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Distributed design and production for distributed care. Investigation on materializing bottom-up open and indie innovation in the field of healthcare.

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Abstract | The paper investigates the role of distributed design and digital fabrication in the materialization of open source healthcare solutions co-developed by designers, makers, and user innovators with or within enabling environments such as makerspaces. A participatory and experimental design-oriented approach allows to refine the nonlinear development path that characterizes new fields in which design, technological experimentation and medical research may find application possibilities can also be identified. With these premises, this work aims to explore the dynamics of designing products related to the emerging field of Distributed Care. Firstly, the paper defines the emerging field of distributed design for healthcare and analyses experimental initiatives exemplifying the field of Distributed Care. The second part of the paper interprets the results of the use case analysis to demonstrate how designers, makers and independent innovators interacting with care specialists, patients and caregivers – can design, produce and distribute solutions with a real market potential.

KEYWORDS | DISTRIBUTED DESIGN, DIGITAL FABRICATION, MAKING, OPEN SOURCE HEALTHCARE, FAB LAB

1. Designing (for) distributed systems: an introduction

Nowadays, terms such as "distribution" and "distributed systems" have become a common, constituent and characterizing part of the production, release and diffusion models of many goods and services on the market. *Blockchain*, *cloud computing* and *manufacturing* are examples of distributed technologies. It was not until the early 2000s that the theme of distributed systems crossed the discipline of design. The scientific literature on the design of distributed systems mainly refers to the world of computer science and in particular to the design of computer systems (software engineering). We speak of distributed systems design or distributed computing environment to define a system whose components are located in different networked objects (e.g. computers). These components act in a coordinated way by sharing information to achieve a common goal. A distributed system is basically a set of independent processors that enable the sharing of resources through the use of software and allows the system components to operate autonomously, independently and geographically spread. The distributed systems are characterized by certain properties: *transparency* in the access and use of its resources, *openness* that facilitates the configuration and modification of the system, greater flexibility and interoperability, reliability in the resolution of errors and problems, and the ability to concentrate performance capacity and to scale physically, geographically, organizationally (Wu, 1999).

Another strand of scientific literature on distributed systems comes from the world of industrial engineering and management, more specifically related to the concept of *distributed manufacturing* (Marsh, 2012; Künhle, 2010). Basically, distributed production is a decentralized and networked model to organize local manufacturing processes. Digital transformation, especially the development of digital fabrication, has empowered this model and its operability. Organisations and individuals (professional, citizen, and *indie* innovators) can use a network of production facilities and technologies geographically dispersed but connected and coordinated through ICT technologies (Seravalli, 2013; Wolf et al., 2014). The spread and the convergence of a growing number of small-scale production activities, which are fuelled by a plurality of subjects and organizations and characterized by a democratized access and use of manufacturing resources, fosters the growth of forms of *Commons-based peer production* based on distributed production (Gershenfeld, 2012; Rifkin, 2013). Open and distributed production refers to an emerging collaborative production model which may be web-based or in physical facilities such as makerspaces and Fab Labs. This form of production is going beyond the Maker movement (Anderson, 2013; Dougherty, 2016) and allows an open and close-to-the-user materialization of artifacts.

Distributed Design (DD) is a very recent concept that has a strong link with the two abovementioned domains of knowledge and practice. Essentially, DD connects participatory, open source and DiY design processes with parts of existing production and distribution models, digital manufacturing technologies, thanks to computational capability and systems.

Moreover, Distributed Design - intended as open design for distributed products, services and systems - (Diez, 2018; Armstrong et al., 2019) requires users and indie innovators to question themselves, to overcome their limitations and to experiment with new ways of making and doing things. Creators and innovators make use of digital-enabling technologies as digital fabrication platforms, prototyping spaces and community-based labs to make tools and tech accessible. Personal and personalized solutions can be created on- demand, on-site, and then shared with others. Recently, the theme of innovation, as far as design disciplines are concerned, is increasingly linked to experimental practices directly related to the dimensions of open and distributed knowledge and production. According to Aleinikoff (2014), *"innovation is a dynamic problem-solving among friends".* Innovation is a practice closely linked to the bottom-up experiential dimension, often coming from a group of users who seek to respond to design niches through the increasing accessibility to spaces, places, communities and technologies more widespread in cities. This aspect can be connected to a constant growth in the dimension of participatory design, intended not only as a methodological approach but also as a spontaneous practice, with the aim of developing design solutions together *with* or *by* the citizens-users.

2. Patient innovation and open care: an emerging scenario

Unquestionably, digital transformation increased innovation capabilities in designers but also in final users. When that kind of design-driven and user-driven innovation become *mission-oriented* (Mazzucato, 2018), it can be work support the autonomy and quality of life of people, especially those affected by diseases or disabilities, as well as their families and caregivers. According to Bertalan Mesko (2016), the development of new forms of care enabled and enhanced both socially and technologically, the increasing digitization of patient data, and the increased permeation of so-called disruptive technologies, acquire a meaning only if they put the person at the center of their action. This means, first of all, strengthening his or her personal knowledge, and making him or her an expert capable of autonomously managing the prevention, self-diagnosis, and collaboration with the doctor to actively participate in the development of his or her own care. It is precisely the emerging trend of active participation by patients - both individually and in the organized manner of associations and caregivers - that brings to light new levers and new ways of innovation. What gradually emerges is the concept of patient innovation (Zejnilović, 2016; Maffei et al., 2017), a bottom-up and user innovation formula that is divided into four main dimensions: design, production-technological, social, regulatory and legislative (Maffei et al., 2019).

As far as the design dimension is concerned, there is an important need to aggregate different skills, professional and non-professional, in a collaborative dynamic through informal design practices. The productive-technological dimension of patient innovation is expressed in the choice and use of technologies - particularly digital technologies - which can also be modified by the patient himself or built ad hoc. The creation of communities united by the desire to solve specific needs, goes to perimeter the social and/or socializing dimension. Finally, patient innovation must necessarily confront (face of) the regulatory and legislative aspect, which often slows down or blocks the production and diffusion of certain design solutions, as they are not part of the traditional certification chain.

Digital transformation allows patients to access and exchange data and information, create a dialogue with health services and ministries, organise and participate in associations, and raise funds to develop scientific research. The health system is becoming increasingly advanced when it comes to monitoring the body and its physical performance, with biometric data collected by interactive personal and environmental devices.

One of the areas in which this shared synergy can give concrete expression to relevant ground-breaking solutions is the *open care* (Day et al. 2017). Nowadays, types of products such as aids and prostheses can be designed using open source knowledge, software and hardware, and materialized within makerspaces combining makers' skills with digital manufacturing technologies (DeMonaco et al., 2019). Starting from this logic, a multiplicity of different solutions can be conceived and implemented answering to personal or social needs related to diseases or disability conditions. The personal and collaborative dimension in the path of disease management is, probably, the main catalyst that has made possible a series of innovative open care projects.

Within this transformation framework, it is interesting to explore the role of distributed design and production for open healthcare that we go to define as *Distributed Care* (DC), investigating emerging design skills and the use of digital fabrication within makerspaces, distributed labs where bottom-up experimentations developed by communities of makers, professionals and users are recently condensed. In particular, after a preliminary introduction on the main dynamics of open and distributed design, we will try to trace areas of opportunity and criticality, points of convergence and difference that may emerge in designing solutions for DC. The methodology proposed is the analysis of two case studies related to experimental initiatives developed by designers, makers and user innovators, materialized within an Italian Fab Labs, Polifactory - the makerspace of the Politecnico di Milano, and released through a distributed design platform (distributeddesign.eu). The analysis of these experiences in the field will serve to reflect on the development of Distributed Care, an innovation area characterized by a design culture strongly hybridized with the maker culture (Bogers et al., 2010).

3. Distributed design for open healthcare: two stories

Thanks to the systemic interpretation of the main elements of the emerging healthcare scenarios, it has been possible to scale up the proposed interpretation within a funded design project, explicitly conceived to be open and distributed.

FabCare and Next Steps[1] are two experimental initiatives part of Distributed Design Market Platform (DDMP, distributeddesign.eu), a project funded and supported by the Creative Europe Program of the European Commission to implement the global network of Fab Lab promoting and improving the connection between makers and designers with the European market. DDMP is an opportunity to consolidate this network, focusing on the development of a European Distributed Design Market Platform for makers and designers. it is particularly relevant as a specific case study in order to explore the dynamics of product design in the healthcare sector within the Fab Labs.

FabCare (2018) and Next Steps (2019) are experimental initiative promoted and developed by the makerspace Polifactory in order to stimulate designers, makers and independent innovators to design open source products for healthcare that can be distributed through digital platforms and materialized in Fab Labs. Both these experiences aim to demonstrate how designers, makers and independent innovators – also interacting with patients, caregivers and their associations – can concretely design, produce and distribute open source healthcare solutions with a real market potential.

The reasons why this is a relevant case study can be properly traced back to the nature of distributed dissemination with which the project outputs were originally conceived. According to Armstrong et al. (2019), the distributed design idea is one outcome of the intersection of two global trends: the maker movement and the digitisation of the design discipline. The entire DDMP European project integrates design skills and the making approach to enable the development of new entrepreneurial types of professional producers and in the case of the FabCare and Next Steps initiatives, this has generated open and distributed healthcare projects.

The parameters adopted for the case studies analysis are:

- physical and virtual places where the design process become "distributed" (Fab Labs, makerspaces, digital manufacturing platforms, etc.);
- enabling tools and digital technologies used to materialize the solutions;
- kind of solutions developed (e.g. product, product-service, on-demand, customizable, shareable solution);
- actors and stakeholders involved in the design and materialization process (e.g. community of users, caregivers, patient associations, etc.);
- release of the solutions (e.g. marketplaces, open source form although not necessarily free).

[1] Other interesting cases studies that cannot be analyzed in this paper are: *Hackability, Careables.org, Open Rampette*. Detailed information on these cases have been published within the MakeToCare reports (see www.maketocare.it/report)

3.1 FabCare. Open devices for smart monitoring and care awareness

Table 1. Synthetic overview of the FabCare initiative.

Level of analysis	Short description
Places (Physical and or virtual)	Fab Lab, university, medical centre, online platform
Technologies and enabling tools	3D printing, 4D printing, Laser cutting, CNC Milling machine, Electronics, Soldering station,
Kind of solutions developed	Electronic devices and analog products for monitoring and prevention
Actors and stakeholders involved	Designers, makers, researcher, doctors and specialists (CM Santagostino), users, patients
Distribution	Release of the solutions through CC-BY license; download available on the online platform distributeddesign.eu

For the first year of DDMP research, Polifactory based on the experience gained in the healthcare field, thanks to the MaketoCare research initiative (makertocare.it). Nowadays, types of products such as aids and prostheses can be designed using open source knowledge, software and hardware, and then be materialized in Fab Labs combining makers' skills with digital manufacturing technologies. Starting from this logic, a multiplicity of different solutions can be conceived, intertwined and implemented answering to the needs of prevention or care for everyone. The experimental initiative that has been developed has taken the name FabCare, with the purpose of stimulating designers, makers and independent innovators to design open source products for healthcare that can be distributed through digital platforms and materialized in Fab Labs. FabCare was developed by Polifactory, within the Distributed Design Market Platform project. Therefore, FabCare's challenge aims to demonstrate how designers, makers and independent innovators – also interacting with patients, caregivers and their associations – can concretely design, produce and distribute open source healthcare solutions with a real market potential. Furthermore, Fabcare was technically and scientifically supported, as well as endorsed, by Centro Medico Santagostino, that is one of the first Italian network of specialist polyclinics managed by a social venture capital company, and it is aimed at experimenting healthcare service models economically sustainable and socially responsible.

The whole project lasted only a few months: from May to October 2018, FabCare has developed an intense mix of events and activities. The main milestones of the project were: (i.) the Open Call for Ideas, (ii.) the selection of ideas to prototype, (iii.) the projects' implementation and materialization, (iv.) the projects distribution and promotion.

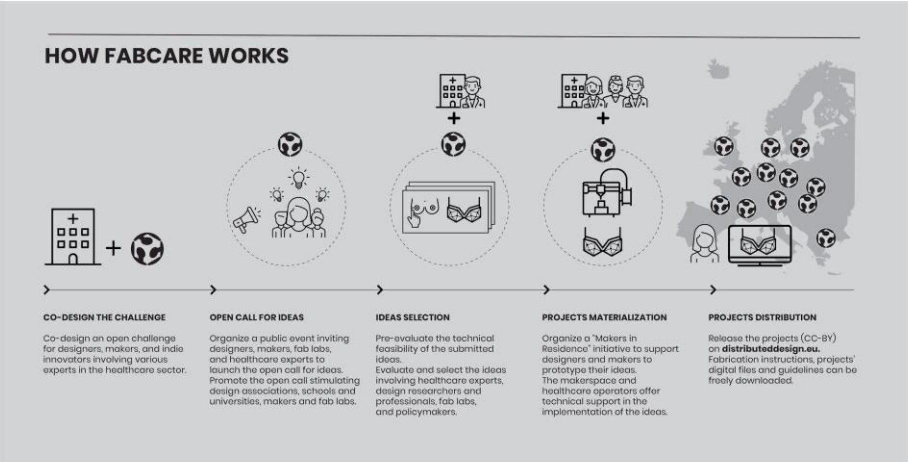

Figure 1. Fabcare's project phase scheme

First the Open Call for Ideas (i.) was co-designed, launched and promoted. Polifactory and CM Santangostino have collaborated to define themes and design challenges, and participation rules for designers, makers and independent innovators. Then, FabCare's Open Call for Ideas was officially released during the European Maker Week, and from May to July the it has been promoted to the italian Fab Labs network and the main design schools and university in Italy. Afterwards the selection of ideas to prototype (ii.) was made. Starting from a list of twentyone projects submitted by a group of sixty designers and makers, in July 2018 a panel of experts in design, healthcare and digital fabrication have selected the five ideas to be developed and prototyped within Polifactory. The winning ideas were: DermAware, Dermap, Mole Mapper, Palpatine and Zero2. It is important to note that they are specifically defined as ideas, because they were mainly interesting intuitions and concepts, still far from the logic of open and distributed design and production.

For this reason, the evolutions acquired during the phase of projects' implementation and materialization (iii.). From July to October 2018, seventeen designers and makers have operated in Polifactory with the aim of developing the five selected projects. During the phases of executive design, experimental prototyping and digital fabrication they have been supported by a network of technicians, professors and researchers of the Politecnico di Milano. In the end the phase of distribution and promotion (iv.) was held. The five projects were published on the platform distributeddesign.eu and on Polifactory's website, thus promoted and presented at European Maker Faire Rome through an exhibition and a talk.

Despite the fact that these are projects with very different complexities, it is important to emphasize that anyone can actually reproduce them, because for each project the documentation is still available online, which includes digital files for production, fab-instructions, and the user manual. It is important to point out that all projects developed within FabCare are not medical devices. These are open source solutions at the first stage of release and development that can be freely implemented following the instructions provided by the CC-BY license. All FabCare solutions provide informative support and/or help with prevention or monitoring activities regarding the problem or pathology for which they were designed. In no case can these solutions replace a consultation or relationship with a doctor or a medical specialist.

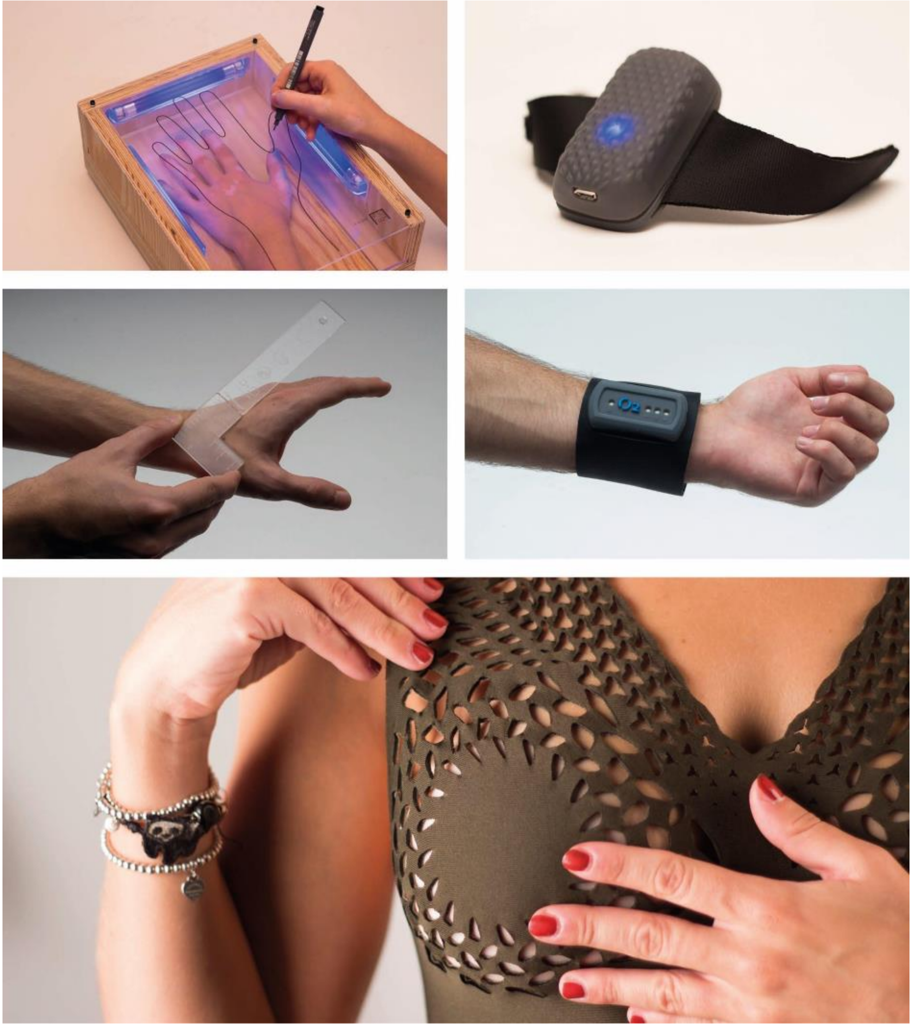

Figure 2. From left to right and from top to bottom: "Dermap", a device that supports people in measuring the evolution of their vitiligo, designed by Marianna Accorsi, Giulia Sala, Giuseppe Valentino; "DermAware", a digital bracelet to educate people on the burden

associated with atopic dermatitis, designed by Nicolò Bisi, Nur Eral and Mattia Fantoni with the support of Angelo Geraci, Nicola Corna, Fabio Garzetti and Nicola Lusardi; "Mole Mapper", a small tool for your skin health. Keep your moles in check and share info with your doctor, designed by Ilaria Vitali, Patrizia Bolzan, Mila Stepanovic; "Zero2" a device for patients with respiratory deficiency used to monitor their blood oxygen levels, designed by Tommaso Brioschi, Lorenzo Lanzoni, Giovanni Luca Fidone; "Palpatine", an analogue wearable educational device to learn the correct breast palpation techniques, designed by Francesca Poli, Daniel Sanchez, Benedetta Beltrami, Luca Sommariva, Chiara Parise.

3.2 Next Steps. Co-designing open source walking aids

Table 2. Synthetic overview of the Next Steps initiative.

Level of analysis	Short description
Places (Physical and or virtual)	Fab Lab, university, co-design workshop, online platform
Technologies and enabling tools	Available walking aids, 3D printing, Laser cutting, Electronics, Soldering station,
Kind of solutions developed	Aesthetic and/or functional solutions for the customization and reconfiguration of walking aids
Actors and stakeholders involved	Designers, makers, researcher, patient association (AIG), healthcare company (Sanofi Genzyme), lead users, patients
Distribution	Release of the solutions through CC-BY license; download available on the online platform distributeddesign.eu

In the second year of the DDMP project, Polifactory has once again proposed to work on the issue of healthcare, this time articulating differently the identification phase of the project areas of intervention. The new action, called Next Steps, started from the desire to stimulate designers, makers and patients (as user innovators) to co-design and prototype a collection of open source walking aids that can be distributed through digital platforms and materialized in Fab Labs. Next Steps was developed thanks to the collaboration with Italian Glycogenosis Association (AIG), a patient association that represents people affected by this rare and degenerative metabolic disease. AIG prompted the involvement of patients in the co-design and prototyping of walking aids and for that very reason, the whole project was built around the co-design phase. Thanks to Next Steps, patients were able to experience a real process of patient innovation. Next Steps was articulated in three steps: (i.) the Challenge assessment; (ii.) the Maker in Residence activity; (iii.) the the projects distribution and promotion. During the Challenge phase (i.), from March to May 2019, the starting point was an open call to action that stimulates the engagement of a group of patients that will be involved in the co-design of walking aids together with a team of designers and makers of Politecnico di Milano. During the Challenge phase, the product ideas were presented and shared with AIG, within one of more events. Patient innovators such as Antonella Ferrari[2] caregiver innovators such as Fabio Gorrasi[3] were able to participate in this phase.

From May to September 2019 the Makers in Residence phase (ii.) was held. In this phase patients interacted with the designers who supported them in the development and prototyping of open source walking aids, thanks to the technical and scientific support provided by Polifactory, and the medical and scientific support provided by Sanofi Genzyme.

The last step, the promotion and distribution of the projects (iii.), took place in September and October 2019. As for the previous edition of DDMP, the results of co-design and prototyping were published both on the distribuddesign.eu platform and on the Polifactory's website, and were also presented in Rome during a speech at the European Maker Faire 2019, and in Milan during the Manifatture Aperte event. Reflecting on the previously established co-design phase, an in-depth examination of the type of information obtained by strengthening the involvement of patients and caregivers is reported.

The results of a first survey with the patients from AIG association, the suggestions received by the patient-innovators during the co-design workshop, and the feedback obtained interacting with patients and their families during the AIG meeting evidences aspects that influence the design phase. First of all, the aesthetic dimension of the walking aids is as important as working on functional aspects. Secondly, walking aids tents to become physical extensions of the people; personalization is an important issue because characterizes the identity of the walking aids in order to be tuned with that of their users. Then, Next Steps solutions must be adaptable to the walking aids already available on the market. Last but not least, the digital manufacturing processes and the digital technologies embedded in the walking aids have to be adaptable for DIY, makers and Fab Labs, craftsmanship but also industrial sector. The result was four projects, focusing on different aspects of walking aids. The first project is Twistr, a parametric stick that has developed a design and digital fabrication method to materialize personal parametric sticks – with kinect and grasshopper – having a 3D printed structure. The stick is printed with the carbonium material. Another stick project, this time made with a generative logic is called Taylor. This is a project of a method to create generative sticks, which change according to the weight, height and gender of the user. Another result was the project of an IoT rollator named Wander3d.Thanks to this hacking it is possible to transform a traditional walker into a motorized and sensorized object. The user can activate or not the motors according to the needs. The last project dealt with the aesthetic dimension of walking aids. Clip Clap is a project that allows the personalization of your crutch. This project concerns the co-design of removable clips for all

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[2] Antonella Ferrari is an Italian actress suffering from multiple sclerosis who, acting as an innovative patient, has designed and developed her own collection of hand-decorated crutches.

[3] Fabio Gorrasi is an Italian caregiver innovator who has designed and make a special brace for his daughter affected by Spinal Muscular Atrophy, in order to give her more movement and freedom.

kinds of crutches that can be easily personalized and digitally fabricated. The projects developed will have to be available in open source mode according to the Creative Common License (cc-by and cc-by-sa).

Figure 3. From left to right and from top to bottom: “Twistr”, the parametric stick designed by Angelo De Iesi, Andrea Ascani, Ewoud Westerduin, Aurélie Marie Glaser; “Taylor”, the generative stick designed by Alessandro Ceriani and Marco Ceruti; “Wander3D”, the IoT rollator designed by Leonardo Lucchetti and Silvia Meregalli; “Clip Clap”, the customization of crutches designed by Lorenzo Cereda, Nicola Colombo, Giovanni Cortellessa and Andrea Stefanelli.

4. Designing for Distributed Care. A new scalable model?

The literature review and the experiences analyzed stimulate two levels of reflection.
The first level concerns the key elements of a distributed design and production process for the development of open source solutions in healthcare. The second level concerns the characteristics and properties that define Distributed Care as a possible area of innovation.

The analysis of project experiences in the field identify the following key elements previously highlighted in the summary tables of the initiatives:

- *Actors.* The importance of cooperation between heterogeneous subjects such as designers, makers, but also specialists in the institutional care sector, patients, caregivers and associations. Distributed design stimulates the creation of transversal project teams that participate with different contributions in the development of the final solutions, especially during the initial phase that range from needs analysis and development of the project brief.
- *Places*. The importance of the places where the project development process is materialized. From the initial idea to the final solution distributed design generates a progressive delocalization of the innovation process. In fact, the first phases generally need the support of different "physical" places that function as "facilitators" and aggregators of (Fab Labs, research labs, medical and rehabilitation centers, schools, etc.) where the different subjects involved in the project development have the opportunity to meet, confront each other, work together. The prototyping and design development phases generally take place thanks to the support of a Fab Lab network.
- *Technologies.* The importance of the access and use network of advanced digital manufacturing technologies thanks to which production can be customized, decentralized and potentially close-to-the-user.
- *Distribution/release.* The importance of the concept of "openness" applied to the distribution and release phase of the final solutions. Distributed design makes the solutions accessible and materialize everywhere by downloading digital files from peer-to-peer platforms (e.g. GitHub). The available documentation allows to elaborate subsequent customizations and implementations of the solution, opening the entire design process and connecting it to a distributed production network.

What can we learn from the promising direction of distributed care?

- *Not only medical devices:* Distributed design promotes and stimulates a biodiversity of solutions, exploring the theme of prosthetics, orthosis, medical devices and a new generation of personal objects. Many solutions – especially in the field of healthcare – are influenced by the regulatory system, which is fundamental to protect users and patients. This is a bottleneck for distributed design, but it is also an opportunity. The development of non-medical devices can be complementary to medical ones. Distributed design can support users and innovators to create solutions that demonstrate how existing rules, standards and market barriers could be reconsidered.
- *Not only functional solutions*: Many solutions are designed following functional and technical requirements, but their aesthetic dimensions can be as important. Healthcare objects and aids tend to become physical extensions of people. Aesthetic personalization is important, because it characterizes the identity of objects and establishes a personal or familiarity for users.
- *Not only complex and expensive solutions:* Many objects and devices are complex and expensive. Distributed design can design solutions that can be adapted from

objects already available on the market, taking into consideration open hardware and low-cost technologies that are easily accessible for the everyday user and disadvantaged or vulnerable people.

- Not only new products: Many objects are unique and irreplaceable owing to a relationship that is established with their users and owners. Distributed design perfectly fits with hacking, repairing and upgrading practices and is compatible with remanufacturing and refurbishing processes.

What's next? We could be at the beginning of an augmented concept of 'care' where people can develop a distributed awareness, responsibility and participation in the design of innovative open source solutions that work to take care not only of people, but also other living beings and the environment. This can be Distributed Care.

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