Toolboxes for the Advancement of Responsible Industrial Technologies in 3D Printing in Biomedicine

The Industrial Dialogue workshops produced a number of proposals, which, to varying extent, put RRI principles into practice. It has to be noted that the participants broadly shared and strongly emphasised that responsible innovation depends on an ecosystem of diverse and interacting players. This insight has the consequence that tools for responsible innovation in industry should not be confined to a discrete action taken within a specific company. Rather, it is in multi-stakeholder constellations that a company can cooperate for instance with a hospital and a regulator to address a genuine societal concern. Because of this multi-stakeholder nature of RRI, participants proposed complex toolboxes, rather than individual tools.

The following briefly describes the proposals developed in Munich and Milan.

The service platform in 3DMed toolbox

The toolbox in brief

This tool has been co-designed by a group of participants in the Milan event and aims at developing a web market place where patients share 3D printing product requests that can be screened and selected by physicians, who act as checkpoint actors, and produced by companies. At the same time the platform addresses the issue of RRI compliance and only companies that successfully conduct an RRI self-assessment can gain access to this platform. This toolbox aims at connecting patients' needs to industrial production, fostering the development of personalized devices, according to a physician-mediated process. Successful patients' case stories are also collected on the platform as valuable and inspiring information for further developments of such a multi-stakeholder exchange and collaboration.

How does it work?

The tool proposes a service infrastructure that is accessible to patients/patients' organizations, industry/industries' organizations, research centers, universities and physicians. At the first stage, stakeholders have to fill out a self-registration form (profiling) and to publish either their demand (patients need) or offer (companies product or service). In order to have access to the platform, companies are required to provide a certification that includes an RRI self-check assessment. This means that companies not RRI-compliant cannot access the infrastructure. Further access can be permitted if, after a negative response from the RRI self-assessment, the company starts procedures and initiatives to embark on RRI principles and practice.

Patients or patients' associations classify their needs in: part of body related needs, environmental needs and new solutions. Companies intercept these needs proposing new products and services, which are submitted to a technical review and to a scientific/medical evaluation. Research players as well as other stakeholders (i.e. Fablabs) also participate to the assessment process. If the product is approved, it is delivered to the patients and then described in the platform as a case story in order to inspire further experiences. If the product is not approved by the evaluation group, it can be modified, improved and then re-submitted for a second round of evaluation.

All the products developed thanks to the platform are continuously assessed in an ongoing process. A post sale service is provided by the companies.

Key requirements and open issues

The service-platform in 3DMed cannot work if there is not a broad participation of patients, companies and physicians. Such a service infrastructure requires an initial investment to set-up the platform, to recruit and engage participants. It is not clear who should be the owner and the manager (public institutions?) and what degree of independence between the owner and the participants can be guaranteed.

Once the patient's needs are released on the platform, the selection process of the companies that should answer to these needs is not clear. It was proposed that the patients' association can mediate the process and the "matching" method of needs and products/services. During the discussion on this issue, participants observed that if the competition is based on the means of production, big industries will always prevail over the small companies. In order to facilitate an active role by small and medium enterprises, the focus should shift from the machines to the production process.

Participants also discussed about the benefits of this tool. From the companies' perspectives, the tool can be promising as it can increase their portfolio; it can help them in developing better customized products and it can improve their business. The service platform and the interaction between patients and researchers can lead to the development of new markets. Successful case stories could also inspire ideas to set-up new companies that could easily have access to an already existing broad community.
Some open questions relate to intellectual property issues: the more the products and the processes are open, the better it is, according to the participants, even if they also highlighted that intellectual property rights should be somehow acknowledged.

RRI 3DMed open course toolbox

The toolbox in brief

This tool has been developed during the Milan ID event. It consists of an open training for citizens and professionals on RRI in 3D printing. It is structured as a multi-module, open and blended course to train citizens/activists/patients as well as professionals in 3D printing and related RRI issues. The course is intended to be delivered on-line and off-line both at companies' premises and at makerspaces. The name of the toolbox, according to participants' agreement who have developed the idea, is "3ducare", summarizing the aspects of 3D printing education as well as

the idea of care. The toolbox was divided in two pathways: (1) a professional course that aims at equipping professionals with 3D printing RRI-related skills and competencies, and (2) the development of an awareness programme addressed to citizens on promises and potentials of 3D printing in biomedicine, exploring also the societal impacts.

How does it work?

Professional course: radiologists and imaging professionals, surgeons, and technicians (in particular those who can be impacted by 3D fabrication and manufacturing) need to be trained in technical specificities and competencies of additive manufacturing for biomedical products such as implants or prostheses. These kind of skills are at the cross-roads of several sectors, and consequently comprehensive training is not yet provided by companies or institutions. Moreover, as the application of 3D printing in biomedicine entails several issues in terms of liability and regulatory procedures that are quite new or forthcoming, or open questions on patients' data preservation and ethical concerns, a specific training in these aspects should also be provided to equip professionals in the field with a full and effective range of competencies.

Citizens course: Different actions can be addressed to and organized together with schools and patients' organizations to promote discussions and tinkering activities on 3D printing technologies thanks to hands-on activities carried out in Fablabs, where people can try out how to use 3D printers to produce medical devices and increase their knowledge on the topic. Storytelling activities can be also carried out in neutral spaces such as libraries or museums. Patients and citizens can take advantage of knowing more about such a technology. As increased awareness of the impact and the benefits of 3D printing in medicine, patients might choose hospitals and care institutions that offer this kind of approach. Awareness campaigns and open courses can be a benefit also for companies because knowledge and interest can create a new demand, thus a new market. Touching

points between the two pathways – professional and public training – have been also foreseen.

Key requirements and open issues

The professional part of the tool should be funded by public institutions (at central or local level) as well as by the industrial sector because thanks to such training, companies could improve their chances to hire highly skilled professionals. Since these activities are grounded within local settings, the contribution of local public institutions – i.e. municipalities - is crucial.

Companies, which act as promoters and drivers of the tool, may offer training in hospitals and universities. A similar approach, called Fab Academy[1], by which this toolbox has been inspired, is pursued by the wide community of FabLabs coordinated by the Fab Foundation. The missing part of Fab Academy is the RRI skills and experiences to be embedded in the course.

RRI register of 3DMed cases toolbox

The toolbox in brief

This toolbox has been co-designed by a group of participants in the Milan event. This toolbox is intended as a repository of activities, projects, processes, and actors dealing with RRI (and certified in acting accordingly) in 3D printing in biomedicine. Its main objective is to support the design and development of products in this realm that are affordable and certified. The register is based on RRI principles and on affordability/efficiency basis. It is composed of several concentric layers.
The register works in the context of a niche market where innovation and public funds dominate, in contrast to the mass market that is dominated by private capital. The advantages of being part of the register come with the positive

[1] http://fabacademy.org/ (accessed June 29, 2018)

reputation of belonging to this niche group (i.e. access public funds, trust seed in crowd-funding campaigns). The register is a method to screen technical, economic and social quality of products and processes in 3DMed.

How does it work?

Different players can access the register (i.e. companies, public, clinicians, etc.). A company might have a particularly innovative printing material, another one a specific printer, and a clinical team can be puzzling over a particular problem. Each of these assets compose a layer in an onion-like structure. To access the register, actors earn an RRI score, based on the pillars of RRI – gender, public engagement, science education, open science, ethics. Low RRI score stakeholders can improve their ranking and move towards the center of the register.
The registration helps players to share their information, activities and products. It is public and built on a community of trust. The system helps the participants to locate each other and find synergies between their needs and products.
The registration of 3DMed cases answers the questions such as: What materials are usable? Which printers can work with what kind of materials? Which printer/material can be used for a specific application? Which application is ethical?

Key requirements and open issues

The register needs to be managed by public European authorities or other public actors. The RRI barriers to the entrance can be assessed by applying a sort of key performance indicators (KPI). Even if not fully explained, the register is not only for companies since patients can be represented in the review board that advise on the correctness of the register maintenance.
Some key points need to be further discussed:

- Who is granted access to the system? One opinion propounds that actors cannot enter without a minimum level of responsibility. Another asserts that it is not a certification instrument, but an instrument of information sharing;

- The idea of the registration is to start 'seeding' RRI with a niche market that will be mature as the market becomes a mass market. Participants discussed if 3DMed would become a mass market.
- The registration can be modeled on existing approaches to rare diseases. Small numbers of cases potentially change the notion of evidence-based medicine.

3DMed Certification

The toolbox in brief

This certification toolbox, addressed to the 3DMed field, is one of the outcomes of the Munich event. The participants highlighted the importance of developing a tool for certification of quality to assess the production process of 3DMed products according to specific standards. In fact, 3DMed fabrication and implementation of the final product, developed by a 3D printing technique, cover several stages in which companies and hospitals interact with each other to finalise and deliver to the patients the 3D printed object as a medical aid device. The whole process can be awarded a seal of quality only if it meets the standards. Thus, a "perfect" 3DMed object can be classified as such if it is in line with these specificities. The toolbox can find a concrete application in hospitals and clinical settings and relies on some form of patients' engagement.

How does it work?

The idea of this toolbox revolves around the fact that hospitals act as intermediaries between manufacturers and patients. The toolbox aims at evaluating the whole process of production and implementation (implant or usage) of a 3DMed object. The ethical committee of the hospital is involved in validating the process. Patients, who receive or use the 3DMed device, are involved in the certification process. The certification is valid at the European level.

Key requirements and open issues

To turn this tool into a practical instrument, a certification body is required. Participants clearly identified this toolbox as ISO standard-like even if managed and supervised by a neutral body. There are other check-list tools for industry devoted to medical products and devices, so the risk is that this kind of toolbox could be envisaged by the industrial sector as nothing new or without additional benefits. Moreover, from an RRI point of view, there is no clear understanding how RRI principles are embedded and pursued in such a process and it seems that responsibility is interpreted only as liability and safety.

3DMed Legal Check

The toolbox in brief

The toolbox has been developed by a group of participants during the Munich Industrial Dialogue event. The production chain of additive manufacturing in biomedicine entails different risks at any step of the process. The risks and the related needs to overcome the issues can be summarized as following: 1) securing the rights to use patients' data, such as in a CT scan; 2) manual works of segmenting; 3) 3D model manufacturing; 4) post-processing; 5) therapy (i.e. implantation, delivery, usage). How to assess liability in each of these stages and how many actors can be involved in (and affected by) such a process? This toolbox provides legal guidance along the whole product cycle.

How does it work?

An initial multi-stakeholder conference, in which quality management professionals, health insurance representatives, surgeons, radiologists, pharmacists come together, is needed to negotiate and establish common Standard Operating Procedures (SOPs) for 3DMed. These procedures are not legally binding but act as guidelines for the field. A training for the actors in the sector has to be designed according to the agreed SOPs.

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Key requirements and open issues

The missing part is the voice of patients in such a toolbox. According to the group, patients play a role in starting the process of accepting to use a 3DMed device for their medical treatment, but they cannot actually be defined as active players. Responsibility is understood as reaching beyond legal liability. Hence, the need for such a toolbox emerged as a key request for this interdisciplinary field in which clear regulations and rules are still missing. Nevertheless, it seems rather unrealistic that this kind of tool can be promoted by a single company instead of an industrial association or an independent body, as the group itself had highlighted.

RRI 3DMed information platform

The toolbox in brief

This toolbox has been the result of the co-design exercise performed by a group of participants in the Munich event. In essence, it is a web platform with several features. There is a space to find information on RRI principles and how they can be incorporated in 3DMed, and a room for training materials at different levels. Moreover, a 3DMed materials-repository and a social media space in which the 3DMed community can interact are part of the toolbox as well. The objective of the tool is to favour and spread knowledge and awareness on 3DMed and RRI as well as putting into contact different actors that are interested in such a topic.

How does it work?

Different players can access the platform (i.e. companies, public, clinicians, etc). Companies can have access only if they are RRI compliant. The "whitelist" of RRI virtuous 3DMed firms are listed in the platform so that patients can check who is in or out. An RRI advisory board is foreseen and composed of experts in RRI as well as representatives from all the categories of stakeholders in the field. The board has the duty of supervising the correctness of the platform usage (i.e. it is not allowed to advertise products; it is not permitted to access the platform if not RRI compliant,

etc.).
Material and information within the platform are shared under creative commons licensing. Scientific publications in the field are also available according to open access rules.
It has been underlined that a gender balance in the participants of the platform has to be pursued.

Key requirements and open issues

The platform has to be managed by public European bodies or other public actors. Companies accessing the platform can gain visibility and accountability. The limitation of the platform is that RRI-credibility of the participating companies is not based on their presence on the platform as such, but on the successful RRI certification as a prerequisite to join the platform. The toolbox functions as a collector of RRI 3DMed information rather than a trigger for innovating responsibly.

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Tools proposed for piloting in companies

Selection criteria

During the second year of SMART-map, the project piloted some of the proposals that emerged during the Industrial Dialogues in three companies, one per field (Precision Medicine, Synthetic Biology, 3D Printing in Biomedicine). The toolboxes co-designed by the participants and described above are often characterised by a higher level of complexity than the one that can be achieved during the relatively short timeframe of the pilots. Therefore, the project team analysed both the six toolboxes and the ideas that were put forward during the fast prototyping sessions in order to compile a list of pilotable proposals. The aim was to identify a list of tools that could feasibly be piloted within a company. Tools in this list had to pass three criteria in order to be included to the selection process. These criterias are:

1. Does the tool address a technical question (e.g. the development of a standard for data interoperability)? If yes, exclude.
2. Does the tool contain activities performed within a company? If yes, include.
3. Can the tool be piloted within the budget and timeframe of the project? If yes, include.

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Portfolio of tools

Description	Details	Similar experiences
RRI certification	This tool is a means for companies to enter into a "white list" of responsible enterprises and to increase their legitimacy and trustworthiness. If it can influence the access to funds and awards, it could induce organizational and cultural transformation towards RRI compliance. However, a badly implemented standard might lead to a tick-box exercise, without spurring organisational change. While the function of a certification organ is hard to pilot, a standard's criteria can be implemented in a company for testing purposes.	There are existing examples of RRI or at least of responsible innovation certification, i.e. the UGO certification[2] . Further standards linked to ethical and societal implications of technology are currently under discussion in some specific fields as AI and autonomous systems (i.e. IEEE Ethical Aligned Design Global Initiative[3]).
RRI self-assessment: a check-list to assess RRI compliance for companies	A series of evaluation steps during a research and innovation process can help the companies to keep on track with their wider societal goals. Its potential to foster change depends on the commitment of the company to RRI - the tool per se is not a trigger for	RRI Tools project self-reflection tool[4]. KARIM project's "Introduction to Responsible Innovation Criteria" is a practical guide for implementing RRI

[2] http://www.ugocertification.org/index.htm?lang=ENG (accessed June 29, 2018)
[3] https://standards.ieee.org/develop/indconn/ec/our-ai-vision.html (accessed June 29, 2018)
[4] https://www.rri-tools.eu/self-reflection-tool (accessed June 29, 2018)

Description	Details	Similar experiences
	change.	addressed to entrepreneurs and innovation-support organisations[5].
RRI score: a value oriented assessment tool	The aim is to highlight the value of transformation towards RRI ambitions by providing a concrete ranking system for companies, based on RRI-Key Performance Indicators (KPI).	The MoRRI Project has collected a core set of 36 RRI indicators[6]. TRANSITION project has developed a Social Innovation Journey tool, which comprises a Responsible Innovation Grid[7]. Moreover, some Corporate Social Responsibility standards overlap RRI features[8].
RRI training: a course on RRI principles and practices for the industrial sector	Such training is easy to be implemented but its transformative potential depends on whether RRI is embraced by leadership and reflected in staff performance	CSR departments in big companies. The RRI Tools project has developed some resources for RRI

[5] https://www.rri-tools.eu/-/karim_tools (accessed June 29, 2018)
[6] http://morri-project.eu/reports/2017-04-12-d3.2 (accessed June 29, 2018)
[7] http://transitionproject.eu/the-social-innovation-journey-toolbox-is-now-available-online/ (accessed June 29, 2018)
[8] https://www.rri-tools.eu/how-to-stk-bi-corporate-responsibility-tools (accessed June 29, 2018)

Description	Details	Similar experiences
for professionals as intermediaries between patients, industries and other stakeholders	assessments. Some difficulties in implementation could occur in small companies where the number of employees is low.	training, even if not focused on industry[9].
Multi-stakeholder RRI 3DMed information workshop: a participatory event to inform and exchange ideas and knowledge on the impacts and needs of 3DMed	A tool to build-up local as well as international community around the topic in order to favour exchange of information and best practices, also in terms of rules and regulation needed and bottom-up driven. It does not have a transformative potential within the company.	There are several examples of methodologies and experiences to organize and run multi-stakeholder dialogue events, even if not focusing on 3DMed. For instance, the Co-Construction method developed in the realm of Res-Agora project[10]. Several examples of engagement methods, even if more addressed to the general public, are listed in the Action

[9] https://www.rri-tools.eu/training/about (accessed June 29, 2018)
[10] http://responsibility-navigator.eu/co-construction-method/ (accessed June 29, 2018)

Description	Details	Similar experiences
		Catalogue delivered by Engage2020 project[11].

[11] http://actioncatalogue.eu/search (accessed June 29, 2018)