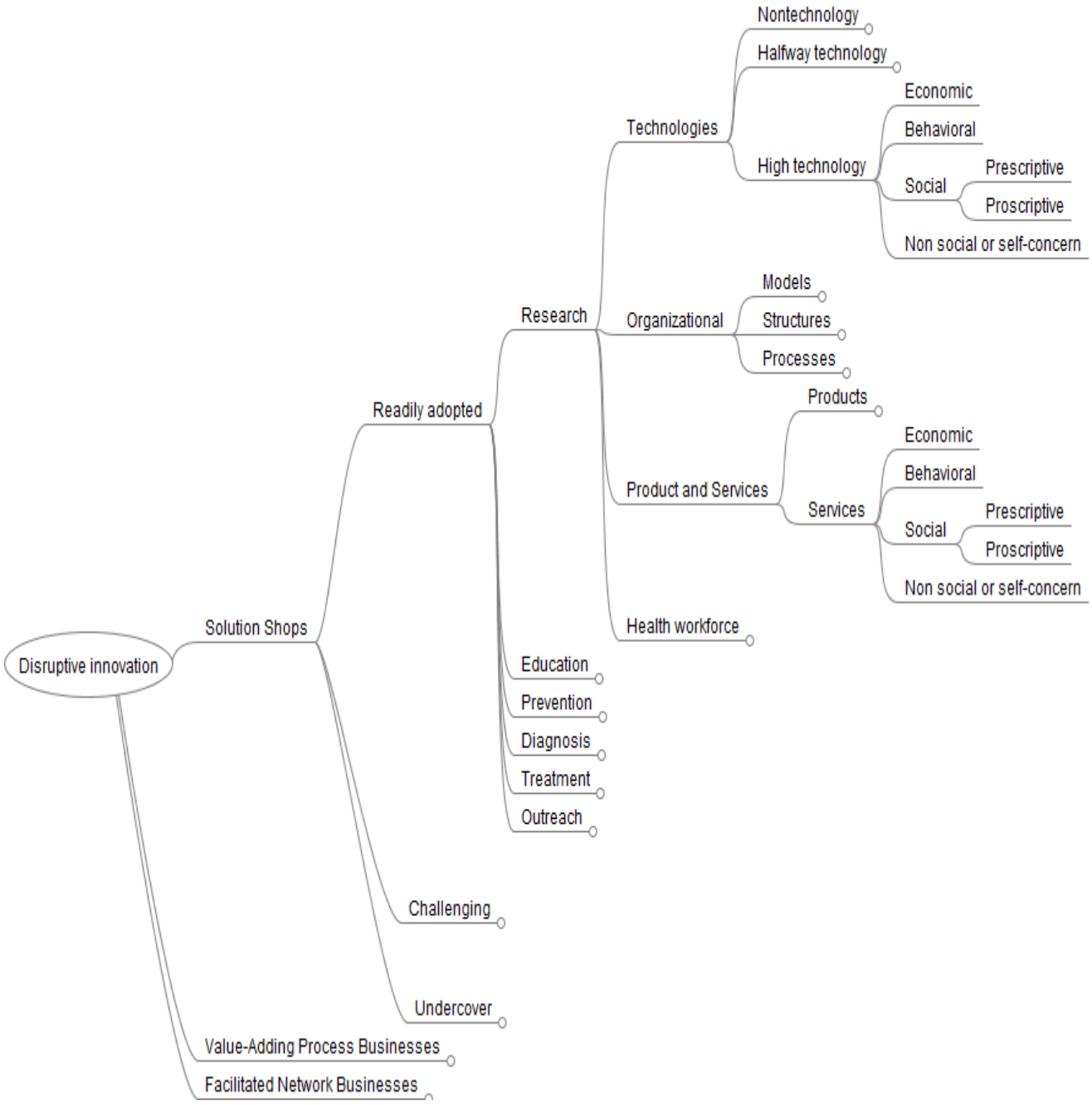
- *Undercover* disruptive innovations are perceived as being less of an improvement against initial conditions. Furthermore, they are less observable by others outside the innovating core group and appear to impact little outside such group.

- **The health purposes** level distinguishes between the six purposes of health care organisations: research, prevention, education, diagnosis, treatment and outreach. In serving these purposes, health care organisations must effectively manage quality, costs, safety, equity, access, efficiency, sustainability and outcomes.

- **The field of application level describes** the context in which the disruptive innovations take place. The fields are: technological (nontechnology, halfway technology, high technology) organisational (models, structures, processes), product and services, health workforce and community/active patients and population.

- **The pivoting values** level indicates the value which triggers the interest of the persons in a type of disruptive innovation. The values are: economic, behavioural, social (prescriptive and proscriptive) and non-social/self-concern.
  - *Economic* values, related to the balance between outcomes and costs, refer to object possessing values
  - *Behavioural* values refer to internalised guides in the production of behaviour
  - *Social* values are values arising from inter-personal relations
  - *Non-social/self-concern* values are self-oriented or egocentric values

Figure A. Taxonomy of disruptive innovations: typology of business model → Fluency of implementation → Health purposes → Fields of application → Pivoting values

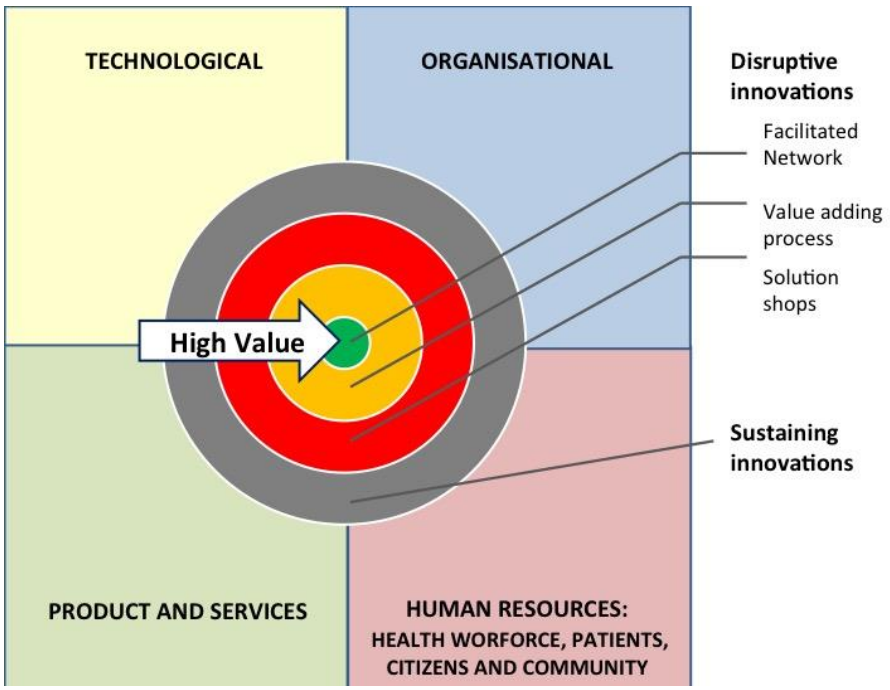


However, given the complexity of the taxonomic tree, taxonomy can be developed in a visual display (Figure B) to make clearer and more understandable the proposed classification.

The bull's eye distinguishes the three different typologies of models in health care: solution shops, value-adding process businesses, facilitated networks.

When a model substitutes another, the gains in affordability and accessibility are even more profound than when innovations occur within the same type of health care model. This movement between health care models usually represents the obtainment of high value.

Figure B. Visual taxonomy of disruptive innovations



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ANNEX 2. DISRUPTIVE INNOVATION: DATA-MINING PROCESS

The data-mining process consisted on the reviewing of a set of papers on disruptive innovation. These papers spanned across distinct areas, ranging from transfer of skills, health care venues, financial, among others. Nevertheless, there is an overall take-home message from all the data-mining process as the key issues discussed by the authors do not vary much across the papers.

In this sense, the following paragraphs highlight the main results and conclusions that can be drawn from the data-mining process.[13]

First of all, there is a general idea of what disruptive innovation is. Following Geoff Mulgan, disruptive innovation is much more "a combination of lots of other people's great ideas" than a single out of the box magnificent idea. Hence, it becomes apparent that disruption does not necessarily mean to cut off a process and may simply imply a different way to improve procedures. Again as Geoff Mulgan said, the novelty is drawing together ideas in a different manner. Other authors share this view and both the iPod and digital photography were pointed as perfect examples disruptive innovations. On the other hand, Clayton M. Christensen says that "a disruptive innovation is a technology that brings a much more affordable product or service that is much simpler to use into a market. Glabman (2009) distinguishes disruptive technology from disruptive innovation. A disruptive technology, or technological enabler, is a new technology that unexpectedly displaces an established technology, but only if it is accompanied by an innovative business model. The enabler is generally cheaper, simpler, smaller, and frequently more convenient to use (e.g. personal computers). A disruptive innovation is one that brings to market products and services that are much more affordable, and, in the end, much higher in quality. It improves a product or service in ways that the market does not expect, typically by being lower priced or being designed for a different set of consumers.

In what concerns health services, disruptive innovation should lead health care delivery systems to increase the focus on efficiency rather than expecting every new product and process to improve quality, regardless of cost. Clayton M. Christensen argues that we will make health care accessible by enabling or making more capable lower-cost providers and lower-cost venues of care (e.g. enabling nurses to do things that historically a doctor had to do, technology that allows you to do in an outpatient clinic or doctor's office things that historically you had to do in a hospital).

[13] http://ec.europa.eu/health/expert_panel/opinions/docs/011_disruptive_innovation_datamining_en.pdf

However, despite the existence of a general idea, there is no consensus on a precise definition of disruptive innovation. As a matter of fact, the concept is complex and often misused. In particular, many technologies and procedures are recursively labelled as disruptive without a thorough analysis. Some of the papers highlighted the fact that it is impossible to know whether a certain innovation will actually be disruptive instead of sustaining, meaning that innovations are typically labelled as disruptive based on their potential to be so. Of course many times innovations end up not being disruptive one put into practice. Other important features are the timing and appropriateness of the innovation at the time it is being implemented, which can jeopardize its effectiveness from the beginning. Bearing this in mind, Schulman (2009) proposes a framework to independently assess the disruptive potential of innovations and an express regulatory pathway for innovations which are considered as being disruptive.

Besides papers devoted to general discussions of the concept of disruptive innovation itself, there were also papers analysing specific innovations and assessing whether they were indeed disruptive or not. Many of the innovations proved not to be disruptive, despite the fact that they exhibited disruptive potential. Other innovations analysed were still on paper and had not been put into practice yet, so no conclusions could be taken as one cannot really assess disruptiveness just based on prospects. But there were also innovations which were considered disruptive, as it is the case of Retail Clinics (also referred to as Convenient Care Clinics), telemedicine, medical tourism, personalised biomedicine and point-of-care payments. In addition, drugs that lower cholesterol are disruptive to angioplasty, just as angioplasty was disruptive to open heart surgery.

The added-value resulting from the application of disruptive innovations usually consists in one or more of the following: improved access to specific populations (i.e. remote areas, economically disadvantaged, uninsured, etc.); improved communication between health care professionals within and across sites; reduced costs; improved quality of care; new philosophy; more learning opportunities.

Christensen (2007) classifies three classes of medical problems according to their disruption potential: 1) acute and amenable to precise diagnosis, which then enables rules-based therapy – most amenable to a disruptive approach; 2) chronic diseases that people just are learning to live with - amenable but in a lower-impact way; 3) the high end, nonstandard, medically complex cases— non amenable by a disruptive approach.

The active engagement of each health care professional involved in the changing process was pointed by several authors as key for the implementation of disruptive innovations

and to the establishment of new relationships and partnerships to create new businesses. Additionally, a strong leadership was crucial for the mobilisation of all the stakeholders in the change-making process. Health care professionals training has also been subject of several changes towards innovation. However, modifying academic structures is a complex and sensitive exercise, especially as it envisages enabling other practitioners of providing services that have always been the responsibility of medical doctors.

There are also obstacles that need to be overcome in order to break with the status quo and successfully implement a disruptive innovation. Such obstacles usually relate to lack of preparation among the involved agents or to the established interests of specific stakeholders and their fear of losing influence and power within the system. Christensen and Hwang (2008) argue that in health care, most technological enablers have failed to bring about relevant costs, higher quality, and greater accessibility. The author believes that the primary reason is a lack of business model Innovation, for a variety of reasons: fragmentation of care, lack of a retail market, regulatory barriers and reimbursement. Policy-makers need to address these barriers to innovation and discuss the ways to reduce or to eliminate them.

Finally, the data-mining process also suggested a new trend for the transformation in the way health care is delivered, not just the way it is provided. This is the case of the rising of patient-centred models of care, such as medical homes, accountable care organisations and new payment models to improve care and reduce costs.