



# IFMSA

International Federation of  
Medical Students' Associations

## IFMSA Policy Document Responsible Research and Innovation

Proposed by Team of Officials

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## Policy Statement

### Introduction:

Responsible Research and Innovation (RRI) is a framework that aims to ensure equity and sustainability in future Research and Innovations in all fields, including Medicine. While its concept dates way back in the past, RRI started branching in early 2000, with the development of nanotechnology and the rise of concerns around the ethical, legal, and social issues (ELSI) of the Human Genome Project. The EU's Horizon 2020 defined six key agendas for RRI; "engage people and civil society organizations in the Research and Innovation process, gender, science education, open access, ethics, policy-makers duty to encourage RRI". Some of the outcomes of RRI's implementation are tackling Global Health issues and improving the quality and accessibility of Healthcare, but unfortunately, there are still some barriers to its implementation. Holistic and interdisciplinary approaches are needed to address it. Youth have a key role in stressing on its importance and promoting it in different levels.

### IFMSA position:

The International Federation of Medical Students Associations (IFMSA), as medical students representative, considers the future of individual patients and communities at all levels as one of the main priorities. IFMSA recognizes Responsible Innovation in Healthcare's (RIH) role in solving Global Health Issues, achieving Health Equity and contributing to Sustainable Development Goals (SDGs), namely SDGs 3, 5, 10, 12, and 13. IFMSA emphasizes the need for more Research in this field to develop more evidence-based frameworks and regulations on implementing RRI principles in Health Research and Innovation (R&I). IFMSA highlights the need for science education in Medical Researchers, Healthcare Innovators, Medical Students, patients, and all parties susceptible to take action or be impacted by Health R&I. Therefore, the IFMSA calls upon all stakeholders to consider RRI principles in their Healthcare-related Research, Innovations, education, regulations, and governance structures. IFMSA calls for meaningful Youth Engagement in Health R&I policy-making to support more resilient and sustainable Healthcare and Health R&I structures.

### Call to Action:

IFMSA calls on:

#### The World Health Organization (WHO) and Global Health Institutions to:

- Raise awareness and show recognition of the merits of RIH approaches among Health R&I Stakeholders;
- Encourage and promote the inclusion of RRI's value domains, dimensions, and policy keys when discussing Scientific breakthroughs in RIH;
- Collaborate with other Stakeholders to establish universal Frameworks and Strategies for the implementation of RRI value dimensions and policy keys in Medical Research and Health Innovation while taking into consideration the barriers faced by stakeholders throughout the process;
- Coordinate local, regional, and global efforts to advance RIH and develop platforms and events for dialogue, communication, and sharing of RIH Opportunities, Resources, and Breakthroughs between relevant Stakeholders.

#### Governments and Policy Makers to:

- Raise awareness and show recognition of the merits of the adoption of RRI among Healthcare Innovation companies;
- Address the challenges and fulfill the needs of Research institutes and Healthcare industry Innovators upon the implementation of RRI policy agendas in their process;
- Adopt, enforce, and monitor national laws for Research institutes and Healthcare industry Innovators to implement RRI dimensions and critical policies in their process and governance structures;
- Allocate sufficient funds to national health Research programs tackling Global and Public Health issues and SDGs;

- Set and support Research programs to assess the obstacles and needs of RIH implementation and create national Frameworks and Strategies that support Responsible Research, Medical Sciences, and Healthcare Innovation.

**Scientific Societies, Researchers, Research Institutes, and Research Programmes to:**

- Lead Research Projects to identify the obstacles and needs of RIH implementation.
- Collaborate with other Stakeholders to establish Frameworks and Strategies for implementing RRI value dimensions and policy keys in Health R&I;
- Establish governance structures and routines that value and enable the dimensions of RRI and consider the key policies of RRI in their work.
- Ensure balance in gender representation among researchers, increasing access to formal mentorship of women in academic Medicine.

**Healthcare Industry Innovators to:**

- Establish governance structures and routines that value and enable the key policies and dimensions of RRI and the value domains of RIH;
- Consider the societal value of their Innovations in addition to the financial gain;
- Collaborate with other stakeholders to create Frameworks and Strategies for implementing RRI value dimensions and policy keys in Medical R&I.

**Healthcare-providing institutions to**

- Encourage and provide resources for the Science Education of the general public;
- Adopt Responsible Health R&I Outcomes in their Healthcare services and systems.

**Civil Society Organizations, Patient Organizations and Human Rights Organizations to**

- Take an active role in RIH advocacy, its dimensions, and key policies.
- Raise awareness of RRI among Health R&I Stakeholders;
- Create and promote Science Education Material and Resources for the general public;
- Encourage the general public to get involved in the decision-making process of Healthcare R&I;
- Collaborate with Governments, Policy-makers, Researchers, Health Innovators, and other stakeholders to create Frameworks and Strategies for Public Engagement in Health R&I.

**Educators, Universities, and Medical Education Organizations to**

- Raise awareness among Healthcare Students of the benefits of Research Education, Medical Sciences, and RIH;
- Provide quality Research and Science Education to Healthcare Students;
- Involve Students in Medical Research and Health Innovation Opportunities;
- Collaborate with Students and other stakeholders to create Frameworks, Strategies, Material, and Opportunities for RIH and Science Education for Healthcare Students;
- Include RRI components in the Medical curriculum and assess the efficiency, quality, relevance and equity of the resources to ensure Social Accountability.
- Ensure free subscriptions to Medical journals for Medical Students;
- Take an active role in implementing and promoting RRI key policies, especially Open Access and Science Education;
- Create and promote Science Education Material and Resources for the public to enhance their engagement in Health R&I.
- Ensure balance in gender representation opportunities, including women in sponsorship and networking opportunities.

**Students and Student Organisations to:**

- Advocate for including RRI components in the Medical curriculum, quality Research and Science Education, access to Research Opportunities, and Open Access.
- Collaborate with Universities, Medical Education Organizations, and other stakeholders to create Frameworks, Strategies, Materials, and Opportunities for RIH and Science Education for Healthcare Students.

## Position Paper

### Background information:

When the Human Genome Project began in the 1990s, several ethical, legal, and social concerns were raised. Media and politicians feared that a greater understanding of the human genome might be utilized for prejudice, especially by employers and health insurance companies who might refuse to hire individuals or provide insurance to people because of a health concern indicated by someone's genes. [1] The U.S. Department of Energy (DOE) and the National Institutes of Health (NIH) devoted 3% to 5% of their annual Human Genome Project (HGP) budgets toward studying the ethical, legal, and social issues (ELSI) surrounding the availability of genetic information.

In 1994, within the setting of the 4th EU Framework Programme, ELSA (ethical, legal and social aspects) was created as a label for advancing and sponsoring the study of the moral, legal, and social implications of new scientific and technological developments. Later in the 2010s, a new label was forged, namely Responsible Research and Innovation (RRI) [2], to emphasize social-economic impacts (valorization, employment and competitiveness) and collaboration with private and industrial partners. Responsible Research and Innovation is a transparent, interactive process by which societal actors and Innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the Innovation process and its marketable products (to enable the proper integration of technical and scientific advancements into our society). [3]

RRI has become an increasingly important phrase within policy narratives, particularly in Europe, where it is a cross-cutting issue under the prospective EU Framework Programme for Research and Innovation "Horizon 2020".[4]

The European Commission defined more concrete normative practices in the form of six key policies that RRI should develop: Ethics, Science Education, Gender Equity, Public Engagement, Open Access, and Governance[5]. Some Authors mention a seventh policy: Environmental Stewardship[6]. To focalize the concept of RRI and highlight the methodology of its governance and measurable integration in Research and Innovation operations, Stilgoe et al. (2013)[7] developed a framework based on four fundamental aspects: Anticipation, Inclusion, Reflexivity and Responsiveness. These dimensions are integrated in each of the seven key policies to systemize the application of Responsible Research and Innovation. Responsible Innovation in Health (RIH) provides health and Innovation policy-makers with a common framework that supports the development of Innovations that can tackle significant system-level challenges, including sustainability and equity.[8] It alludes to developments that improve our capacity to address shared demands while tackling health inequalities, reduces as much as possible the negative environmental effects of health Innovations over their entire lifespan, delivers high-performing and affordable products, is in line with business objectives through which an organization gives a greater value to users, customers, and society (5 value domains of RIH). Therefore, Scientists are optimistic that RRI and RIH would solve some Global Health Issues and achieve some Sustainable Development Goals and Social Accountability of Healthcare.

However, the different relevant stakeholders encounter multiple challenges to adopt RRI principles in their systems, some of which are the lack of awareness and interest. These issues slow the progress toward the outcomes of RIH and require more collaboration of all involved parties to achieve the enchanted goals.

## Discussion:

### 1. Definitions

**a. Medical Research:** “Medical Research involves Research in a wide range of fields, such as biology, chemistry, pharmacology and toxicology with the goal of developing new Medicines or Medical procedures or improving the application of those already available. It can be viewed as encompassing preclinical Research (for example, in cellular systems and animal models) and clinical Research (for example, clinical trials)”. [9]

**b. Healthcare Innovation:** “WHO defines health Innovation as a new or improved solution with the transformative ability to accelerate positive health impact.” [10] “They can be as simple as changing a form to check out a patient five minutes faster or as complex as an immunotherapy that targets specific types of cancer cells”[11]. We differentiate three types of Healthcare Innovations:

- i. Product: example: A new vaccine or a new treatment.[12]
- ii. Process: example: Digital Health.[12]
- iii. Service: example: A new surgical procedure. [13]

**c. Responsible Research and Innovation (RRI):** According to René von Schomberg, “Responsible Research and Innovation is a transparent, interactive process by which societal actors and Innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the Innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).”[4]

**d. Responsible Innovation in Healthcare (RIH):** “RIH consists of a collaborative endeavor wherein stakeholders are committed to clarify and meet a set of ethical, economic, social and environmental principles, values and requirements when they design, finance, produce, distribute, use and discard socio technical solutions to address the needs and challenges of health systems in a sustainable way”[8].

**e. Global Health:** According to Koplan et al., Global Health is “an area for study, Research, and practice that places a priority on improving health and achieving health equity for all people worldwide”[14].

**f. Sustainable Development Goals (SDGs):** “Also known as the Global Goals, were adopted by the United Nations in 2015 as a universal call to action to end poverty, protect the planet, and ensure that by 2030 all people enjoy peace and prosperity”[15].

**g. Ethics:** According to the Oxford Dictionary, Ethics are the “Moral principles that govern a person's behavior or the conduct of an activity.” **Medical Ethics** are “The obligations of moral nature which govern the practice of Medicine”[16]. The three principles of Medical Ethics are

- i. Autonomy: In Healthcare, people have the right to make their own decisions based on deliberation;
- ii. Beneficence and non-maleficence: Healthcare workers must produce net benefit over harm.
- iii. Justice: Healthcare workers must act based on fair adjudication between competing claims, thanks to an equitable distribution of scarce resources (distributive justice), respect for people's rights

(rights-based justice) and respect for morally acceptable laws (legal justice)[17].

**h. Digital Health:** According to the WHO, Digital Health is “The field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers with a wider range of smart devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data and robotics.”[18]

**i. Artificial Intelligence (AI):** According to the WHO, AI is “An area of computer science that emphasizes the simulation of human intelligence processes by machines that work and react like human beings.”[18]

## 2. Responsible Innovation in Healthcare (RIH) five Value Domains

The primary goal of RRI is to improve scientific production, diversify Research programs, and consider the complexities of the real world. “Responsible Research and Innovation,” as a phrase, can be divided into two, “responsible Research” and “Innovation”, which sometimes might be in opposition or collision since the first may focus more on social and economic concerns and the second one on technical and commercial goals. RRI aims to bring these together[6].

### **Social and Economic concerns:**

As science got more open towards society, both favored the emergence of new approaches but also led to social conflicts and controversies. As a result, it is increasingly being questioned, which leads to broader social tensions and conflicts[19]. RRI could help anticipate social risks and reduce non-social-desirable outcomes[8].

At the same time, it aims for Innovation that requires an informed public ready and eager to debate and legitimation that goes beyond arguments that mainly concern economic growth [20]. Overall, RRI includes a dynamic process leading to socially desirable and socially acceptable ends in science and Innovation. Meeting these asserts should be achieved in a way that is ethically acceptable, socially desirable, safe, and sustainable[21]. More broadly, realizing economic and social value has led scientific institutions to the concept of science meeting societal challenges[20]. Apart from the economic side, there are a lot of curiosity-driven scientists that are working in the field of Innovation. From these, it is believed that RRI was created naturally, following the path that had already started forming the previous years[21].

### **Technical and Commercial goals:**

RRI does not aim to limit commercial activity because Innovations cannot be understood without paying attention to their commercial value, affecting stakeholders’ perspectives, motivations, and contributions. It aims to add value by ensuring that ethical considerations underpin community and societal norms are considered, emphasizing the need for clarity and engagement with stakeholders[6]. It is believed that RRI might be better suited to respond to the multiple challenges and needs of Healthcare systems. The technical challenge that has to be faced in Healthcare is to balance the growth of public health expenses and to provide patients with the best Healthcare while managing the investments and controlling the governance of Innovations in Medicine.

### **How can RIH solve Global Health Issues?**

Following RRI to **RIH**, stakeholders are committed to ethical, economic, societal, and environmental

goals when they develop socio-technical solutions, using a sustainable way to address health system needs and challenges [19].

By applying these, Medical Innovations could be designed to develop a better alienation between the value system and social activities and inquiries in health, understanding the uses of Medical Innovations and their importance, and users being more engaged in the Innovation process[4,19]. According to Silva et al. 2018, the RIH conceptual framework defines five value domains of a total of nine dimensions[8]:

**a. Population health value:** RIH should increase our ability to attend to collective needs while tackling health inequalities[8]:

i. **Health relevance:** seeks to ascertain the importance of the health needs addressed by Innovation within the overall burden of disease, considering the risk factors and **causes of morbidity and mortality specific to the region** where the intended users are located[8]. For instance, based on the Global Burden of Diseases, Injuries, and Risk Factors Study 2015 (GBD 2015), whereas some infectious diseases (such as HIV/AIDS and tuberculosis) represent a substantial burden in developing countries, others (such as bladder and kidney cancers) create a substantial burden of mortality and morbidity in high-income countries. This means that assessments of epidemiological patterns and health system performance help to prioritize investments in Research and development and monitor progress toward Sustainable Development Goals (SDGs)[22].

ii. **ELSI:** Digital Health solutions' handling of patient data has frequently been linked to ethical considerations, specifically **privacy** and **confidentiality** concerns. Some of these considerations are illegal (such as hacking), while others are legal or are not yet subject to legal regulation[23]. The Human Genome Project was also associated with ethical and legal issues as questions were raised about using gene identification to discriminate amongst people based on the diseases they can potentially develop[1]. Although such issues cannot be entirely identified in advance, RIH calls for a careful examination of mitigation strategies that are needed according to the context of use[8].

iii. **Health Equity:** tackles the “capability to achieve good health” among different **social groups** and associates the achievement of health with “broader issues of **social justice** and overall equity”[24]. Current evidence indicates a correlation between Healthcare disparities (accessibility, continuity and comprehensiveness of care) and vulnerability factors, such as poverty, ethnic minorities, incarceration, immigration status and underserved areas[25]. In addition to these factors, vulnerability may also be generated or exacerbated by[8]:

1. health technologies used to legitimize discrimination and social inequalities, as illustrated by the built-in racial bias of the spirometer against black people.

2. new forms of Healthcare that are simultaneously innovative forms of clinical Research (e.g., precision Medicine), which increase the number of complex decisions that have to be made by patients and their Healthcare providers.

3. Healthcare delivery models in which access to services is based on the ability to pay rather than equity, imposing financial barriers and contributing to significant and damaging financial loss. **b. Health system value:** Health Innovation should respond appropriately to contemporary challenges of health systems[8]:

i. **Inclusiveness:** For Klaassen et al., opening up science and Innovation practices to multiple societal actors is important for “democratic reasons and also to broaden and diversify the sources of expertise and perspectives.” RIH should rely on engaging a well-justified set of **stakeholders to achieve inclusiveness**. How their inputs will or will not be integrated into the Innovation should be clear and explicit[8].

ii. **Responsiveness:** recognizes that unforeseen consequences may result from Innovations and that

the context in which they are disseminated may shift unexpectedly [8]. This principle is represented by the ability to develop an answer (response) and react (respond) to external developments caused either by other actors or the natural environment[26].

iii. **Intensity and level of care:** seek to ascertain the extent to which the Innovation is compatible with health system equity and sustainability[8]. policy-makers should encourage Innovations that reduce the labor intensity of care to manage health spending growth better. For example, following the principle of subsidiarity, wherever possible, care should be provided by the most decentralized unit in the system: the patient[27]. Responsible Innovations (in this example, teleMedicine and mobile health units) may lower geographic access obstacles typical in rural and remote areas.

c. **Economic value:** RIH must deliver high-performing, affordable products to support equity and sustainability[8]:

i. **Frugality:** emphasizes the importance of providing **more value** to **more people** using **fewer resources**[8]. Frugal Innovations in health may result from

1. *Lean tools:* simplifying and adapting using current technologies to cut costs and drastically offer everyone access to health advances. (examples: portable electrocardiogram and low-cost bubble continuous positive airway pressure)[28];

2. *Opportunistic solutions:* use of modern, cheap and available-for-everyone technologies to tackle “old problems” (it goes from sending messages to improve adherence to antiretroviral therapy to 3D printers that may alter the availability of Medical devices by enabling almost anybody to produce them)[28];

3. *Contextualized adaptations:* diversion of existing tools for completely different purposes[28] (example: the usage of urinary reagent strips used to evaluate cerebrospinal[29] or synovial fluid[30] in under-resourced environments); and

4. *Local bottom-up Innovations:* refer to original and simple ideas to obtain results not previously attainable[28] (for example: In populations without access to conventional methods of disinfecting drinking water due to lack of resources, or in the case of a disaster, solar water disinfection may drastically lower morbidity)[31].

d. **Organizational value:** business strategies and enterprises should provide value to users, purchasers and society[8]:

i. **Business model:** emphasizes “the rationale of how an organization creates, delivers, and captures value”[32] and tackles the conflict between value capture (i.e., financial income) and value creation (i.e., social output)[8]. Literature shows that companies that are focused on the economic returns of their Innovations produce technologies that cannot be afforded by the health system[33]. Charitable organizations, on the other hand, encounter difficulties in retaining their economic viability[34]. Therefore, hybrid organizations that rely on different, commercially viable business models, such as social purpose corporations, cooperatives, and business non-profits, may be better equipped to support RIH[8].

e. **Environmental value:** RIH should reduce, as much as possible, the negative environmental impacts of health Innovations throughout their entire lifecycle[8].

i. **Eco-responsibility:** stresses the significance of Healthcare's carbon footprint and the effects of health advances on the environment throughout their lifecycle[35]. Hospitals and the areas around them frequently use energy and raw materials and generate various hazardous compounds that might be lethal, infectious, poisonous, or radioactive. Therefore, initiatives to decrease the existing negative environmental effects of health-related activities may be justified, as could the creation of “green” technology[36]. For instance, a new product may be developed without latex, heavy metals, or other chemicals that are dangerous to the public's health or poisonous to ecosystems. When it approaches the end of its useful life, it can be composed of recycled or renewable materials and



constructed in a way that makes it simple to recycle, reuse, remanufacture, compost, or biologically decompose[8].

### 3. The 4 RRI Process Dimensions

To steer the process of RRI, a framework based on four fundamental aspects was developed and generalized by Stilgoe et al. (2013). This framework aims to focalize the concept of RRI and highlight the methodology of its governance and measurable integration in Research and Innovation operations. It was developed to work in a multidisciplinary and multisectoral fashion. The framework consists of four dimensions that are interwoven but with a clear definition of action. The dimensions are Anticipation, Inclusion, Reflexivity and Responsiveness [7]. All are included with the recently proposed acronym "AIRR." These processes are all done in concern of the social, ethical, political, technical and commercial backgrounds of Medical Research and Innovation outcomes. When integrated, these dimensions offer the necessary ethical conduct to Research, Innovation and governance practices. In each of the seven key elements of RRI (described below), each dimension is considered and implemented to systemize the approach of making Research and Innovation more responsible. [6]

#### a. Anticipation:

Anticipating future concerns and consequences offers an important, consequential approach to Research and Innovation. This involves foreseeing and assessing both opportunities and risks that Innovation generates, either in the short-term or long. This process uses prospective tools of analysis that are systemic, so it considers future needs as well of the Medical field. [7]

Anticipation as part of Research and Innovation is of special need to improve Research outcomes and resilience. Since implications of rapid technological and social changes and development are often unpredictable, prompting scientists to plan to the trajectory of their Research actions can limit any produced harms and also explore new paths which can be integrated into their study designs and visions to lead to more desirable impact and wiser use of Healthcare system clinical, human, technological and financial resources. [7]

Healthcare stands as a huge sector in which anticipation is needed due to the high-risk nature of the Research done. Responsible Innovation in Health (RIH) is expected to work for Patient-centered care where the anticipation of patient needs is favored over pushing technological Innovations without catering these solutions to the specific needs. An example of this lack of alignment has been described by Demers-Payette (2016) in his experiment between the needs of Alzheimer patients and technological solutions[37]. Other applications of this approach include work to discover new preclinical possibilities while assessing their impact and social, ethical and political risks [19].

Healthcare workers are highly recommended to consider time a vital factor when doing this predicatory analysis. The analysis should take place early to be impactful to the decision-making and not so early that it affects the accuracy of anticipation. So, to better understand the impact of Medical Research and Innovation, Healthcare workers and scientists must unwrap the possibilities by asking predicatory questions and creating scenarios. [7]

#### b. Inclusion:

RRI relies on Medical Researchers being open to new suggestions and other's points of view. Inclusion challenges the concept of institutional top-down approaches to the Innovation process as it calls for the

enablement of broad public engagement and deliberation even at the early stages of Research development. This gives rise to integrating members of a wider range of the public in the governance of Research and Innovation, ultimately shifting the impact power dynamic across all parties. [7]

Patients' autonomy and involvement in Healthcare decision-making are imperative for clinical practice and its development in RRI. Public participation and attentive contribution have played a proactive part in Healthcare. They are recognized for their advantages in obtaining common ground between producers and consumers of health Innovation, as each of those sides holds a perspective that can be vastly different than the other. Inclusion works to increase Healthcare system value for different stakeholders of the Healthcare environments between patients, physicians, Healthcare center staff and the industry on the opposite side with governments and Medical Innovation producers. [37]

Inclusion applications in the health sector involve the development of new technologies. Users' input is welcomed to enhance the production of products that meet the needs of the patients, staff and doctors and develop their implementation and use. Medical Researchers have involved patients in health technology assessment, drafting guidelines of clinical practice, and community health processes of listing priorities. Demers-Payette has found that Public deliberation on systemic health issues can be highly advantageous. [37]

Practices that ensure inclusion are Consensus conferences, citizen's juries, focus groups, deliberative mapping and polling. The practice of inclusion has met opposition hence the irregularity of its usage and impact. This resistance came from the recognized limitations inclusion has, which to decrease requires criteria. Callon et al. (2009) established three criteria to measure the quality of engaging in public dialogue as a procedure in Research. These three criteria are Intensity (how early members of the public are consulted and how much care is given to the composition of the discussion group), openness (how diverse the group is and who is represented) and quality (the gravity and continuity of the discussion). [7]

### **c. Reflexivity:**

Transparency and unbiased practice of Research methodology are key to obtaining reliable Research. One of the qualities that a Researcher ought to have is being able to reflect and scrutinize their own work and knowing the limitations that the process has encountered. The reflexivity approach isn't exclusive to Researchers and scientists as it also demands institutions to have reflexive capacity while being open to the public. [7]

Critique of one's actions, assumptions and perspectives, as well as the value systems, theories, and conceptions about the moralities of Science and Innovation in itself, is what is needed to build reflexivity. [7]. In Healthcare, this is resembled through socio-political analysis of Innovations and assessing societal norms and value systems guiding Research. [37]

Scrutinizing the social principles of Healthcare gave rise to patients' autonomy and empowerment. Medical Innovations users have reported wanting Research and Innovation to be directed at activating their role in their Healthcare as an issue of dignity. Also, Medical Research development is governed by financial and regulatory contexts, which causes obstacles for both developers and patients, as it's seen that good health problems are prioritized in the Healthcare sector. Working to resolve these issues can only be made possible through questioning individual and industrial activities in Medical Research and Innovation and aligning it with the value systems. [37]

Laboratory-level Research has particularly been exposed to this approach as social scientists and philosophers to help improve scientists' reflection on the socio-ethical side of their work. This proves that an approach is an indicative tool of reflexivity. This also can hold a broader implementation with multidisciplinary collaborations and training. Institutional mechanisms like codes of conduct and moratoriums are also examples of institutional reflexivity. [7]

#### **d. Responsiveness:**

The ability to adapt and modulate Innovations to constant changes in Healthcare and Medicine is what responsiveness describes. As new knowledge and experiences are continuously gained in this rapidly developing field, RRI must meet these updates along with the needs, perspectives and expectations of stakeholders and users of Healthcare. While the other three dimensions work to question processes of Research, responsiveness seeks to take actions to answer these questions and address needs and consequences. [7]

Applying responsiveness makes shaping Medical Innovation's trajectory flexible despite a regulated Innovation environment that imposes structured policies on funding and licensing. This is significant in challenging the status quo of limited public engagement, which has been one of the criticisms of its impact. [7]

Innovation processes in health should be reactive to the diversity of clinical environments and their specificities; for example, one technology might be utilized and useful in one place but not the other. These processes are described as not linear as they evolve, and space and adjustments are inevitable in their trajectory. Medical Research development can adjust throughout the process by incorporating patients' preferences and creating institutional changes. We can understand that responsiveness is also needed in utilizing Innovations and not only process stages. [37]

Not only is Innovation trajectory recommended to be responsive, but Healthcare systems are related to technological Innovations. A challenge facing the sector is that because of these rapid changes and pressures from health professionals to get the latest cutting-edge technology, Healthcare centers face cost control issues. Thus, responsiveness requires creating funding, regulations and audits for Medical Innovations adaptive to and able to mobilize emerging practices. [37]

Responsive RRI should be placed in a political economy of science governance with deliberation on purposes and outcomes of Innovation. Techniques to be used in raising responsiveness are establishing regulations and standards, improving transparency and open access, nurturing diversity, stage-gating and value-sensitive design that formalizes ethical values and embeds them in technology. [7]

#### **4. Key Elements of RRI (Seven policies/concepts): Ethics, Scientific Education, Gender Equity, Public Engagement, Open Access, Governance, Environmental Stewardship.**

The European Commission has provided more concrete normative practices in the form of six policy keys that RRI should advance: Ethics, Science Education, Gender Equity, Public Engagement, Open Access, and Governance[5]. The European Commission does not include Environmental Stewardship as a "thematic" component for RRI. Given the importance placed on sustainability within the six main principles and more widely throughout European and international policy, its inclusion in these recommendations is legitimate[6]. We will explain below how each of these key elements relates to RRI and contributes to solving Global Health Issues and SDGs.

**a. Ethics:**

When designing, financing, producing, disseminating, and using socio-technical solutions to address the needs and challenges of health systems sustainably, stakeholders are committed to clarifying a set of ethical, economic, and environmental principles, values and requirements. This is known as "responsible Innovation in health" (RIH) [19]. Medical ethics is defined as "the obligations of moral nature which govern the practice of Medicine." Ethics is an essential aspect of human Research, especially as regards Healthcare. Responsible Research and Healthcare Innovation aim to birth health practices, treatments, and information that are ethically acceptable, socially desirable, and sustainable. The approaches to developing these activities may differ, but there should be a common characteristic: origin from a set of common moral values and norms.

The first principle of Medical Ethics is **Autonomy**: In Healthcare, people have the right to make decisions based on deliberation. Obtaining informed consent from Research participants is a cardinal aspect of Research ethics[19]. The World Medical Association Declaration of Helsinki states protocols guiding scientific Research involving human subjects, materials, and consequent Research data and animals. It demonstrates that Research should never take over the rights of individual subjects[38]. The Nuremberg code (declared in 1948) states that "the voluntary consent of the human subject is essential." The Tuskegee study of untreated syphilis (1932-1972) is an example of Research carried out with human rights violations and deception of Research subjects[39]. Participants need to consent before taking part in any Research Project. Informed consent for Research requires that the patient or subject be competent to understand and decide, receive full disclosure, comprehend the disclosure, act voluntarily, and consent to the proposed action.

The second principle we describe in this part is **Justice**: Healthcare workers must act based on fair adjudication between competing claims, thanks to a fair resource allocation (distributive justice), adherence to human rights (rights-based justice) and respect for morally acceptable laws (legal justice). Health Justice can be achieved through

- Cost-effectiveness: The National Institute for Health and Care Excellence (NICE) believes that opportunity costs for large numbers of unidentified people should be considered in Healthcare priority-setting decisions. In other words, opportunity costs to unidentified patients must be taken into account in the same manner as benefits to the recognized patients who utilize the healthcare technology in question. Following this strategy, Health R&I would address "Population Health" with a responsibility of "beneficence" towards all the residents they serve to do as much good as they could with the limited resources of the government.[40]
- Non-discrimination: To achieve wholesome societal representation, the inclusion of vulnerable groups is key. Vulnerability in Research is 'when a participant is incapable of protecting his or her interests and, therefore, has an increased probability of being intentionally or unintentionally harmed; this can be due either to an inability to give informed consent or to unequal power relationships that hinder basic rights'. Vulnerability can be extrinsic or intrinsic factors.[40] Extrinsic factors include low-income, low literacy, subordinate subjects like Students, employees and convicts, gender, migrants, orphans, children, elderly, or any condition with the risk of social stigmatization. Intrinsic factors can be due to health status as persons living with a disease(s), people with disabilities, people with impaired mental status, people able to get pregnant and pregnant individuals. Inclusion or exclusion of a participant or subject in Research solely because of association with a vulnerable group is unethical[41]. In addition, The Council for

International Organizations of Medical Sciences (CIOMS) guideline emphasizes 'that unless a good scientific reason justifies their exclusion, children and persons who are incapable of giving informed consent must be included in Research investigations, provided that appropriate safeguards are in place'[42]. AI-based Research uses biased input in all the stages of its algorithmic processes, as Medical Research has been historically focused on white males and excluded females and other ethnicities from the Research samples. AI has been therefore accused of exponentiating existing bias in Healthcare. Numerous Stakeholders have called to adopt inclusive Innovations in Healthcare to ensure the whole population can be benefited.

- Priority to the worse off in terms of both current severity of illness and lifetime health: Health Policy concern must be directed to distribute Healthcare according to need, as the severity of illness is an important component of need. Only by targeting the needs of the population the Health R&I can create socially desirable outcomes and solve Global Health Issues.[40]

The third principle is **Beneficence and non-maleficence**: The principle of beneficence is "the obligation of physicians to act for the benefit of the patient and supports several moral rules to protect and defend the right of others, prevent harm, remove conditions that will cause harm, help persons with disabilities, and rescue persons in danger". Nonmaleficence is "the obligation of a physician not to harm the patient. This simply stated principle supports several moral rules – do not kill, do not cause pain or suffering, do not hinder, do not cause offense, and do not deprive others of the goods of life." [43]

Physicians are obligated not to disclose confidential information given by a patient to another party without the patient's authorization.[43] Following the Research publication, the use of the data generated is an area of interest. Research subjects' privacy and the use of the Research data by enterprises and educational institutions for analysis is a scope of data governance. Ethics is about the practice of Research and the use of Research. Data governance in Research is an insufficient area. Given the increasing use of electronic Medical records in Research and Healthcare in general, there has been an erosion of **confidentiality**. This puts the personal data of individuals at risk of being accessible to a broad number of parties who are not intended and do not need this confidential information. Ethical use of Research published and disseminated is of necessity, particularly in Healthcare AI Research. The development and implementation of data governance regulations are cardinal, by either existing Research ethics bodies or de novo ones[44]. Governments and Policy Makers should establish and enforce local, national, and international legislation to protect personal health information from unlawful, discriminatory, misleading, or harmful usage following the principles of Medical Ethics.

Ethics of Healthcare Research subjects are not only limited to humans but also include animals. Although non-human animal subjects cannot give informed consent, compassion and justice should guide every action carried out on the animal subjects. Reasons for inflicting pleasure and pain should be scientifically justifiable[45]. Some innovative digital methods in Medical Research methods are said to cause less animal suffering (due to organ-on-a-chip and other in-silico applications related to the digital twin of cell cultivation)[46]. This will help produce more ethical basic science Research.

In need of emergency responses, as in epidemics and pandemics, unconventional measures set up to ensure a shorter Research timeline should not compromise acceptable ethical standards. Review by ethical committees should be rigorous[47].

Regular review of ethical laws guiding Healthcare Research helps account for updates and novel

developments in the Research world. In 2008, the Norwegian health Research act was passed to 'promote good ethically sound Medical and health Research and apply to all Medical and health Research on human beings, human biological material or personal health data, including pilot studies and experimental treatments.' However, in 2016, a pilot study surveyed Human Papilloma Virus (HPV) screening in 60,000 female patients was debated on whether it was covered by the act and met ethical requirements[48]. Of thirteen countries of the Middle East (Saudi Arabia, UAE, Qatar, Bahrain, Kuwait, Jordan, Egypt, Lebanon, Syria, Iraq, Oman, Palestine, and Yemen), only ten countries protect informed consent, seven for confidentiality and benefits, and risks of participation, four for Research involving children, and two for Research involving vulnerable persons[49]. A scoping review of the literature featuring Research ethics and Research integrity cases identified Research misconduct involving fabrication, falsification, and patient safety issues[50]. There is no current evidence to support the claim that fundamental ethical principles are applied in many countries that conduct clinical investigations, particularly regarding safeguarding the rights of individuals and the privacy of sensitive material, such as information derived from the human genome. Education about fundamental ethical principles is recommended for Research study participants as a first step in cognitive training in ethics, along with the promotion of ethical behavior to encourage the adoption of reasonable policies in the area of values, attitudes, and behavior, as one potential solution to this issue[51]. The guideline that states that studies that can be carried out in better-resourced countries should rather not be done in developing countries given by the CIOMS is debatable[52]. These show that international and national laws need modification to address the limitations of already existing guidelines.

Healthcare Students and professionals can develop ethical culture through ethical education and training. Ethical training and education should comprise the formal curricula of health-training institutions to build ethical health professionals with adequate knowledge, a proficient skill set, and appropriate habits to implement ethical practices at every stage of Research development. These professionals will treat Research participants with human dignity while promoting good health and well-being. Exposure of Healthcare Researchers to ethical training and education facilitates the application of ethical evaluation[53].

#### **b. Scientific Education:**

There is a need to incorporate responsible Research and Innovation in formal and informal education systems (SDG 4) for all categories of humans. In formal education, the development and adoption of encompassing school curricula and pedagogies at the bachelor and master levels of health education are recommended to incorporate necessary skills for responsible Research and Innovation[54].

#### **Scientific Education of Healthcare Researchers and Innovators:**

In 2018, IFMSA launched a global survey to assess Medical Students' exposure to Research Education and Research opportunities and their satisfaction with Research in their Medical curriculum. The study showed that less than 20% of the participants agree that Research Education is sufficiently addressed in their Medical curricula. Other studies were conducted in Lebanon[55], the UK[56], Saudi Arabia[57], Kuwait[58], Bahrain[58], Pakistan[59], and Nepal[60] to determine medical Students' barriers to getting involved in Research. The main obstacles identified were the lack of mentoring and guidance, the lack of knowledge and expertise and the lack of time. The other barriers noted are inadequate funding, training, skill, and limited access to databases. A few participants reported a lack of interest and motivation in some of these studies, while others did not report a lack of motivation at all.

Undergraduate participation in Research increases the publication output of Medical Schools and the number of Researchers in countries with a lack of workforce. It fosters the Students' Research Competencies to produce quality Research projects[61]. It is, therefore, important that Medical Schools, Medical Education Organizations, and Academia converge efforts to create Research Opportunities for Medical Students and provide them with the necessary Academic and Financial resources to get involved in Research. IFMSA has developed the Basic Research Competencies Framework[62] (BRCF), a systematic approach to the essential competencies every Medical Student should have to develop the standard skill set in Research and shape the Medicine of tomorrow. It includes five pillars, with each englobing a set of key Research Skills:

- Investigator:
  - Scientific Inquiry
  - Literature Review
  - Critical Appraisal
  - Evidence-based Medicine
- Analyst:
  - Study Designs
  - Methodology
  - Data Collection
  - Data analysis
  - Statistics
- Author:
  - Publishing
  - Presentation
  - Citing
  - Open Science.
- Collaborator:
  - Partnership
  - Autonomy
  - Communication Skills
  - Project & Time Management
  - Leadership
- Professional:
  - Safeguards and Integrity
  - Ethics
  - Good Scientific Practice
  - Responsible Research and Innovation

Following the same perspective, IFMSA, through its Standing Committee on Research Exchange (SCORE), offers over 3000 Research projects to provide annually over 8000 Medical Students worldwide with the opportunity to participate in the IFMSA Research Exchange program. This opportunity allows participating Students to develop numerous Research Skills. SCORE has also created its "Research Resource Database," [63] a compilation of numerous free and easily accessible resources that Medical Students can use to develop their Research Competencies based on the BRCF. This Database includes Educational Activity Resources made by SCORE that tackle: Basics Principles of Medical Research, Research Methodology and Study Designs, and Critical Appraisal.

To suture the existing gaps in Research Education, IFMSA has also developed three Research Education-related Workshops:

- **Research Camp:** a three-day workshop focused on Research Competencies based on the BRCF. Experienced and qualified Medical Students and Research experts facilitate the sessions.
- **Training New Research Trainers (TNRT):** a three-day workshop addressing both Trainers' Education and Research Education based on the BRCF to create a new generation of Medical Students who can teach their peers about Research Research Education topics.
- **Research Education: Advancement and Development for Youth (READY):** a three-day workshop focused on Research Education based on the BRCF and Youth involvement for Research in Global Health, SDGs, and Universal Health Coverage (UHC).

### **Scientific Education of the Public:**

Introduction to Responsible Research and Innovation as early as secondary school education initiates early involvement and engagement of the Public in Healthcare R&I-related decisions. Early introduction and engagement of responsible Research, especially in formal education systems, provides the advantage of life-long adoption by index stakeholders; and consequently at institutional levels[51]. However, Scientific Education directed to Students should not be about transmitting “facts” that scientists have discovered about the world because this classical approach causes misunderstanding and false scientific judgments about Health Issues. Science Education should:

- provide all adults with an ability to investigate scientific problems as scientists do, using logic, experiment, and evidence;
- provide all adults with an understanding of how the scientific enterprise works – and why they should therefore trust the consensus judgments of science on issues like smoking, vaccination, and climate change;
- provide all adults with the habit of solving their everyday problems as scientists do, using logic, experiment, and evidence.

For instance, a collaboration between the Smithsonian Science Education Center in Washington, DC, and the world's science academies aimed to mobilize local scientists and other volunteers in each nation to educate and inspire young people to use science to enhance sustainability. Based on the science behind the 17 UNSDGs, extensive sets of free materials are being designed to enable Students first to examine a global problem, next to actively explore this problem using their local environment as a laboratory, and finally design a community action plan to address that particular issue in their community.[64]

Through holistic education, stakeholders can learn how to incorporate the other key elements of responsible Research and Innovation in practice.

### **c. Gender Equity:**

Diversity and inclusion are important in responsible Research and Innovation. Gender equity (SDG 5) is key in both the content and process[17]. Balance in gender representation portrays inclusivity and credibility of results and ideas. Critical analysis of the similarities and differences across all gender enables the development of gender-specific solutions which precisely meets societal needs. Lack of consideration for gender differences in Research hampers necessary Innovation[65].

Stakeholders and reviewers involved in responsible Research and Innovation must also be aware of gender diversity and inclusion. Training, when necessary, is functional[65].

### **Gender Equity among Researchers and Innovators:**

Gender discordance is seen across multiple aspects of Research, including authorship, editorship, peer review, grant receipt, speaking and leading[66], particularly for women in low-income and middle-income countries[67] and women with intersectional identities, such as those who identify as Black, indigenous



and women of color. Some of the barriers identified by Literature include excessive family obligations, excessive demand for clinical care, discrimination based on gender, sexual harassment, and the gender wage gap[66]. The lack of representation of Women in the R&I design and decision-making leads to non-inclusive R&I outcomes and excludes women from benefiting from quality Healthcare. This is against the inclusivity dimension of Responsible Research and Innovation and makes Science far from being socially desirable and targeted to the whole population. These gender disparities should be addressed by increasing access to formal mentorship of women in academic Medicine, including women in sponsorship and networking opportunities, providing support for parents of all genders, including supportive parental leave policies and flexible work models, supporting women materially to attend formal educational conferences targeted to women in science. The display of a clear intolerance for sexual harassment and discrimination drives cultural change[66].

### **Gender Equity among Participants:**

In Research design, study implementation, scientific reporting, and general science communication, sex and gender disparities are frequently ignored[65]. Male subjects (cells, animals) still dominate in preclinical Research, and it has detrimental consequences for women's health and the quality of science. Opposite bias exists for data obtained mainly in animal models utilizing female subjects (e.g., Research in multiple sclerosis and osteoporosis) with skewed outcomes for men affected by these diseases. For instance, these biases have led to the failure of a designed treatment that works perfectly well for men but does not work for women. The reported rate of adverse drug effects is also higher for women[68]. This supervision restricts how broadly study findings can be applied to clinical practice and compromise half of the population. The SAGER (Sex and Gender Equity in Research) guidelines, an initiative of the European Association of Science Editors, provide Researchers and authors with a tool to standardize sex and gender reporting in scientific publications[65]. They were designed to improve sex and gender reporting of scientific Research, serve as a guide for authors and peer-reviewers, be flexible enough to accommodate a wide range of Research areas and disciplines and improve the communication of Research findings:

- General principles
  - Authors should use the terms sex and gender carefully to avoid confusing both terms.
  - Where the subjects of Research comprise organisms capable of differentiation by sex, the Research should be designed and conducted in a way that can reveal sex-related differences in the results, even if these were not initially expected.
  - Where subjects can also be differentiated by gender (shaped by social and cultural circumstances), the Research should be conducted similarly at this additional level of distinction.
- Recommendations per section of the article
  - Title and abstract: If only one sex is included in the study, or if the results of the study are to be applied to only one sex or gender, the title and the abstract should specify the sex of animals or any cells, tissues and other material derived from these and the sex and gender of human participants.
  - Introduction: Authors should report, where relevant, whether sex and/or gender differences may be expected.
  - Methods: Authors should report how sex and gender were taken into account in the study's design, whether they ensured adequate representation of males and females, and justify the reasons for excluding males or females.

- Results: Where appropriate, data should be routinely presented disaggregated by sex and gender. Sex- and gender-based analyses should be reported regardless of positive or negative outcomes. In clinical trials, data on withdrawals and dropouts should also be reported disaggregated by sex.
- Discussion: The potential implications of sex and gender on the study results and analyses should be discussed. If a sex and gender analysis were not conducted, the rationale should be given. The authors should further discuss the implications of the lack of such analysis in interpreting the results.

#### d. Public Engagement:

According to the World Health Organization, to offer better health for all (SDG 3), it is imperative to increase stakeholder participation and bring people into the foreground by organizing health services around people's needs and expectations. The role of patients in Healthcare Research has received increasing attention, and it is considered imperative for promoting Medical Innovation and improving Healthcare quality [69]. Yet, there is limited evidence of the extent of the actual involvement of patients in Research and Innovation conducted by Medical equipment manufacturers.

The Agency for Toxic Substances and Disease Registry (ATSDR) of the Centers for Disease Control and Prevention (CDC) define five strategies of Community Involvement:

- **Outreach:** Researchers provide Community Stakeholders with information.
- **Consult:** In addition to informing, Community Stakeholders provide feedback to Researchers.
- **Involve:** Both entities cooperate and secure more participation with the community on issues.
- **Collaborate:** Forms partnerships with the community on each aspect of the project from development to solution
- **Shared Leadership:** Final decision-making is at the community level.

Community Involvement, Impact, Trust, and Communication Flow increase from *outreach* to *shared leadership*[70].

However, studies have shown differences in the usage of the terminology among Researchers and nonacademic stakeholders. Thus, there is a need for future Research to harmonize among patients, healthcare providers, Researchers, and funding agencies, mindful of encouraging continued Innovation and diversity in approaches[71,72].

Furthermore, the literature shows that decisions about Research and Innovation in the Healthcare industry are made internally in the company with limited involvement from other stakeholders. Patients are involved only at the final stages of product development to provide feedback and to report their satisfaction regarding the product. The finding that patients are not involved at all in the early stages of the Research process when Research is designed is troublesome, given that there is evidence of a relationship between the involvement of patients early in the Research process and the quality of the health care that is provided[69].

Whereas the private sector seems to not meaningfully involve the community in the development of its health Innovations, some Research funders have advanced active engagement of patients and other stakeholders, particularly in Canada, the United States (US), the United Kingdom (UK), and Australia[71].

#### e. Open Access:

To foster Innovation as part of the Responsible Research and Innovation (RRI) movement, the practice of 'open access' must be discussed. Open Access (OA) is the unrestricted right or opportunity to use or benefit from information, particularly Research output[73]. RRI and OA encompass two co-existing

ambitions for systemic change in creating transparency and inclusivity (SDG 16). Furthermore, they offer a prescriptive nature on how to conduct Medical Research. With the increased accessibility of the internet, OA has presented the ability to improve scientific Research and facilitate fast Innovation. Currently, costs of inaccessibility have troubled Researchers from low to middle-income countries. A study observed that providing access to a few thousand journals increased the publication output in those participating countries by 29% [74]. Hence it is imperative to discuss OA as a mechanism to deliver RRI better – as it fosters growth and more Innovation.

Open Access has been exercised since the 1970s, with Researchers wanting to publicize their Research for minimal costs and greater accessibility. Costs of printing and the rate of inflation ironically reduced access to scholarly papers across the Research community. As a result, institutions such as Libraries and Archives suffered financially, leading to coalitions being created to pursue alternatives[75]. OA journals came into existence subsequently; however, it was not until 1994 that the Subversive Proposal led to the practice of self-archiving by Researchers[76]. The increased demand for self-archiving and Medical Research distribution led to the American Science Open Access Forum in 1998 [77]. In 2001, the Budapest Open Access Initiative was formed and subsequently, they defined the practice as 'Open Access [78]. OA has not been without its challenges, as it rested on a model of ideals. Subsequent sections will discuss OA concerning RRI.

Open Access and RRI align in key areas, for example, with an emphasis on Research integrity. Opening access to Medical journals and Research can strengthen the culture of Research integrity. As Research is in the public domain, higher scrutiny and reduction in unethical actors are possible. This is known as intelligent openness, which refers to accessibility, intelligibility, and scrutiny to enable the reliability and competence of scientific claims [79]. OA supports the need to prevent the unnecessary allocation of resources which bears little to no benefit to society. Opening up access to data and results enables greater reproducibility and discourages falsification and plagiarism. This echoes the position of RRI in defining priorities and concerns surrounding unethical practices that can be addressed through OA. RRI aims to facilitate solutions to complex challenges, whereas OA addresses the general effort to improve capacities in Medical Research activities. The issues concerning Medical Research stem from systemic failures, indeterminacy, and complexity, which are at the heart of societal challenges. The authoritarian nature of RRI benefits from open access to Medical Research, as it calls to attention the need for science to adapt and encourage interdisciplinary collaboration [80].

The use of OA by Researchers may be a solution, but it also adds to the problem of notoriety. Research has historically been underfunded, and the allocation of resources has been hotly debated. This creates a cycle for Researchers, focussing on increased Research output rather than the quality of Research. Through increased Research output and impact, metrics are calculated and, as a result, are noticed by prominent journals and institutions. A key reason Researchers see the benefits of OA is that it provides increased exposure. Prestigious journals and their scrutiny of peer-reviewing may force Researchers to look towards OA Journals. Through this lens, Researchers hope their Research is freely available for everyone to see and be noticed by entities with rich resources to share. In theory, the unintended benefit is access to information by the general public and Researchers looking to collaborate. However, this can bring dire economic consequences.

The inherent model of OA is unsustainable without the help of funding bodies. With the introduction of the internet, prestigious journals have moved from printing to online formats. As a result, this has

allowed Research to be easily accessed through online databases but behind a paywall. In 2015, over 50% of all 37 publications were behind paywalls [81]. Academic journals are lucrative businesses that need to pay for their expenses. Hence this is not out of the ordinary. Quality control, wages of peer-reviewing editors and marketing are among the many expenses academic journals need to meet. This determines the quality of Research being published and the secured trust of the general public. For an OA journal to operate similarly, they cannot rely on barriers such as paywalls to fund their bills. The average production cost for one Research article is less than €3379 [82]. A study noted that journals could increase their profits by six times [83]. Furthermore, the need for peer-reviewing is fundamental for quality, which is why many Research skeptics discredit OA journals. This, as a result, places further limitations on Researchers who want to increase their research publicity. Solutions have existed with traditional journals where universities, institutions and even individuals have given into a subscription model to access articles. This has allowed Researchers attached to those institutions to access available Research freely, but this also has limitations. Institutions are left subscribing to multiple journals that may not house every Research. Hence they need to pick and choose which can be of high impact. But as mentioned earlier, prestigious journals also determine which Research can be published and do not see the significance or fit the journal's ethos. This is not to mention subscriptions can be costly. Hence, institutes must allocate their funds carefully to their Research efforts [84]. To navigate the economics of article publishing, OA Journals have looked into charging Researchers for submitting their Research to their journals. This has been known as Gold Open Access.

Gold Open Access may solve the rising costs of journals delivering accessible Research. However, this comes with questions of sustainability. As mentioned earlier, the financial stability of a journal has been one of the key drivers of limitations to adopting complete OA. Hence, Researchers looking to publish their Research may pay a fee for their article to be published in prospective journals [84]. Firstly, this creates a financial disadvantage to Researchers and favors laboratories that can afford to spend article processing charges (APCs). Marginalizing Researchers through making financial commitments that are looking for Research grants to bolster their Research efforts does not fit into responsible Research and minimizes Innovation. Secondly, questions can be raised about the quality of the Research. Because OA journals are incentivized through APCs, they may be more inclined to publish Research without proper vetting. A further issue with publishing articles is the long wait for traditional journals to peer review and publish. This can take many years and reduces the recency and access of the article. This has led to predatory OA journals coming into existence. These 'predatory' journals act based on OA, promising rapid processing – which inadvertently removes industry standards and editorial reviews[85]. This, again, is against the principles of RRI. Furthermore, the impact metric of OA is in question in traditional journals. So, Researchers are cornered to seek out traditional journals.

Even though OA has presented ethical concerns of reliability and sustainability, the introduction of government interventions and funding agreements can mitigate challenges. Studies have reported that OA articles are cited more than non-OA papers. This can range from 36% to 172% more [86]. This notes the accessibility of OA articles and greater dissemination of information. This has also seen greater media coverage beyond Research, as Nature Communication reported, to have 2.5 to 4.4 times more page views than non-OA papers [87,88,89]. Responsible Research also means educating the non-Medical community, and OA Research allows for this – for example, rising against misinformation through reputed OA Research. However, the challenge remains in improving the validity and the costs of peer-reviewing. The importance of OA Research is slowly being seen by governments allocating funding to journals to create journal articles freely accessible online without paywalls but also fund internal

operations such as peer reviewing. A notable initiative brought together several European countries to negotiate with leading publishers, especially after the Berlin Declaration on OA to Knowledge in the Science And Humanities. The Green Open Access Model was one of the two principles from this declaration (the other being Gold Open Access). Authors published in an established traditional journal then self-archive this in an OA website after 6-12 months from publishing [90]. The United States passed a bill in parliament mandating this initiative for the National Institutes of Health to ultimately have their articles freely accessed on their OA repository Pubmed Central [91]. However, as discussed – the recency of Research is important and improving visibility is a fundamental core of Innovation. Hence to negotiate economic costs, the DEAL project was set up in Germany in 2014 and further agreements by European countries in 2018. The aims of the DEAL project seek to promote OA principles but, importantly, negotiate fair publication fees to cover publication costs [92]. Furthermore, there is a need for discounts and waivers for publications in developing countries. Hence a move towards public funding through governmental and institutional (universities, scientific societies, charities etc.) can help promote OA Research and still maintain the industry standards of traditional journals [93].

In conclusion, enabling OA as a framework within RRI is vital to ‘opening up’ Medical Research, emphasizing innovative use of technology, and welcoming greater quality control through scrutiny. Open access may solve societal challenges RRI set out to achieve and bolster greater output, as collaboration is universal.

#### **f. Governance:**

One of the reasons why responsible Research and Innovation have emerged is to integrate ethical and social values into policy and governance Research and Innovation processes.[94] To ensure successful public policy, it is necessary to improve the vision of governance and implement responsible Research and Innovation in its processes. It all translates into ensuring the quality of policy actions based on topical Research, academic theorizing and practitioner narratives, engaged Researchers, societal challenges, excellent science and the funding of such actions.[95]

Regarding governance in RRI, there are three commonly used models to discuss, which focus on the engagement and involvement of different stakeholders; Standard, Consultation and Co-construction. Some of the discussed levels for governance can be

- Researchers and Research Institutions: At this level, gaps and opportunities can be identified, and new milestones can be set to ensure the plan's effectiveness. This can not be achieved without raising awareness and ensuring shared outcomes.
- Commercial Bodies and Investors: They can ensure onboard change within the process and support Researches that follow the policies.
- Professional Bodies: Here, implementation of RRI perspective within training and postgraduate education activities can be done. By this, they can bridge the gap between different professions to have collaborative opportunities.
- Government and Regulatory Bodies: They can support RRI by ensuring the inclusion of relevant necessary regulations within high-level regulations.
- Individuals and Communities: Bring both-sided trust by ensuring the community's health as they have followed relevant ethics and policies. [6]

#### **g. Environmental Stewardship:**

The impacts of pollution on human health, mainly due to greenhouse gasses, are well known. Therefore, if sustainable Healthcare facilities are to be achieved, actions in infrastructure and Healthcare processes

must be improved to emit a smaller carbon footprint (SDGs 12, 13). [96]

Thus, it is important to monitor the environmental impacts of Healthcare and invest in internationally comparable strategic metrics. This will help to create a safe, low-carbon Healthcare system.[97]

## 5. WHO's stance on RIH

“Using its role as a leader in public health globally, WHO works with Member States and partners to increase awareness, prevent and mitigate the risks posed by dual-use Research and establish and/or leverage on existing mechanisms to adopt changes in practice to support the responsible use of life sciences”[18]. Through its science division, the WHO uses the power of Innovation and science; it offers global leadership in utilizing the most reliable scientific data to advance universal health equity. WHO's mission is to ensure that Member States can utilize cutting-edge Research and technological advancements to accomplish health-related Sustainable Development Goals. The WHO's science division priorities are

- Forward-looking and prioritized global health Research: Research must be demand-driven and contextually sensitive.
- Timely and evidence-driven norms and standards updated in real-time: to bring the best science and evidence to inform best practice setting norms and standards and make accurate scientific information accessible.
- Adoption and scale-up of Innovation and digital health: harnessing the power of digital technologies and Innovation to accelerate the global attainment of health and well-being[15].

Research on health Innovations has focused on single or discrete interventions, most often in low- and middle-income countries. There needs to be more guidance on how to scale up Innovations addressing more complex and multifaceted challenges. Several examples of innovative service delivery approaches in high-income countries have spread beyond the demonstration stages and benefited broader populations. Examples include ParkinsonNet in the Netherlands or the roll-out of a standardized service for treating moderate depression and anxiety in primary health care in the English NHS.

A systematic review of the theoretical and empirical evidence on the spread of Innovations in health services was carried out, which developed a conceptual model which identifies a range of components of the successful adoption, implementation and sustaining of Innovation in health service delivery which is:

- Characteristics of the Innovation: This includes the relative advantage this change provides to its environment, its compatibility with the pre-set conditions and its complexity.
- Characteristics of the adopters: This includes the needs, motivation, values, goals and skills of the intended adopters of this “change.”
- Organizational antecedents: The structure of the organization and how absorbent it is towards new information and knowledge[82].
- Diffusion and dissemination: Its ability to share information through social networks and influential personnel.
- Implementation process: Have stable external collaborations and internal communication with reserved resources, all within devolved decision-making
- Organizational readiness and broader system context: that relate significantly less to Healthcare than the other.

The factors described in this brief represent those identified through an intensive literature review. There

is an urgent need for longitudinal studies that systematically evaluate the introduction of service Innovation to Healthcare over time to understand better the impact of those factors that have so far received less attention[98]

## **6. Barriers Facing RRI**

Responsible Research and Innovation is a relatively new concept in the Research world; its implementation, therefore, faces several barriers that hinder or work against the uptake and usage of RRI and make relevant bodies reject or de-prioritize it[99]. Identifying, isolating and solving said obstacles is essential to create a concrete path forward.

Some of these are

### **a. Lack of knowledge and awareness**

But it is likely to affect the perceived relevance of RRI. In short, the message of RRI and what could be facilitated through the concept is unclear for most Research funding and performing organizations outside a limited group of dedicated stakeholders close to EC science policy. Adding to this barrier is the problem of a lack of conceptual clarity that may hamper diffusion, particularly to the academic community, alongside a perception that several other concepts may be doing the same work, such as sustainability.

### **b. Perceived dominant ideas on academic excellence and Innovation**

Traditional ideas of academic excellence are built on pure curiosity-driven Research, discovering new knowledge, and pursuing truth. It is built on the concept that the Research process governed internally by an autonomous scientific community, unhindered by external agencies or stakeholders (such as ethics boards or governments), which are seen to affect scientific freedom to pursue progression, is more beneficial to the community. This reasoning means that science is an activity judged predominantly from the viewpoint of scientific merit, where merit is the discovery or generation of new knowledge. In some countries, particularly those where academic freedom is taken as a given, there is fear that RRI may give governmental bodies a pathway to influence science and possibly science outcomes unduly.

### **c. Perceived lack of interest and pressure from society as a whole**

For instance, many reports mention that the wider public is perceived as uninterested in what organizations do in science education, process dimensions, and ethics. In other words, a few external pressures, such as dedicated policies or funding schemes, prioritize aspects of the RRI concept.

### **d. The general problem of translation.**

Skilled science translators to broader audiences are not available and must be sufficiently equipped. This is pronounced in science education but also appears as a barrier in other keys where communication to broader audiences outside the science field is required, such as public engagement and some process dimensions[99].

## **7. Social Accountability**

Back in 1995, WHO defined Social Accountability (SA) as "The obligation to direct universities education, Research and service activities towards addressing the priority health concerns of the community, region, and/or nation they have a mandate to serve. The priority health concerns are to be identified jointly by governments, health care organizations, health professionals and the public." SA has four main

values: equity, quality, relevance, and efficiency. It can not be achieved without partnership among stakeholders, including health administrations, the community, policy-makers, health professions, and academic institutions. SA can be seen in three levels; micro (patient level), meso (community level) and macro (connecting politics to public policies). Considering mentioned definitions, social accountability in RRI assessment can be discussed in different forms. Efficiency or evaluating that resources for RRI have been spent in a cost-benefit way, quality or assessing the RRI performance to check if the organization meets a certain minimum level of it or not.

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