ADVOCACY FOR RESPONSIBLE INNOVATION IN HEALTH

An illustrated booklet for innovation ecosystem actors in Quebec and elsewhere in the world

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In Fieri

FOR RESPONSIBLE INNOVATION IN HEALTH | POUR L'INNOVATION RESPONSABLE EN SANTÉ | PELA INOVAÇÃO RESPONSÁVEL EM SAÚDE

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1. Introduction

Why Responsible Innovation in Health? And why now?

Innovation is generally seen as beneficial [1], and the term "innovative" is almost always praised without qualification. This is especially true for innovations in health. By improving our individual and collective health, doesn’t every health innovation have a positive impact? Not to mention the fact that in the health field, strict industry rules ensure that drugs and health products meet established criteria of effectiveness, safety, and quality before hitting the market.

However, the question we ask ourselves is whether the criteria of effectiveness, safety, and quality remain sufficient in the face of growing pressures on the sustainability of health and social services systems. Too many highly specialized, expensive, market-driven innovations not only have a significant ecological footprint, but also do not contribute to overcoming pressing 21st century challenges, including an aging population, the preponderance of chronic diseases, climate change, natural disasters, and the emergence or resurgence of infectious diseases.

The COVID-19 pandemic was a stark reminder of how ill-prepared and ill-equipped we are to deal with events of this magnitude, which are likely to be repeated in the years to come. The crisis also shone a spotlight on innovation blind spots, including unpredictable and vulnerable supply chains, restrictive intellectual property laws, and a business logic preceding over people's needs.

Therefore, we believe that the time has come to innovate "in" innovation so that new health innovations can better meet the current needs of health and social services systems, here and elsewhere in the world. This is the goal of Responsible Innovation in Health (RIH), which aims to increase our capacity to respond to collective needs and challenges.

With this illustrated booklet, we wish to inspire people who are interested in or contribute to the development of health innovation here in Quebec or elsewhere in the world. With the help of eloquent examples (and counterexamples when useful), we present nine responsibility attributes that can guide the development of responsible health innovations or assess the degree of responsibility of existing solutions.

An innovation may solve a problem in a novel way, combine novel components, materials, or social interventions, or propose new processes of production, distribution, commercialization, or delivery. Its innovative character is assessed in relation to its context of use.

The In Fieri team

Through the In Fieri research program, our team examines how alternative entrepreneurship models and impact investing can support the design, commercialization, and institutionalization of RIH. Since 2015, our research aims to provide solutions that contribute to the common good embodied in health systems.

We are affiliated with the Centre de recherche en santé publique (CReSP) of the Université de Montréal and our work is directed by **Pascale Lehoux**, full professor in the Department of Health Management, Evaluation and Policy, and funded by the Canadian Institutes of Health Research (CIHR).

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Writing and graphic design: Catherine Hébert








Note to readers

In Fieri developed the RIH Assessment Tool to determine whether an innovation can potentially be qualified as responsible, and if so, to assess its degree of responsibility. This Tool does not determine whether an innovation is "irresponsible." However, the scientific literature on corporate social irresponsibility is sufficiently clear and leads us to exclude innovations produced by organizations that have committed legal or illegal acts that could harm people, animals, or the environment.

An online Guide helps users apply the RIH Assessment Tool, and we invite you to review it.

We also specify that our team has not formally assessed the degree of responsibility of the innovation examples shared in this document as they serve to illustrate the concepts behind the RIH attributes and should be understood as such.

Finally, our research team does not have collaborative, personal, or commercial relationships with any of the innovations or companies presented in this document.

2. RIH value domains

The number of innovations being introduced into health systems continues to grow: 3D printing, robotics, artificial intelligence, and mobile apps are just a few examples. How do we know if a health innovation is "responsible"? And how do we reliably measure its degree of responsibility?

With these questions in mind, the In Fieri team developed the RIH conceptual framework and its Assessment Tool. They are designed to guide the work of individuals and organizations who shape the supply of health innovations. These include research funding agencies, technology transfer offices, and incubators. The Assessment Tool is also intended to guide decision makers who influence demand through procurement policies, coverage and reimbursement decisions, and health technology assessment agencies, among others.

The RIH framework was developed through an iterative process comprised of two main activities. First, a multidisciplinary analysis of the **scientific literature** allowed us to identify key concepts, dimensions, and indicators that could be applied to RIH. We also conducted a **web-based horizon scanning** to identify a large number of innovations with different responsibility characteristics. Based on this theoretical and practical approach, we define RIH as follows:

WHO RIH consists in a collaborative endeavor wherein stakeholders are committed...

WHAT ... to clarify and meet a set of ethical, economic, social, and environmental principles, values, and requirements...

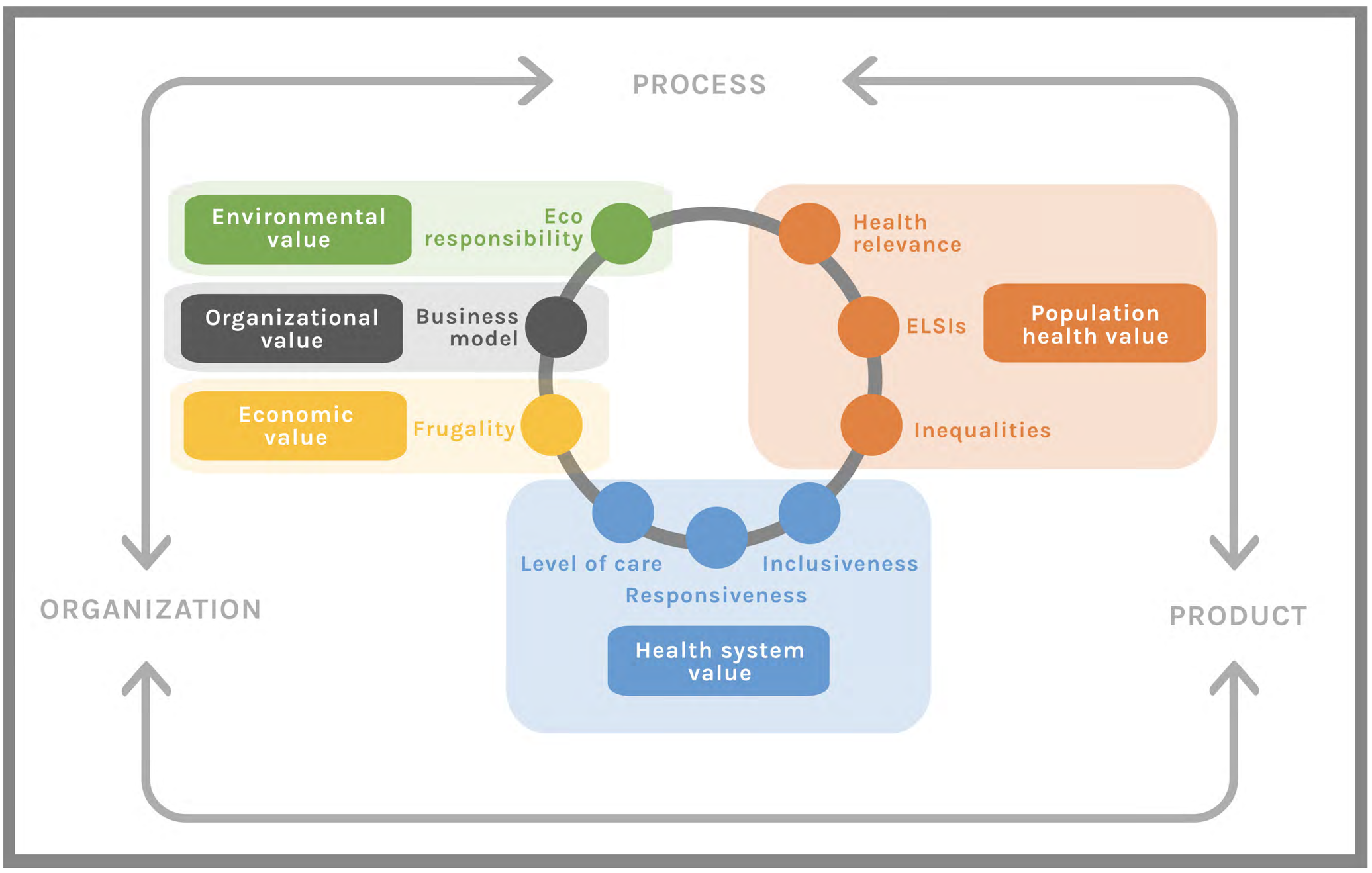
WHEN ... when they design, finance, produce, distribute, use, and discard sociotechnical solutions...

WHY ... to address the needs and challenges of health systems in a sustainable way.

The RIH framework includes nine attributes that assess the degree of responsibility of an innovation. They are organized into five value domains that aim to:

1. increase our capacity to meet collective needs while addressing health inequalities (population health value);
2. provide an appropriate response to health system challenges (health system value);
3. provide products that are both high-performing and affordable (economic value);
4. integrate business models that enable a company to bring more value not only to users and buyers, but also to society (organizational value);
5. mitigate environmental impacts as much as possible throughout the innovation's life cycle (environmental value).

The RIH framework draws attention not only to the **design and manufacturing processes** and **product features**, but also to the different **organizations** that develop them and make them available to users. These may include, for example, startups, small and medium-sized enterprises, social enterprises, nonprofit organizations, manufacturers, or multinational corporations. The principles, values, and requirements of RIH apply throughout the lifecycle of an innovation, promoting social and environmental best practices.



3. The RIH attributes

3.1. Health relevance

Does the innovation address a relevant health problem?

Health problems do not exert the same pressure on all communities and are specific to a given geographic region. For example, some chronic diseases impact populations in high-income countries, while some infectious diseases, such as dengue fever and malaria, are more prevalent in certain regions in the southern hemisphere. While the mortality rate from cancer is significant in the general Canadian population, tuberculosis remains a major cause of death in some Indigenous communities.

Health relevance is therefore based on the idea that a responsible innovation must address a collective health problem that is important in a given region. Without neglecting rare diseases and diseases for which there is no cure yet, this attribute puts population health first.

For many years, the health of populations was assessed solely on the basis of mortality rates and causes and these indicators are insufficient to judge the health status of a population. In the 1990s, the World Health Organization (WHO) developed an assessment method that quantifies the health status of a population and facilitates the identification of priorities for public health action [2]. This method is called the **Global Burden of Disease** (GBD).

The GBD is intended to provide a comprehensive view of the health of a population for policy makers [3]. This assessment is based on different indicators that consider the most important causes of death, injury, and disability, as well as the more significant risk factors that affect the health of a population in a given region.

This analysis is essential for governments to set priorities for research and make health care system investment decisions [4]. These decisions are shaped by complex issues: resource shortages, ever-increasing health care needs, development of new treatments and interventions, and rising health care costs [5].

To make an informed decision, policy makers need a consistent and systematic comparative description of the burden of disease and the risk factors that contribute to it [6]. Geography is therefore of great importance.

HEALTH RELEVANCE

AUTOMATED ANALYSIS OF CHEST X-RAYS

EXAMPLE

Tuberculosis is a highly contagious disease that requires prompt diagnosis and treatment. Although it has a very low disease burden in the general Canadian population, with only 0.6 cases per 100,000 population, the incidence of active tuberculosis in Nunavut, located in northern Canada, is the same as in Somalia, at 261 cases per 100,000 population [7].

In Nunavut, an innovation like the *CAD4TB* (Computer-Aided Detection for Tuberculosis) would be highly relevant. This software uses deep learning technology. It has been commercialized by *Delft Imaging*, which developed it in collaboration with Radboud University (Netherlands) and the Cape Town Lung Institute (South Africa). The prototype was tested as early as 2011 in South Africa and Zambia.

The *CAD4TB* allows non-expert professionals to detect signs of tuberculosis in chest x-rays. Using deep learning, the system has been trained to detect lung abnormalities by analyzing thousands of x-rays — both healthy and diseased — from over 15 countries. It can interpret chest x-rays in less than 15 seconds [8]. To date, *CAD4TB* has been used to screen more than 8 million people in over 40 countries, including Mozambique, Bangladesh, and Nigeria [9].

TELEMEDICINE FOR EYE HEALTH

EXAMPLE

In Quebec, tools that analyze eye health without the help of a physician have been introduced in hospitals. Using artificial intelligence, they optimize screening for diabetic retinopathy, a complication of diabetes that accounts for 80% of diabetes-related vision loss (one in ten Canadians). Early detection allows for timely treatment of retinal damage that would otherwise become irreversible [10].

Early detection has been made possible through innovations such as *CARA* (*Computer Assisted Retina Analysis*), a teleophthalmology platform that can be integrated into existing equipment. *CARA* was developed by the Quebec company *DIAGNOS*, which received support from the Quebec government for its implementation at the Centre hospitalier de l'Université de Montréal (CHUM). Screening is performed at the endocrinology clinic, located at the Hôtel-Dieu Hospital, using a photograph of the back of the eye (retina). The image is then identified and sorted by the *CARA* platform. Patients with diabetic retinopathy are referred to the CHUM ophthalmology department [11]. The platform is currently used in 16 countries.

A responsible innovation has high health relevance when it targets a cause of death, injury, or disability or a risk factor in the top quarter of all causes of death, injury, or disability or risk factors in the region of concern (75% and above).

3.2. Ethical, legal, and social issues (ELSIs)

Was the innovation developed by seeking to mitigate its ethical, legal, and social issues?

A health innovation can have **unexpected impacts** on users and their loved ones. For example: a digital application that allows people suffering from a chronic disease to track the evolution of their symptoms can be problematic if it includes the name of the disease in its title, as some users may need to hide their disease to avoid stigmatization (for instance, with HIV/AIDS) at home, at school, at work, or any other public or private place. In this case, the social aspects of an innovation are at stake.

RIH therefore considers the impacts that are likely to occur (in a society or in a health system) when an innovation is put on the market. In addition to the social aspects, we must consider the ethical aspects, as well as the legal and regulatory issues that its use raises.

Of course, not all issues that may arise from an innovation can be identified in advance. However, RIH encourages innovators to identify the likely impacts that the innovation may have on each of the three types of issues: ethical, legal, and social. Then, consider whether ways to mitigate negative impacts are available where users are located.

The ELSIs attribute therefore does not focus on the magnitude of the issues raised by the innovation, but rather on how its ethical, legal, and social **impacts can be mitigated**. Will an innovation discriminate against a part of the population? Will it infringe on their rights? If so, there must be ways to remedy this.

How can we know? Examining innovations like the one being evaluated can help to identify possible effects and find ways to mitigate its negative impacts. For example, if a home-based treatment requires the assistance of a family caregiver, providing an alternative resource for people who live alone may be a way to mitigate a discriminatory effect (ethical aspect).

If a medical device is made with digital components, privacy may be at stake (legal and regulatory). Ways to mitigate privacy risks include compliance with regulatory frameworks in the region where users are located.

If cultural values or preferences are likely to affect the perception and use of a treatment, culturally appropriate communication tools should be developed (social aspect).

ETHICAL, LEGAL AND SOCIAL ISSUES

For ethical issues, we can, for example, provide patients with tools to help them make decisions, or offer them psychological support.

For legal and regulatory issues, consider laws and regulatory frameworks regarding individual rights, privacy, confidentiality, discrimination (health insurance, workplace), adverse event monitoring, data management, etc. If there is no framework in place to guide the practices of organizations in the jurisdiction in which they operate, innovation developers must commit to adopting best practices for data management in their field, and not exploit the lack of legislation to take advantage of the situation.

Social issues can be addressed through stigma reduction programs, support for caregivers, or encouraging community-based educational forums.

EXAMPLE

MOBILE CLINICS TO MITIGATE THE LACK OF ACCESS TO VACCINATION

While the COVID-19 vaccine represented a major scientific breakthrough in March 2021, the CIUSSS du Nord-de-l'Île-de-Montréal, an institution in the Quebec health and social services network, saw that the vaccination rate remained low in the Saint-Laurent and Montréal-Nord neighbourhoods. The vulnerable population in these two neighbourhoods rarely visited the vaccination sites. A lack of information on the vaccine, an irregular access to the Internet, the impossibility of taking time off work without being penalized, and language barriers are all factors that contributed to this problem. A portion of the population is marginalized and their access to the vaccine was limited.

To reach out to the residents of these neighbourhoods, the CIUSSS set up one-day mobile clinics directly in various workplaces. These clinics were temporarily set up, for example, in agri-food plants. As a result, hundreds of essential workers were vaccinated, many of whom were immigrants living in precarious situations and disadvantaged for the reasons mentioned above.

Responsible innovation developers must ensure that the means to mitigate its negative impacts are available for almost all applicable ELSIs.

Mobile vaccination clinic set up by the CIUSSS du Nord-de-l'Île-de-Montréal
Photo: Catherine Hébert

3.3. Health inequalities

In what ways does the innovation promote health equity?

We are not all equal when it comes to the health care system. If you are a seasonal worker, live in a disadvantaged rural area, or belong to a visible minority group, there are likely to be several barriers that limit your access to health care. Thus, health care disparities do not just happen; current evidence indicates how they are strongly correlated with vulnerability factors.

Despite gains in recent years in Quebec, health inequalities persist [12]. An individual's health status varies according to their socioeconomic status, social position, and ability (e.g., level of education) to benefit from an innovation. Certain groups, who suffer a greater burden of mortality and morbidity because of their social position or where they grow up, live, and work, are therefore considered vulnerable.

Vulnerable groups include, but are not limited to:

- subsistence farmers;
- long-term unemployed;
- informal, seasonal, and day laborers;
- people living in disadvantaged urban or rural areas;
- people living in poverty or experiencing homelessness;
- people living with disabilities or living with mental illnesses;
- visible minority groups and socially marginalized groups;
- asylum seekers and refugees;
- single-parent families, the elderly, and children. [13] [14]

For RIH, an innovation should increase our ability to meet individual and collective needs, while addressing health disparities. The degree of responsibility of an innovation can therefore be examined based on whether the ability to benefit from it is affected by one’s socioeconomic status, social position, or individual abilities. To illustrate our point, we provide two counterexamples below, followed by an example.

COUNTEREXAMPLE

ALGORITHMS THAT REINFORCE SOCIAL INEQUALITIES

Some U.S. hospitals are using commercial algorithms to identify patients with the most complex health needs and prioritize access to care. In 2019, a study found that an algorithm widely used by a major teaching hospital consistently favored White patients over Black patients. After reviewing nearly 50,000 records, researchers found that the algorithm systematically underestimated the health needs of Black patients. If two patients had the same health problem, the White patient was prioritized. The result: even when they were sicker, Black patients were assigned the same level of risk as White patients [15].

COUNTEREXAMPLE

FEE-FOR-SERVICE DELIVERY MODELS

In some health care delivery models, access to services is based on ability to pay rather than health need. This can be detrimental to more vulnerable groups. A good example is Quebec's *Bonjour-Santé* online appointment scheduling platform.

In some areas of Montreal, one third of citizens still do not have access to a family physician [16]. Those who wish to avoid seeking health care in a hospital emergency or in walk-in clinics can schedule an appointment via an online platform. There are two options: the government's free platform, *Rendez-vous santé Québec*, or private solutions, such as *Bonjour-santé*, which often charge a fee. At the moment, medical clinics use the private option ten times more often than the public option [17].

The *Bonjour-santé* appointment scheduling service is free "if you attend a particular clinic or have a family clinic or have a family doctor," as indicated on the company's website. If not, *Bonjour-santé* offers a consultation search service, available exclusively to subscribers. Subscription costs about $20 ($14.95 for the registration fee and a monthly recurring payment of $5.95). Individuals with limited income who do not have a family doctor are clearly discriminated against by this online appointment scheduling model.

EXAMPLE

eHEALTH: BRIDGING THE CULTURAL DIVIDE

Some initiatives aim to address health inequalities, such as *iCON* : *the interCultural Online Health Network*, a community-based health promotion initiative. Their mission is to provide multicultural communities with the information and skills they need to manage their health. Studies show that seniors, immigrants, and ethnic and cultural minorities are the groups that are least aware of and least likely to adopt online health services. For the elderly and immigrants, barriers to using eHealth services include Internet access as well as language and cultural barriers [18].

iCON provides culturally and linguistically appropriate information to cultural communities, particularly the Chinese and Punjabi immigrant populations in British Columbia. This includes information on chronic disease management. By making information accessible to patients from immigrant communities, the organization strengthens their self-reliance and helps to reduce health disparities. *iCON* has also developed a project involving Indigenous communities.

A responsible innovation can reduce inequalities by addressing the specific needs of a vulnerable group or by reducing inequalities by ensuring that the ability to benefit from the innovation is not affected by one's socioeconomic status, social position, or capabilities.

3.4. Inclusiveness

Were the innovation development processes inclusive?

The Inclusiveness attribute refers to the degree to which stakeholders (parties affected by the innovation) participated in the innovation's design and development, as well as throughout the various stages of validation.

How to be inclusive and accountable

Three aspects are considered to determine whether an innovation was developed in an inclusive manner. The first is whether the design team involved a diverse and relevant set of **stakeholders**. These may be institutions as well as individuals: health and social care practitioners and managers, patients and caregivers, community and civil society representatives, etc.

For example, a team developing a new system to triage emergency calls conducted interviews with ambulance attendants, but not with the nurses who work at the call center. Inclusivity is then lacking, as only a limited group of stakeholders were involved.

Next, we examine whether the team behind the innovation used a **formal engagement method**. There are many such methods: co-design, interviews, citizen juries, focus groups, workshops, pilot testing, user evaluation, and feedback.

Finally, we verify whether the **input of stakeholders was meaningfully integrated into the design process**. Were the views of participants truly taken into account? Their input into the design and implementation of the innovation must be tangible.

EXAMPLE

AN APPLICATION DEVELOPED WITH NURSES

A nurse providing home care looks up the address of her next client on her smartphone. She checks *MySE Life*, an application that retrieves real-time information from various databases, both private and public, such as the Ontario Community Health System. "This amazing app pulls all of my clients' records and information, including addresses, medical history and visits, and treatment plans, into one place, and it is very user-friendly." [19]

This application is the result of a co-design process initiated by her employer *SE Health*: a non-profit social enterprise and one of the largest home care organizations in Canada.

INCLUSIVENESS

EXAMPLE

During the first wave of the COVID-19 pandemic, a team of *SE Health* employees, including nurses and digital transformation and operations professionals, was mobilized to explore and better understand how nurses deliver home care. The group looked at the nurses' current tools and brainstormed which new ones they needed.

Prior to the *MySE Life* app, nurses received an email with a long PDF document detailing their weekly workload, including their schedules and a lot of information about their clients, which was not always up to date. It took the nurses several hours to read through this document. In addition, they had to consult another application or website to find the phone number of a family doctor or information about their last visit.

Getting up-to-date information in a user-friendly format was therefore set as a priority. The result: an app by and for nurses that modernizes home care delivery.

Responsible innovation developers involve a diverse and relevant set of stakeholders using a formal method and explain how their input is integrated into the design process.

Photo: Jason Goodman / Unsplash

3.5. Responsiveness

Does the innovation provide a dynamic response to a significant health system need or challenge?

In 2017, a report by the Health and Welfare Commissioner concluded that Quebec's health and social services system faces, among others, two major challenges: accessibility and continuity of care [20]. The wait time for access to care is too long. In addition, information does not always follow the patient throughout the system. "There is little sharing of patient information among health care professionals, particularly from the specialist to the family physician," the report states.

Of course, the nature and magnitude of health and social services system challenges vary from country to country. Health innovations should therefore respond in a timely manner to the most important systemic needs and challenges in a given region. This is what RIH defines as responsiveness.

What are the challenges that RIH should address?

This is a non-exhaustive list of the major challenges facing health systems. They are not prioritized, but are all critical, and many are interrelated. Two examples of innovations are then provided to illustrate how RIH can address these challenges.

Adapting to demographic change
Aging populations, populations affected by climate change, armed conflicts

Addressing epidemiological changes
Chronic diseases, new or re-emerging infectious diseases, rare diseases or diseases for which no treatment is available

Supporting human resources
Training, supervision, turnover

Closing gaps in service delivery
Access to health care, quality of care, patient-centered care

Integrating knowledge into practice
Acquisition, analysis and interpretation of data, development and implementation of knowledge-based tools

Improving governance
Coordination, synergy, cross-sectoral action, community partnerships

RESPONSIVENESS

EXAMPLE

ADDRESSING EPIDEMIOLOGICAL CHANGES

BlueDot is a Toronto-based start-up that uses a platform based on artificial intelligence techniques, machine learning, and big data. On Dec. 30, 2019, the company alerts its customers about a cluster of cases of "unusual pneumonia" occurring near a market in Wuhan, China. There is a risk of a pandemic. *BlueDot* sounds the alarm six days before the U.S. Centers for Disease Control and Prevention (CDC) and nine days before the WHO. How is this possible?

The algorithm developed by *BlueDot* tracks and predicts the onset and propagation of infectious diseases. It processes vast amounts of data in 65 languages, looking for outbreak signals for more than 100 diseases and syndromes, 24 hours a day, 365 days a year. Much of *BlueDot*'s predictive capability comes from data it collects outside of official health sources: climate data from satellites, local information from journalists and health workers, and the global movements of the four billion travelers who board commercial flights each year [21]. *BlueDot* sifts through official reports, professional forums, and thousands of online articles, and scans the text for keywords and phrases. The team has trained the software to recognize whether the identified information poses a real threat [22] and sends alerts to its clients in the healthcare, government, and corporate sectors.

EXAMPLE

ADDRESSING GAPS IN SERVICE DELIVERY

An impressive number of health care professionals are involved in the treatment of cancer (imaging, surgery, chemotherapy, radiotherapy, etc.). Though their services are interlinked, they are often organized in "silos." For hospitals, this is a real headache. For patients, it can be confusing and stressful, which can be detrimental to their recovery [23].

To fill this gap, the start-up *Gray Oncology Solutions* has created a planning software robust enough to manage advanced care pathways, including cancer treatments. Active since February 2020, the platform supports cancer center operations. It helps determine when and for how long a surgery, radiation, or chemotherapy appointment is needed, while ensuring the patient is treated as quickly as possible.

Partnered with the CHUM, the start-up aims to optimize patient flow. “The management of cancer treatments is a complex task [...] explains Kathy Malas, Assistant to the President and CEO and Head of Innovation and Artificial Intelligence at the CHUM. To better meet the needs of patients while improving the efficiency of our staff, *Gray*'s platform shows promise in offering a reduction in administration time for scheduling appointments." [24]

A responsible innovation overcomes a systemic challenge documented as being of high importance in the targeted geographical area.

3.6. Level and intensity of care

Are the level and intensity of care required by the innovation compatible with health system sustainability?

In Quebec, as in Canada, not a day goes by without the issue of health care access and financing being raised. Growing needs, associated with an aging population and the increasing prevalence of chronic diseases, are putting pressure on ever-increasing health budgets [25]. In the 2020-2021 spending budget presented by the Quebec government, the Ministry of Health and Social Services alone accounts for almost 50% of government program spending [26].

In this context, how do we sustain the health care system? How do we ensure that it remains affordable, and that it adapts to health needs that are not static? To remain sustainable, the health system must not only adapt to new diseases and natural disasters, but also to demographic changes, scientific discoveries, and emerging technologies [27].

One of the issues that RIH addresses with respect to health system sustainability is the principle of **subsidiarity**. This principle states that the most decentralized unit of the health and social services system should be mobilized to provide the service when it is safe and effective to do so. Thus, the service is provided by an appropriately qualified person, that is, neither under- nor over-qualified [28]. Responsible innovations should seek to generate high quality outcomes while reducing unnecessary interventions at the most specialized level of the health and social services system.

This means considering where (level of care) the innovation is primarily used and by whom (intensity of care), keeping in mind that its use must be safe and effective.

EXAMPLE

TECHNOLOGY IN THE HANDS OF PATIENTS

For example, a patient suffering from kidney failure must undergo hemodialysis treatments to eliminate toxins in the blood. In-hospital hemodialysis involves the patient going to the hospital three times a week for treatment. A nurse connects the patient to a hemodialysis machine for approximately four hours [29]. A caregiver is often required to accompany the patient home because of the fatigue experienced after each session (lower blood pressure and red blood cell count).

However, it is possible to do otherwise. Since 2005, the McGill University Health Centre has allowed patients to undergo dialysis at home and at night: this is nocturnal hemodialysis. After four to six weeks of training, the patient connects to a (portable) machine five nights a week, for seven hours a night. Treatments are more frequent and less intense than in a hospital setting, allowing the patient to lead a normal daytime life [30]. This solution is available at several sites, including the Hôtel-Dieu de Québec, where patients receive the device free of charge and have access to a 24-hour repair service provided by biomedical technicians [31].

EXAMPLE

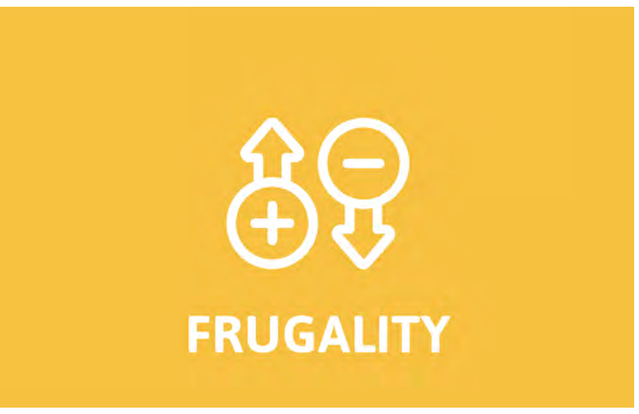
A MOBILE SOLUTION FOR AUDITORY TESTING

The principle of subsidiarity is well illustrated by a mobile hearing screening solution marketed by the Canadian company *SHOEBOX*. It aims to facilitate access to hearing tests for workers at risk (on offshore drilling platforms, for example) or patients living far from urban centers.

The hearing screening test can be performed by non-specialized personnel and is done using an iPad and headphones. In just a few minutes, individuals identified as having reduced hearing ability are referred to an audiologist for a comprehensive evaluation [32].

A responsible innovation aims to be used primarily under the responsibility of patients, informal caregivers, or health and social care providers in a non-clinical setting.

Photo : shoebox.md



3.7. Frugality

Does the innovation apply a frugal approach to deliver greater value to more people using fewer resources?

Frugal innovation is inspired by the Indian concept of "jugaad," the Indian word for resourcefulness. It consists in doing more with less: less capital, less materials, less energy, and less work time [33].

To ensure the equity and sustainability of health and social services systems, we need to provide more value to more people using fewer resources. The era of flashy, expensive innovations (or flashy because they are expensive) is over, and frugal innovation is the way to go. Frugal innovation invites designers to rethink how products can be designed by optimizing their functionality, production and maintenance costs, and the resources and materials required.

FRUGAL INNOVATION TO REDUCE COSTS

EXAMPLE

An innovative medical device from Vancouver-based start-up *Arbutus Medical* is revolutionizing orthopedic surgery: the *Arbutus Drill Cover*. The *Arbutus Drill Cover* is a waterproof and pathogen-resistant textile cover that can be sterilized and reused many times. It provides a completely sealed sterile barrier that transforms a high-performance commercial drill (available at the hardware store) into a surgical-grade drill.

With the *Arbutus Drill Cover*, the turnaround time between operations can take as little as one minute. By simply replacing a soiled cover with a sterile one, surgical teams can treat more patients. The cover can be used with commercial or surgical drills. The cover extends their life and reduces the wear and tear caused by their repeated sterilization through the autoclave. If deployed in all surgical units in the UK, the *Arbutus Drill Cover* would reduce costs by up to 94%. It is estimated that there are 5,000 surgical drills in the UK costing approximately CA$ 39,000 each. The *Arbutus* cover system costs about CA$ 2,500 [34]. This is what we call a "frugal innovation."

Photo: Grand Challenges Canada

FRUGALITY

While frugal innovation has a natural appeal in countries with limited resources, it would be wrong to assume that it is less relevant in high-income countries. In both the UK and Canada, musculoskeletal diseases are one of the major clinical and economic burdens on the health care system. The demand for orthopedic surgeries is only increasing, and the surgical drill is one of the most widely used and expensive tools for operations of this nature. Why wouldn't the *Arbutus Drill Cover*, which is an effective solution that meets the regulatory requirements for medical devices in Europe and North America, be relevant here? The only explanation for not having done frugal innovation until now seems to lie in our habit of paying a lot of money for new technologies.

Three characteristics guide the design of frugal innovations in health.

1. Affordability. Its design should substantially reduce the cost of producing and using the innovation.

2. Ease of use. The innovation should focus on the essential functions that users need. Thus, its ease of use should allow it to reach patients who would not otherwise benefit from the innovation, including in remote or resource-poor areas.

3. Performance optimization. The level of performance of the innovation (robustness, accuracy, durability) must be optimized according to the purpose and context of use [35]. For example, an innovation should be robust if used in harsh climatic conditions, or easily transportable if used in remote areas. Similarly, it should promote economies of scale if it is used in large urban centers.

EXAMPLE

AN ULTRASOUND IN YOUR POCKET

Jonathan Rothberg, a Yale genetics researcher and entrepreneur, has found a way to put ultrasound technology on a chip. So instead of the US$ 100,000 devices used in hospitals, the *Butterfly iQ*, a US$ 2,000 wearable device, connects to an iPhone app. Although not as accurate as traditional devices, "the Butterfly iQ shows promising potential as a portable, less expensive alternative to ultrasound machines." [36]

Photo : Butterflynetwork.com

COUNTEREXAMPLE

THE MOST EXPENSIVE DRUG IN THE WORLD

Each year in Canada, approximately one in 6,000 children is born with spinal muscular atrophy (SMA), a class of inherited diseases characterized by muscle atrophy [37]. SMA type I, the most common subtype, is characterized by onset of the disease at 6 months of age and death before the age of two years [38]. SMA can be curbed by gene therapy, which involves introducing genetic material into cells [39]. Among these therapies is *Zolgensma*, produced by the pharmaceutical company *Novartis*.

As of October 20, 2021, the Régie de l'assurance maladie du Québec offers reimbursement for the *Zolgensma* treatment for children with SMA. Its cost? CA$ 2.8 million per dose, making it the most expensive drug on the planet [40]. In September 2020, three gene therapies were approved in Canada [41].

Of course, developing a gene therapy is expensive, but "the only thing that brings the price down is competition," says James Robinson, director of the Berkeley Center for Health Technology (University of California) [42]. According to an analysis by the Institute for Clinical and Economic Review, the subjective value of *Zolgensma* is estimated at US$ 900,000 per treatment. The only other competitor to *Zolgensma* is *Spinraza*, which in comparison requires a few procedures per year, and can cost a total of US$ 30 million over a lifetime [43].

While new advances are reducing production costs, it will be many years before these savings translate into lower selling prices.

A responsible innovation integrates the three characteristics of frugal innovation described above.

3.8. Business model

Does the business model of the organization that produces the innovation offer more value to users, buyers, and society?

In examining the business model of innovative firms, RIH highlights the fact that alternative business strategies can provide more **value** to society as a whole [44].

A business model usually involves a tension between redistributing financial returns to shareholders and bringing high-quality innovations to market. This tension increases when the organization's performance is measured exclusively in economic terms and when the return to shareholders is expected to constantly increase (as in the stock market).

A company can, however, free itself from undue shareholder pressure and narrow economic performance measures. It can create value for society by better articulating its economic (jobs, tax contributions), social (support for communities), and environmental (reduction of carbon footprint) contributions [45].

A SEARCH ENGINE THAT PLANTS TREES WITH EVERY CLICK

EXAMPLE

Founded in 2009, *Ecosia* is a company with a social mission whose business model is unique. The company created a search engine to allow Internet users to fight climate change: it uses about 80 percent of its surpluses to plant and protect trees in South America, Africa, and Asia where they absorb carbon dioxide. In 2014, *Ecosia* was the first German company to achieve a B Corp certification, and in 2019, the first company in the digital sector to become carbon negative. That year, it produced twice as much renewable energy as it consumed. To date, *Ecosia* has supported over 9,000 reforestation sites.

While its revenue primarily comes from the sale of digital advertising, *Ecosia* refuses contracts from companies that generate negative social and environmental impacts. The company does not pay dividends to its owners. Profits remain within the company and are used to plant trees or to finance environmental projects (regenerative agriculture, solar power plants, etc.).

Operating in a digital sector that remains largely unregulated, *Ecosia* has a strong competitive strategy. To gain and maintain user trust, its privacy policy is strict. It does not sell data to advertisers, quickly anonymizes searches, does not use external tracking tools, and makes its *do not track* option easy to locate.

Finally, the company also publishes a monthly financial report showing how the revenues generated by the searches are spent. It also maintains a blog providing readers with key information about the communities it works with. Staying away from tax evasion and contributing to the well-being of local communities are part of its business vision.

HEARING AIDS BY AND FOR USERS

EXAMPLE

Solar Ear is a well-known example of an organization with an alternative and economically viable business model. The non-profit company has co-developed high-quality and low-cost hearing aids with users. According to Hearing Aid, a hearing aid device costs between US$ 1000 and US$ 6000 [46]. In addition to this large amount, there is the economic burden of buying single-use batteries every week. That is why *Solar Ear* developed hearing aids that range in price from US$ 50 to US$ 200 and come with a charger and solar-powered rechargeable batteries.

Solar Ear employs and trains individuals who are hearing impaired to make hearing aids and encourages them to pursue their education. This is an important part of its mission, as maintaining employment, generating a stable income, and strengthening one's social network are important determinants of health.

All profits are reinvested in the company or used to replicate and expand its social mission. *Solar Ear* has not patented its technology: it is free of rights. And competition? It is encouraged. Founder Howard Weinstein wants the industry's leading manufacturers to adopt *Solar Ear*'s technology and lower their prices. "Our goal is to prevent hearing loss, not to sell more hearing aids," he says [47].

B Corp

B Corps are certified Beneficial companies — the letter "B" stands for “beneficial.” Their purpose is to create value for society in addition to generating revenue. They meet high transparency and accountability standards and create positive social and environmental benefits.

Source: Business Development Bank of Canada

Tree nursery, Brazil.
Photo: Ecosia.org

COUNTEREXAMPLE

PLACING SHAREHOLDERS BEFORE BENEFICIARIES

Less than 12 months after the onset of the pandemic, major pharmaceutical companies released several vaccines against COVID-19, the development of which was largely funded by governments. Vaccines developed by *AstraZeneca/Oxford University*, *Moderna*, and *Pfizer/BioNTech* have received more than US$ 5 billion in public funding [48].

Two years later, low-income countries have vaccinated less than 4% of their population, partly because patents on these vaccines limit access to care [49].

In the medical field, a laboratory can obtain exclusivity on its discovery for 20 years, during which time it will be the only one able to offer treatment based on this innovation [50]. With this business model, pharmaceutical companies can charge the maximum price that the market is willing to pay. It is only after about 20 years that new production sites appear, bringing generic drugs to the market at lower costs.

The World Trade Organization has the power to suspend patent monopolies. Since the mission of large pharmaceutical firms is to generate as much revenue as possible, its executives and shareholders have no interest in supporting the lifting of patents.

In sum, business models that combine the following properties can better support RIH.

- Pursue a social and/or environmental mission, operate on a not-for-profit basis, or reinvest the majority of revenues in their mission (e.g., social enterprises);
- Make the innovation freely usable or exploitable by others (e.g., open access, reduced licensing fees, do-it-yourself);
- Adopt a pricing system based on ability to pay or a redistributive logic (e.g., customers who “buy one, give one”);
- Employ individuals with particular needs (e.g., low literacy, living with a disability);
- Comply with social responsibility programs (e.g., B Corp certification, SA8000 standard for decent work, or ISO26000 for social responsibility).

A responsible innovation is brought to market or made available by an organization whose business model has three or more of the properties described above.

3.9. Eco-responsibility

Are environmentally responsible principles applied throughout the innovation's lifecycle?

"Already, disposable masks and gloves are polluting the sidewalks of the city," said Agnès Le Rouzic, head of the Oceans and Plastics Campaign at Greenpeace Canada in May 2020 [51]. Because of the COVID-19 pandemic, these objects, which are non-biodegradable and sometimes contaminated, are likely to end up in large numbers in landfills, in sewers, and in waterways.

However, disposable masks and gloves are only the visible face of the health sector's ecological footprint. Its impact on the environment and the climate is significant: it is estimated to be responsible for 4.4% of total global greenhouse gas emissions [52].

Activities in and around hospitals consume a great deal of energy and natural resources, and produce hazardous, infectious, toxic, and radioactive materials. Examples include the disposal of equipment, chemicals used for cleaning and disinfection, expired or unused pharmaceuticals, and drugs and vaccines [53].

For RIH, being environmentally responsible means using a product, process, or method that reduces the negative environmental impacts of an innovation. There are five key stages in the lifecycle of a health innovation [54] and environmental responsibility can be considered at each of these stages. The explanation of the key lifecycle stages below is not exhaustive, but we illustrate them with concrete examples.

100% recyclable polypropylene vials
Photo: EcoloPharm.com

Eco-responsibility in five key lifecycle stages

1. Raw material sourcing

Eco-responsibility can start with the use of products or materials made from recycled or renewable materials, free of substances such as latex, metals, or chemicals that are harmful and toxic to ecosystems.

EXAMPLE

Using circular economy principles, medical equipment manufacturers like *Philips* are demonstrating that it is possible to extend the life of their equipment. In 2016, *Philips* opened a refurbishment center for medical imaging systems in Best (southern Netherlands). The large high-powered magnets integral to all magnetic resonance machines that produce a strong magnetic field are disassembled, recuperated, and then reused to make refurbished devices.

Philips Medical Imaging Refurbishment Center in the Netherlands
Photos: Philips.com

2. Manufacturing

The eco-responsible manufacturing of an innovation should optimize its energy consumption, comply with environmental regulations (national or international), or reduce its impact on wastewater management and solid waste production.

EXAMPLE

The average pharmacy generates 45 tons of waste per year, 12% of which is from plastic [55]. In 2009, *EcoloPharm* set out on a mission to transform packaging design in the pharmacy sector by offering environmentally responsible solutions. The company eliminated PVC and replaced it with polypropylene, a highly resistant and 100% recyclable plastic. All their products — vials, pillboxes, ointment jars — are manufactured in Quebec and shipped in minimal packaging without plastic bags. The eco-design of EcoloPharm products generates a 55% energy saving, a 39% reduction in packaging waste, a 55% reduction in greenhouse gas emissions, and a 30% reduction in plastic consumption.

3. Distribution

The environmental impact of packaging and transportation should be reduced.

EXAMPLE

Operating rooms are energy- and waste-intensive spaces that have a negative impact on the environment and, consequently, on human health. However, there are strategies to reduce waste, including the waste generated by toolkits used in the operating room.

Many hospitals use surgical toolkits that are pre-prepared by manufacturers. They often contain items that are not routinely used. This "surplus" equipment is usually discarded because of its potential exposure to biohazards during surgery. However, the composition of these kits could be more responsible: rarely used items could be removed from the kits, the size of the items could be reduced where possible (e.g., saline vials), and the use of plastic packaging could be minimized by switching to rigid and reusable sterilization containers [56].

4. Use

The innovation should be energy efficient, durable, and reusable.

EXAMPLE

Individuals with breathing difficulties commonly use metered dose inhalers (MDIs), which are medical devices used to deliver inhaled medications. Doctors usually prescribe them for the treatment of asthma and chronic obstructive pulmonary disease. There are different inhalation devices that deliver the same medication, but they do not all have the same carbon footprint.

Metered-dose inhalers (MDIs) use HFCs propellants. These are artificial fluorinated gases that act as powerful greenhouse gases when released into the atmosphere. The carbon footprint of these MDIs is much higher than that of other inhalation devices. For example, MDIs have a carbon footprint that is 10 to 37 times larger than dry powder inhalers (DPIs) [57]. The Center for Sustainable Health Systems at the University of Toronto suggests that, where possible, nebulizers and aqueous mist inhalers should be used, as they are less polluting [58].

While all models have an environmental impact, opting for nebulizers and aqueous mist inhalers can help reduce the carbon footprint of inhalers.

CARBON FOOTPRINTS

Seretide Evohaler (MDI)	Ventolin Accuhaler (DPI)	Respimat Soft Mist	Electric Nebulizer
234 kg CO_2e	**7.3 kg CO_2e**	**0.08 kg CO_2e**	**0.05 kg CO_2e**

CO_2e = Carbon Dioxide equivalent

Source: Center for Sustainable Health Systems

5. Disposal

The product should be designed so that its components or materials can be recycled, disassembled, refurbished, composted, or biodegraded.

EXAMPLE

Let's go back to the example of *Philips* and its refurbishment center located in the Netherlands. Reusing components and materials ensures the continuous recycling of resources. In addition, the Best facility has its own paint shop where refurbished systems are rejuvenated. *Philips* also refurbishes scanners and ultrasound equipment at several sites in the United States.

This allows the company to market remanufactured devices at a lower price. Remanufacturing is a viable strategy to improve the availability of medical equipment and contributes significantly to the stability and sustainability of health and social care systems [59].

Although we have used separate examples to illustrate each of the five key lifecycle stages of sustainability, an innovation should be designed by considering its entire lifecycle. It is important to remember that the eco-design of an innovation starts upstream of production and consumption, and that it is possible to integrate circular economy principles early in the process.

A responsible innovation is designed by integrating eco-responsibility concerns at three or more key lifecycle stages.

4.Conclusion

Supporting RIH now, the way of the future

The nine attributes described in this booklet are intended to serve as a guide to help you reflect about key responsibility issues. They provide guidance on the questions that should be asked by any stakeholder in the ecosystem who wishes to participate in the emergence of responsible health innovations.

Why do this exercise? Because effectively addressing population health problems and the shortcomings of health and social services systems has become an inescapable challenge, and RIH is the ideal way to meet it. RIH makes it possible to understand the contemporary issues surrounding health innovations in order to better resolve them; issues that may arise upstream, but also throughout an innovation's lifecycle.

RIH has a transformative power on conventional practices in the field of innovation. It is desirable, feasible, and profitable to design and market responsible innovations that solve social, economic, and environmental problems. And we need to do it now, because, to quote Hubert Reeves: "To look 'far' is to look 'early'."

Memo

A RIH aims to:

HEALTH RELEVANCE	Meet a relevant health need.
ETHICAL, LEGAL AND SOCIAL ISSUES	Mitigate ethical, legal, and social issues.
HEALTH INEQUALITIES	Reduce health inequalities.
INCLUSIVENESS	Meaningfully involve stakeholders throughout the development process.
RESPONSIVENESS	Offer a dynamic solution to a key health system challenge.
LEVEL AND INTENSITY OF CARE	Empower and equip patients or caregivers in non-clinical environments.
FRUGALITY	Be affordable and provide usable, affordable and optimized solutions.
BUSINESS MODEL	Encourage companies to deliver more value to society.
ECO-RESPONSIBILITY	Reduce environmental impacts.

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