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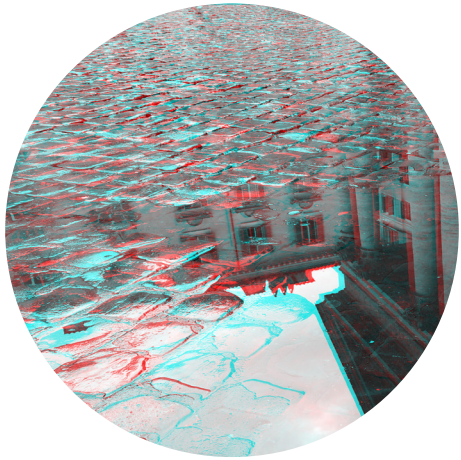

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The Patient Revolution. New design perspectives in healthcare innovative processes.

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Abstract | This paper explores the emerging role of patients and caregivers as user innovators within design processes. The phenomenon of user-driven healthcare has been recently renamed 'patient innovation' (Olivera et al. 2015). The first part of the paper presents a literature review to explore the phenomenon of patient innovation, especially in Italy. The second part analyses a range of European research projects on patient innovation, carried out and participated by makerspaces and fab labs, according to several indicators, such as the role of patients, the role of healthcare' stakeholders/providers, the design processes implied and the outputs of these design processes. The final part of the paper systematizes the results and use case analysis in order to qualify the nature of collaboration between different healthcare stakeholders as a key to design innovative roles, skills, spaces for patients, doctors and institutions.

KEYWORDS | PATIENT INNOVATION , USER - DRIVEN HEALTHCARE , MAKERSPACES , DISTRIBUTED DESIGN FOR ALL , DIGITAL HEALTHCARE

1. Introduction

Nowadays, we observe an increasing need and willingness for patients, patient associations and caregivers to be involved in cure and recovery processes for economic, time, social, and psychological reasons. However, a major role of patients should not correspond to the absence of the medical staff from the whole process. The involvement of patients in the cure and in processes to envision new solutions might be the right answer to avoid the so-called do-it-yourself care and medicine. Indeed, more than 47,4% of Italian citizens prefer self-diagnosis (Eurispes, 2017) and self-care.

Within the healthcare system, the personal relationship between patients and general practitioners has been reduced and replaced with specialist visits augmenting and disintermediating human relations. Patients and doctors nowadays seem to be more distant than in the past: 54.3% of citizens are not satisfied with our health system, only 57.8% are confident in the effectiveness of influenza vaccines (Eurispes, 2017).

Enabling innovation communities and spaces such as Makerspaces and Fab labs can favour technological and social innovation in healthcare. Design can act as a mediator between different stakeholders, and as a facilitator of innovative processes; makerspaces can act as platforms for co-creation. As the design process and its results are concerned, “Research has shown that many users ‘drop out’ of the innovation process before having realized a prototype and may be doing so too early for what is socially optimal, leaving potentially valuable ideas undeveloped.” (Svensson & Hartmann, 2018: 278). Makerspaces and Fab Labs can act as enablers of patient innovation processes avoiding cases of dropout. Italy can be considered an advanced country in this area, and Italian makerspaces collaborate and operate on these issues together with patient associations, policy-makers and RRI experts in several European projects.

2. Framing the Patient Innovation

Healthcare needs are changing according to society changes. One of the most relevant highlights stressed by OECD Health Statistics 2018 is the need for health systems to be more people-centred, in particular in facing life-threatening diseases and to be able to exploit the potential of new digital technologies to strengthen prevention and care.

The approach to health as a system, the focus on people (both as patients but also caregivers), the exploitation of digital technologies and robotics (Butter et al., 2008; Brose et al., 2010) can be identified as relevant elements that have to be taken into consideration when we talk about Patient Innovation.

In order to talk about Patient Innovation is necessary to frame this phenomenon within the wider concept of Grassroots Innovation, which is defined as “a network of activists and organizations generating novel bottom-up solutions for sustainable development and

sustainable consumption; solutions that respond to the local situation and the interests and values of the communities involved" (Seyfang & Smith, 2007: 585). For the discussion here presented we find in this definition two main relevant keywords: network and sustainability.

The need for communities and networks in order to be able to activate and implement an innovative solution is particularly relevant. Indeed, the capability to have a systemic view and rely on a critical mass of intentions and interests are fundamental elements for the success of an innovative idea. The very first limit to the development of an innovative solution is based on the fact that patients (in many cases) are not experts or entrepreneurs, and their objective is basically and clearly oriented to the improvement of their own critical condition without any regards to the market or other users. For this reason the concepts of "network" and "alliance" are very relevant; first of all this concept refers both to the geographical and value-oriented proximity of members of these networks (Boschma, 2005). In addition to that, even if Grassroots Innovation is primarily generated by civil society (Tang et al., 2011; Hossain, 2016), it has to engage other relevant stakeholders, such as government and business, especially when innovation happens in the healthcare domain. Indeed, these networks include a "social dimension" composed by people who have different needs and goals; hard components, such as tools and devices; normative components like permissions, obligations and power (El-Hassan, Fiadeiro, and Heckel, 2008). This view is very close to what Harvey Molotch (2003) called "lash-up", that is an integrated and networked system which is at the basis of the creation of a product or a design solution: "Tracing the connections in products can show how the social and the material combine to make, depending on circumstance, both change and stability happen in the world" (Molotch, 2003: 3). Every innovation to be effective, in this sense, enroll a socio-technical network, different stakeholders, tools and technologies. Harvey Molotch uses the "lash-up" concept also to address the issue of sustainability, which is very important also for our discourse.

The concept of sustainability is very relevant but complex, as well. Sustainability has multiple facets and does not refer only to the environmental sustainability but also to the economic and social ones. Also sustainability has to be approached with a multidimensional perspective (Davico, 2004). Therefore, when we take into consideration healthcare, it is very important to look at the ethical-social sustainability, which refers to issues of social equity between individuals, groups, between broader social aggregates, fair distribution and equal access to services in order to strengthen the population's capacities and opportunities (Davico 2004).

The Open approach is very much related both with the discussion on network and sustainability. Indeed, innovation owns the characteristic of openness when it is participated by subjects that usually do not enter in these processes (such as patients and caregivers), and when it is free to be used and shared (not for business purposes). As the NESTA report "Open Innovation in Health" (Gabriel, Stanley, and Saunders, 2017) states that innovation in order to be "open" has to involve a wider range of people that "can generate better ideas, at lower cost. They can also democratise innovation, giving a wider range of people a say in

setting priorities" (Gabriel, Stanley, and Saunders, 2017: 4). As the economic sustainability is concerned, the affordability of solutions implemented, according to the Frugal Innovation approach, is connected with low-cost and low-tech productions.

Previous research (Dreier et al., 2016) identified some common characteristics to define a "low level" of Patient Innovation:

1. independence: in most of the cases the idea was born from the personal condition and to face a personal issue;
2. repetition: in many cases the solution identified already existed but the patient did not know;
3. sharing: when a solution was found in general patients tend to share their positive experience with other people in their same condition lack of connection with doctors and professionals.

In this view, Design might act as an important mediator, connector of health services and institutions with patients and citizens, and as an activator, thanks both to tangible (availability of facilities and infrastructures) and intangible (knowledge and networks sharing) factors.

2.1 The "space" for Patient Innovation

Grassroots Innovation and co-creation processes can happen in those places where networking between different actors is facilitated and performed, where knowledge is shared, where experimentation is easily performed (in terms of availability of tools and competences). Focusing on design-driven innovation, Makerspaces and Fab Labs are places where it is possible to face the previously mentioned issues of independence, repetition and sharing which characterize Patient Innovation at a very first stage. Makerspaces and Fab Labs are facilities but also actors of a socio-technical system, where social and economic sustainability can be performed thanks to the adoption of processes of open and distributed production.

The first, open production, refers to an emerging production model, based on cooperation between different subjects. Often this production model is connected to open design approaches that lead to the development of projects (under free IPR Creative Commons license) based on the sharing of digital project files released freely to allow their replication or distributed production (Maffei, et al. 2017). The second, distributed production, is essentially a decentralized form of production developed by organizations or individuals who use a network of structures and production technologies geographically located through ICT technologies. This form of production is the basis of the Maker movement (Anderson, 2013; Dougherty, 2016) or the Do-It-Yourself culture and allows remote production of objects, at a microscale close to the end user. In technologically more advanced forms distributed production is present today in the concepts of Industry 4.0 (Europe) and Smart

Manufacturing (USA) with the introduction of cyber-physical systems or the development of autonomous systems managed by Artificial Intelligence (Maffei, et al. 2017).

From the socio-technical network point of view, we want to stress here the importance of Makerspaces and Fab Labs to be in connection with wider networks of stakeholders; in many cases, Universities, Research Centres, Hospitals, etc. take part in these networks. In addition to that, there are some examples of Makerspaces, Fab Labs, Innovation Centres which are not only located but even promoted and managed by Universities (e.g. POLIFACTORY at Politecnico di Milano, Lab4Living at Sheffield Hallam University, UCL Centre for Co-production in Health Research at University College London, Helix Centre located at the St Mary's Hospital in London but managed by Imperial College London and The Royal College of Art); this means that theoretical and applied research can be performed in very close connection. In addition to that, the reputation of Universities as "reliable" institutions can favour the involvement of different stakeholders, since, according to Quadruple Helix approach (Carayannis & Campbell, 2009), innovation is favoured and better performed thanks to the connection and the collaboration among Academy, Government, Civil Society, and Enterprises. In the following section, we are going to focus on the Italian context, presenting a selection of case studies of Design-driven Patient Innovations (DPI).

3. Patient Innovation case studies

The following case studies were selected looking also at previous research, such as MakeToCare1 and MakeToCare2,(Maffei et al., 2017; Maffei et al., 2019), La cura che cambia (NESTA, 2018), Digital Social Innovation: DSI4EU platform[1].

The 5 selected case studies are: NEXT STEPS, CAREABLES, BODYSOUND, Patient Innovation Platform, Hackability. We are going to present them according to three main sections:

1. DESCRIPTION: which will contain general information about the typology of project and funding, the partner we are going to take into consideration, area of interest of the project, actors involved.
2. PROCESS: will be dedicated to the research and design processes used in Patient Innovation journeys.
3. OUTPUTS: resulting from the process previously described; typologies of outputs and their distribution.

Finally, according to the identification of several variables, a model for the comparative analysis and synthesis will be proposed and used on the selected case studies.

[1] https://digitalsocial.eu/

3.1 NEXT STEPS (Distributed Design Market Platform)

DESCRIPTION. NEXT STEPS is an experimental initiative developed by Polifactory, the makerspace of the Politecnico di Milano[2], within the Horizon2020 project Distributed Design Market Platform[3] (DDMP, Creative Europe Programme 2017-2022) that stimulates designers, makers and patients to co-design and prototype a collection of open source walking aids that can be distributed through digital platforms and materialized in Fab Labs, starting from the Design Distributed Market Platform perspective. The initiative developed in collaboration with AIG – Associazione Italiana Glicogenosi[4], a patient association that represents people affected by Glycogenosis.

PROCESS. The project was divided into several phases involving patients, caregivers and designers through participatory activities and workshops both in presence (at the Fab Lab) and remotely. The results collected by a survey were the starting point for the co-design workshop aimed at collecting project ideas for mobility aid solutions. During the following phase, called "Makers in Residence", patients worked in close collaboration with designers and makers supporting them in the development and prototyping of open source walking aids. Technical and scientific support was provided by Polifactory' researchers; medical and scientific support was provided by Sanofi Genzyme (a pharmaceutical company) with a specialty care unit focused on rare disease.

OUTPUTS. Five solutions have been developed:

- Twistr: a parametric stick generated through a scanning made by a Kinect Cam;
- Taylor: a generative stick based on three parameters: gender, height and weight;
- Wander3d: an hacking project to transform a traditional walker into a motorized and sensorized rollator. Users can decide to activate the motors according to their needs.
- Clip Clap: a family of 3D printable clips for personalizing crutches;
- Crutches adds-on: a system of accessories that integrate on crutches to facilitate users' movements and activities (hooking systems, battery charging systems, lights, tips, holders, etc.).

All projects files and the INSTRUCTIONS FOR FABRICATION are distributed with a Creative Common License (CC BY-SA) on the distribuddesign.eu platform and Polifactory website.

[2] www.polifactory.polimi.it/en

[3] distributeddesign.eu

[4] https://www.aig-aig.it/

Figure 1. Taylor one of the solutions developed within the NEXT STEPS project.

3.2 CAREABLES (made4you)

DESCRIPTION. Made4you it's an Horizon 2020 project (2018-2020) that involves several Fab Labs around Europe, participated by the Italian Fab Lab OpenDot. The project was aimed at connecting local communities of citizens with disabilities, their families, and healthcare professionals with makers and designers. The collaboration between these separate communities was based on the development of open-source interventions and solutions, so called "Careables".

PROCESS. In made4you project people became creators, not only users of innovation. Patients, their families, healthcare professionals and designers were involved in a co-design process as experts in their specific field, and were asked to collaborate with makers, who are -on the other hand- experts in the use of digital tools, such as 3D printers, laser cutters, etc. OpenDot chose a method already tested in other projects on the development of healthcare through co-design. This method is composed of 8 main steps, as shown in *Fig. 2.*

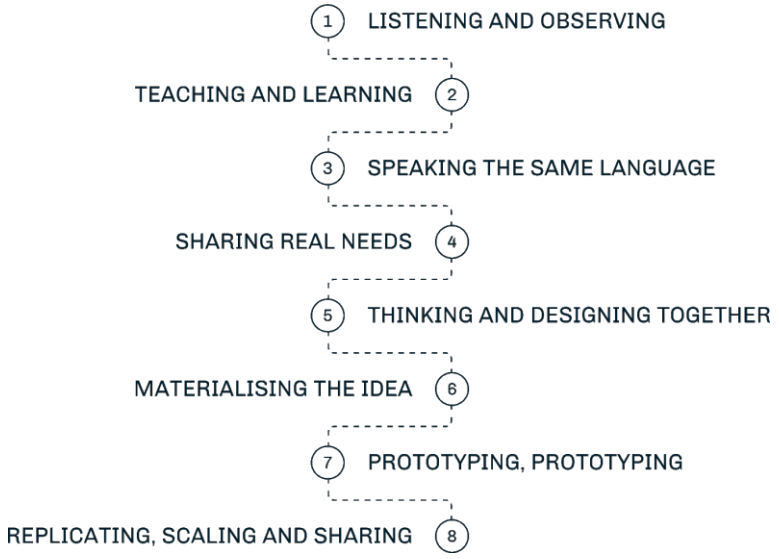

Figure 2. Steps of Method developed by OpenDot from 2015 with the TOG Foundation and other organizations, ranging from patient associations to companies operating in the field of healthcare, extract to "manifesto of co–design for health and care" inside Made4You project.

OUTPUTS. Made4You project had a series of different outputs both connected to co-design, prototyping and open distribution. Careables products are solutions for healthcare co-designed, replicable, accessible, adjustable, and shareable online, using digital technologies. These products are collected and distributed on the platform careable.org, where also a wider collection of open products is available to be downloaded. The platform collects about one hundred products and solutions, such as:

- *Davido*: a musical instrument that allows children with motor disabilities to maintain a rhythm, produce music and play alongside other people;
- *Hack a toy*: DIY low-cost mod to help turn toys into accessibility devices;
- *3D printed orthotic swimming fin* for the arm suitable for rehabilitation after a stroke.

3.3 BODYSOUND

DESCRIPTION. The Horizon2020 project SISCODE Co-design for Society in Innovation and Science (2018-2020) is aiming to understand the co-creation phenomenon that is flourishing in Europe and to analyse the context and conditions that support its effective introduction, scalability and replication. Within SISCODE, 10 pilot projects have been developed, involving different stakeholder in the co-creation of solutions addressing societal challenges. One of

these pilot projects, called BODYSOUND, is run by Polifactory, in collaboration with the Patient Association FightTheStroke; it investigates the physical-motor needs of children diagnosed with cerebral palsy.

PROCESS. BODYSOUND was developed starting from the process developed and proposed by the project leaders (Politecnico di Milano) in collaboration with other partners.

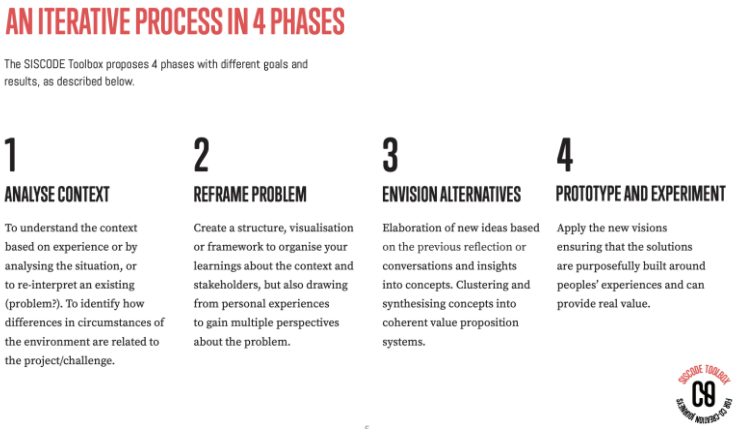

Figure 3. Process within the SISCODE toolbox for co-creation. and co-design.

Different moments of co-creation have been conceived and planned, in order to involve different stakeholders:

- the patient association FightTheStroke, who took part in the whole process from the definition of the challenge;
- children and families who have been involved in co-design workshops, experimental laboratories, and tests;
- therapists, sports doctors and sports scientists who were involved to test the solution and during the service co-design workshop;
- policy makers who were also involved in different moments of the process, through interviews and during the service co-design workshop.

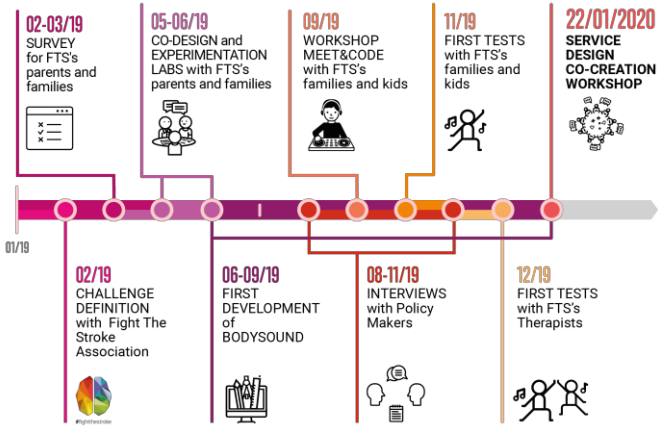

Figure 4. BODYSOUND pilot co-design process timeline

OUTPUTS. The output of BODYSOUND will be a product-service system intended for all children, with particular attention to the needs and requirements of children with cerebral palsy, aimed at motor reactivation through music that uses touchless technologies and will be able to collect data related to the movement. In particular, the product BODYSOUND will be a system based on coreutics and on the transformation of movement into sound. Within this system, children can perform a “choreography” and transform it into a “melody”.

3.4 PATIENT INNOVATION PLATFORM

DESCRIPTION. Patient Innovation platform was an output of the research "Visualizing user innovation in the healthcare" (2011), supported by Pieter Pribila Foundation, The Portuguese Science and Technology Foundation and Carnegie-Mellon Portugal Program, in collaboration with Universidade Católica Lisbon with Università di Roma Tor Vergata and the Universität Innsbruck. The project was aimed at studying user innovation developed by patients and non-professional caregivers. During the project, the need for these innovations to be shared with other patients, researchers and makers, became clear. For this reason, the Patient Innovation Platform was created in order to open distributing these solutions.

PROCESS. The process here presented it has not to do with the development of the platform in itself but with the process that the platform follows to collect (patients) innovations. Anyone interested in sharing an idea or solution can join an existing Patient Group or create a new group and can post information and multimedia content that can be implemented over time. Platform managers enable user-innovators interested in sharing their product-service solutions: solutions are analyzed by the Patient Innovation medical team, only those validated are published, thus ensuring a security check.

OUTPUTS. An international, multilingual, non-profit platform, and social network that connects patients and caregivers, and enables the sharing of their solutions. Since the launch of the platform, over 650 care and disability product and service solutions from over 40 different countries have been presented by patients (non-professionals) or caregivers, validated and then shared online.

3.5 HACKABILITY

DESCRIPTION. Hackability is a Non-Profit Organization born in Italy (2013) that aims to identify, invite, inform, interest and involve makers, designers, technicians, Fab Labs and people with disabilities, in an on-line and off-line community, to realize products for everyday life using new (or improved) digital fabrication processes. The initiative was born in Torino, but today in Italy there are several Hackability communities. The initiative is based on a meeting formula inspired by hackathons aimed at developing solutions based on the needs of patients and caregivers.

PROCESS. The challenge of Hackability is to build strong relationships between the local communities of makers and people with disabilities. This is done by encouraging people of both communities to work together with the aim of developing an assistive device, which solved a specific need expressed by a person with physical impairments. The basic idea behind the process is that people with disabilities already are hackers and makers since they often modify or develop their own ATs solutions.

OUTPUTS. Hackability developed three kinds of outputs:

- *Event*: standardization of a format inspired by hackathons (popular events in the community of makers) to propose systematic occasions where people with disabilities and makers can meet and work together, creating workgroups that are led by patients (i.e., begin-user).
- *Products:* are solutions for healthcare co-designed inside Hackability events by patients and designer/makers, to solve a personal need. These solutions are documented and distributed with on hackability Platform, we mention here only few examples like *Tournée (*folding table for wheelchair completely made by 3D printing), *Hackability Geo* (interactive 3D map of Italy for blind children).
- *Platform:* collects the documentation related to projects developed with the Hackability co-design methodology. All material is released as Open Source, with a Creative Commons License (CC-BY-SA-NC).

3.6 Synthesis

Case studies previously presented are going now to be synthesized according to 5 main characteristics. The variables identified for each of them are limited to our case studies but -

for sure - they should have to be improved if other Patient Innovation case studies would be taken into consideration (see Tab.1).

Table 1. Grid analysis with variables to be considered in designing for patient innovation

The leading subject	Research center
	Fab Lab
	Association
The involved stakeholders	Patients
	Caregiver
	Patient associations
	Healthcare professionals
	Designer and makers
	Researcher
	Policy makers
The process	Co-design
	Co-production
The outputs	Products
	Platform
	Product-services
The characteristics of the outputs	Accessible
	Customizable
	Digitally fabricated
	Open
	Distributed

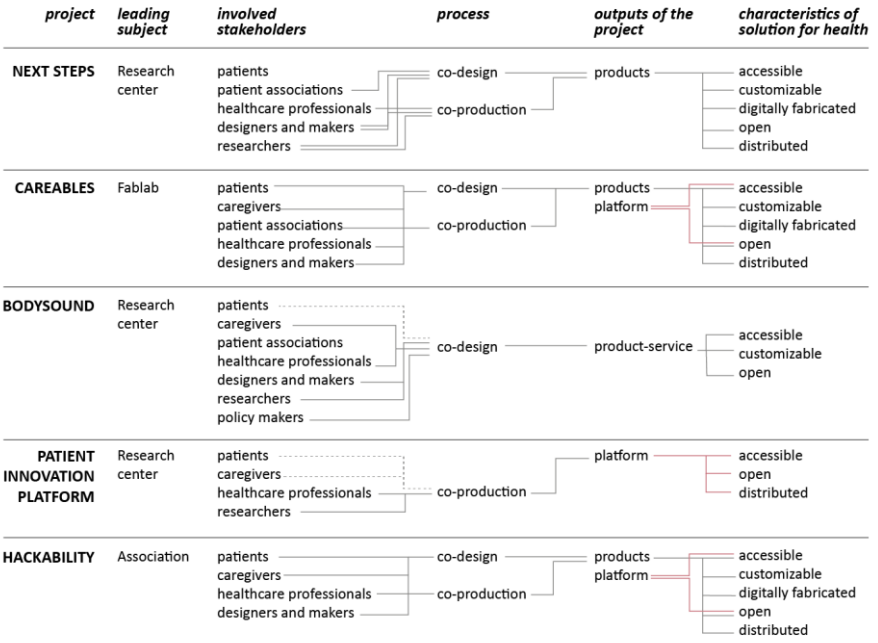

Figure 5. Summary table of the case studies analysed

As it is possible to see in the chart above, design-drive Patient Innovation pays great attention to different stakeholder in the healthcare field. Therefore, both patients and caregivers are involved and often, as we will see later, asked to work in close collaboration with designers and makers. However, innovation, in general, and Patient Innovation, in particular, need to communicate, engage and discuss in order to be efficient and effective both with researchers, healthcare professionals and policy makers.

These stakeholders are usually in co-creation processes. In the wide definition of co-creation, we could distinguish between:

- Co-design processes, which put in place specific actions of co-creation, where collective creativity is applied across the whole span of a design process (Sanders and Stappers, 2008; Sanders and Simons, 2009; Freire and Sangiorgi, 2010)
- Co-production processes, are temporally following actions to co-design and refer to the collective materialization or creation of knowledge.

Co-design and Co-creation processes, which we can collectively name, Co-creation are often *ad hoc* designed by researchers and designers and they can also be very different one from

the others. Since we took into consideration especially Fab Labs (and in one case - BODYSOUND - a Fab Lab which is part of a Research center) outputs are mainly products; however due to the nature of these projects, in many cases platforms are other very important outputs since they represent the virtual spaces were to disseminate and distribute these projects. Looking at the outputs, we could define their main characteristics. The accessibility of these products is very relevant. Indeed, in many cases these solutions answer to needs connected to the economic accessibility of healthcare products.

Accessibility is also very much connected with the possibility to customize these products. The customizability of a solution has to be taken into consideration in the very first-stage of the design process; therefore products have to be thought in parametric perspective to ensure that even a non-expert can enter his/her preferrable measurements.

The digital fabrication consent to use the same "language" which can be easily distributed and shared (open). Finally, openness and distribution are characteristics at the basis of the maker philosophy, as we discussed before.

4. Conclusion

Design-driven Patient Innovation is based on the observation and the recognition of a fact: patients (especially chronic patients) are daily facing issues connected with their disease, of which they become experts. The expertise is very relevant in managing these problems and, especially in cases of physical impairments, they tend to adapt the (standardized) medical aids which they need to use. However, to be so, innovation has to be known and shared, and not all the patients have the knowledge and the power to go beyond a personal level of innovation. To this end, Makerspaces and Fab Labs can act, in connection with other relevant experts, to empower patients who own an innovative idea, providing them the "space for innovation", composed by infrastructures, tools, methods, networks and money, thanks also to public or private fundings, which are more and more taking into consideration Patient Innovation as part of Responsible Research and Innovation domain. In addition to that, research and calls focusing on patients involvement, allow engaging in co-creation processes also those patients who aren't already conscious and confident not only in their possibilities but also of their capabilities and opinions. In order to make innovation possible, design-driven Patient Innovation looks at the whole healthcare ecosystem and to the need of a product or service to be inserted in a socio-technical framework in order to stimulate the conversation between healthcare providers and patients, but also improve the healthcare professional acknowledgment on patients' preferences and values. Finally, another important aspect is to propose more flexible medical aids and even cure processes, taking into consideration patients' general wellbeing and quality of life.

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