Responsible Innovation in Health

Concepts and Tools for Sustainable Impact

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Foreword

Science and engineering students are selecting careers that combine their interests in helping people with their love for technology. As a student, I helped design and test medical imaging technology for diagnosing cardiovascular disease. My attention gravitated towards the question of how average citizens, seniors on Medicare, gain access to our emerging high-tech device? This was relevant to me because of the preponderance of cardiovascular disease in the African-American community and for Americans at large. Unfortunately, I anticipated that our lab's novel cardiovascular ultrasound diagnostic tool would be (1) extremely expensive when first produced, (2) not easily adopted by medical practitioners, and (3) not immediately covered by any health insurance (government-based or private). Conversations with other graduate students and faculty in the engineering college and in the science policy center strengthened my conclusions. I was unable to see outside the anticipated constraints to a frugal and useful technology solution. Ultimately, I found it disheartening to work on research that would never be able to impact those closest to my heart or the millions of other people in similar circumstances.

With the help of this book, I now reimagine those conversations ending with a different conclusion. I would use the questions and graphics helpfully provided by Dr. Pascale Lehoux and her co-authors to structure the discussions with my lab research group, other students, and faculty. We would have vocabulary to articulate our various concerns and focus on the needs of vulnerable groups. My anticipation of poor outcomes for African-Americans as a vulnerable group would not be shrugged off with words such as 'What can we do?' or 'That's the way it is.' Our re-imagined

brainstorming sessions would assemble our collective knowledge concerning the health research problem. Together we would create a solution emphasizing as the authors write 'degrees of responsibility' and 'materializing' that responsibility in the creation of the start-up company, the design of the tool itself, and the company's approach to relationships with suppliers, manufacturers, insurers, physicians, caregivers, and patients. I would feel empowered that my interests in serving people could work hand-in-hand with my passion for technology.

Today, this book makes such discussions and solutions possible. Dr. Pascale Lehoux and her In Fieri team offer practitioners a guide that is theoretically informed with actionable goals and suggested measures of impact. Her unique background in industrial design and public health shines through every page. It is exciting to read such a carefully crafted book by early leaders in Responsible Innovation in Health.

Washington, DC   Logan D. A. Williams

Forging a New Health Innovation Path by "Doing" Responsibility

This book invites innovators to forge a new health innovation development path that delivers inclusive and sustainable solutions to twenty-first-century social, environmental, and economic challenges. To do so, readers will learn how the concepts and tools of Responsible Innovation in Health (RIH) can guide innovators in developing and bringing to market health innovations with a sustainable impact. Rather than lecturing innovators and asking them to "be" responsible, this book enables them to "do" responsibility by applying nine measurable responsibility attributes throughout the innovation lifecycle, that is, from ideation to assessment. Drawing from the Responsible Research and Innovation (RRI) literature, the RIH attributes are informed by our empirical research and rigorously validated through several peer-reviewed publications. They can support the design, production, and evaluation of medical devices, health and social care interventions, digital tools, and solutions based on artificial intelligence.

The RIH concepts and tools will interest those who lead or are involved in innovation hubs, incubators, or accelerators where projects are brainstormed, shaped, and structured. In their bringing together of academia and the private sector, such "intermediating platforms" strive to create vibrant spaces for researchers, trainees, and non-academic experts to imagine, develop, and bring to market innovative products, services, and digital tools. We aim to equip these platforms as they orchestrate the contributions of engineers, industrial designers, digital technology developers, clinicians, patients, entrepreneurs, and investors along the innovation pathway. Because RIH brings together several disciplines and bodies of

knowledge, the concepts and tools can support the work of interdisciplinary teams as they develop solutions to multifaceted problems.

The book will also resonate with innovators who aim to have a meaningful impact on society and with entrepreneurs who aspire to do business differently. Innovation consultants will find inspiration and practical advice to open new professional frontiers, while public policymakers and policy analysts in multilateral or intergovernmental organizations will find guidance to promote innovation and entrepreneurship that add social, environmental, and economic value.

The Research Behind This Book

Led by Pascale Lehoux, the In Fieri research program aims to develop new knowledge on the design, commercialization, and institutionalization of RIH. It is a seven-year research program based at the Université de Montréal and funded by the Canadian Institutes of Health Research (CIHR) in 2015. *In fieri* is a Latin expression that refers to what is beginning to be or is in the process of accomplishment. It thus captures the essence of RIH, a movement already in motion and aspiring to come fully into existence. Throughout the book, we share the lessons learned by our research team, which has benefited from the hard work of several researchers, graduate students, postdoctoral trainees, and knowledge transfer and exchange experts.

The RIH concepts and tools are informed by practitioners who generously participated in our research projects. We conducted more than 85 interviews with health innovators and entrepreneurs based in the Canadian provinces of Quebec and Ontario and in the Brazilian state of Sao Paulo, a longitudinal case study on 16 organizations engaged in the production of RIH in these three regions, a codesign study with 17 health innovation researchers and practitioners in Quebec, as well as numerous workshops and training activities on RIH.

Our research is concentrated in Ontario, Quebec, and Sao Paulo for various reasons, including our team's linguistic skills and cultural origins. From a scientific standpoint, it is important to know how RIH may transform entrepreneurial practices in the health sector in both mature and emerging economies. While industrial capacities in several sectors are declining in Canada, countries like Brazil, Russia, India, China, and South

Africa (commonly referred to as BRICS) are increasingly active in the development of vaccines, drugs, and medical devices. Because Brazil has an important publicly funded health system and a mix of population health needs that call for products and services that Western countries tend to neglect, Sao Paulo State has a particularly rich research setting. Sao Paulo is the most populous and economically developed Brazilian state, accounting for 31.8% of the country's gross domestic product (GDP) in 2019. Ontario and Quebec are, respectively, the first and second largest Canadian provinces, accounting for 38.6% and 19.9% of the country's GDP. The Canadian drug and medical devices industry is concentrated in these two provinces, and their respective health systems are also publicly funded.

As we will explain throughout the book, the lessons we learned from Canadian and Brazilian entrepreneurs and innovators are applicable to and can inspire several countries where the need to renew health innovation practices is salient.

Acknowledgments and Conflict Disclosure

This book was made possible thanks to the contributions and support of several individuals and organizations. We are particularly grateful to the innovation experts and practitioners who graciously enriched our understanding of the motivations and challenges underlying their work by participating in our research activities.

Our team obtained research ethics approval from the Health Research Ethics Board of the Université de Montréal (CERES-D #17-024) and from the National Commission of Ethics in Research in Brazil (CONEP #2.673.002). As per our informed consent agreement with each individual we interviewed, we do not disclose the name of their innovation or organization in our publications. This is meant to reduce possible breaches to confidentiality when we use direct quotes from research participants or provide details about their background and responsibilities.

Readers will nonetheless find in this book several real-world examples of innovations or of inspiring practices that have been established in various organizations around the world (e.g., businesses, hospitals, universities, incubators, and non-governmental agencies). Most of these examples

are summarized into boxes and thus easy to locate throughout the book. We do not entertain any financial or personal relationship with the show-cased organizations, and we do not hold any interest in their activities that could have direct or indirect influence over the information we share. Our intent is not to suggest that these examples are "perfect" or devoid of any possible drawbacks. Rather we invite readers to take note of the way these real-world solutions help move health innovation in the right direction, reflect on their likely shortcomings, and recognize the inherent challenges responsible innovators must learn to overcome.

About the Book

The book is structured around the innovation pathway, from the initial idea to the assessment of its responsibility features. It comprises three parts and 11 chapters. Readers may choose to jump from one chapter to another depending on where they are in their innovation or entrepreneurial journey. Innovation is indeed an iterative process, wherein several back-and-forth between problem-setting and problem-solving are both frequent and necessary to come up with an optimal solution. Each chapter explains the key concepts or tools addressed, as well as their practical implications. We also present examples of best practices from around the world or drawn from our own empirical research. Each chapter ends with summary points and a list of references for readers who would like to expand their understanding of the concepts or tools.

Part I—RIH Concepts—relies on five chapters to gradually unpack the nine attributes of RIH, which provide health innovators with a practice-oriented roadmap. Chapter 1—"Introduction"—underscores the health sector's capacity to trailblaze a new innovation path, one that delivers inclusive and sustainable solutions to twenty-first-century challenges. Chapter 2—"Getting Started"—explains the RIH concepts underlying the RIH design brief and invites readers to work with our Responsible Design Compass. Chapter 3—"Generating a Responsible Health Innovation Idea"—is organized around four RIH attributes. It will help readers generate ideas that can improve population health (*Health relevance*, *Health inequalities*) and strengthen health systems (*Responsiveness*, *Level and intensity of care*). Chapter 4—"Fleshing Out a Venture That

Can Responsibly Tackle the Problem"—is organized around two RIH attributes. Readers will learn about practical avenues for mobilizing at an early stage relevant innovation stakeholders (*Inclusiveness*) and structuring a responsible venture, whether not-for-profit or for-profit (*Business model*). Chapter 5—"Designing a Responsible Solution"—is organized around three RIH attributes. It will show how those who develop a responsible product, service, or digital tool can optimize its design and production processes (*Frugality*), reduce its environmental impacts throughout its lifecycle (*Eco-responsibility*), and find ways to mitigate potential unintended consequences (*Ethical, legal, and social issues*).

Part II—Tools to Make and Measure RIH—shows how innovators can materialize the nine RIH attributes introduced in Part I. While readers will learn how tools borrowed from different fields of practice can be adapted to this end, they will also become skilled at measuring whether they are meeting key responsibility targets by using the RIH Assessment Tool. Chapter 6—"Making RIH"—describes and illustrates with examples the tools and approaches that can be leveraged to fulfill RIH attributes. Chapter 7—"Bringing It All Together"—clarifies how innovators can make informed decisions not only by identifying the tensions that may exist between some RIH attributes but also by searching for design variations that can concurrently satisfy multiple attributes. Through various examples, this chapter will thus contextualize the synergies and tensions underlying RIH. Chapter 8—"Assessing the Degree of Responsibility of a Health Innovation"—describes how to consolidate the basis upon which design decisions are made while increasing transparency throughout the process.

Part III—"A Sustainable Path for RIH"—adopts a systemic perspective to address how those who lead innovation development processes can organize RIH and the key drivers and obstacles that must be understood for a collective way of doing responsibility to thrive. Chapter 9—"Orchestrating RIH"—reviews the ways in which intermediating platforms (e.g., incubators, technology transfer offices, innovation hubs) can use the concepts and tools described in the book to foster and implement RIH within their activities. It discusses how and when different stakeholders can nurture and grow RIH. Chapter 10—"Clearing Obstacles, Harnessing Drivers"—explains why responsibility in health innovation cannot solely rely on individual innovators: multiple organizations must innovate for health innovators to find and work with multiple allies. "Doing" responsibility collectively is what will enable health innovation

stakeholders to break away from the beaten path. Chapter 11 concludes this book's journey by inviting readers to envision responsible health innovators as "care-*makers*." Their creativity and problem-solving skills not only directly benefit care-*givers* and care-*receivers* but can also make health and social care more equitable and sustainable. By leveraging the multiple yet currently scattered responsible innovation drivers, a new generation of care-makers can deliver meaningful as well as impactful twenty-first-century solutions.

CONTENTS

About the Authors

Pascale Lehoux cumulates 25 years of research experience and over 150 scientific papers. Born in Quebec, a largely francophone Canadian province, she completed a bachelor's degree in Industrial Design, a PhD in Public Health (Université de Montréal), and postdoctoral studies in Science & Technology Dynamics (University of Amsterdam). She is a full professor with the Department of Health Management, Evaluation, and Policy at the School of Public Health of the Université de Montréal and Researcher at the CReSP. Her work examined computerized medical records, telemedicine, science/policy networks, home care equipment used by patients, and the impact of health technology assessment on policymaking. When holding the Canada Research Chair on Innovation in Health (2005–2015), her research clarified the impact of business models, capital investment, and economic policy on technology design processes in academic spin-offs. As director of the In Fieri research program, she leads a research team defining RIH and examining the way hybrid organizations, impact investing, and alternative business models lead to innovations that better address the needs and challenges of health systems. She is the author of *The Problem of Health Technology. Policy Implications for Modern Health Care Systems* (2006). She was awarded the 30th anniversary medal of the Canadian Agency for Drugs and Technologies in Health and received the 2022 Peggy Leatt Award from the University of Toronto for her achievements in developing transformative health system evidence.

Lysanne Rivard holds a bachelor's degree in Psychology, a master of arts in Child Studies, and a Ph.D. in Educational Studies (McGill University).

A Francophone born in Ontario, the largest Canadian province, she is a senior research advisor with the In Fieri research program on RIH at the CReSP. She conducts qualitative research with health innovators on the design and operationalization of RIH. With a strong background in participatory research, she is particularly interested in novel methodologies that engage participants in both reflective and dynamic ways to tackle health, social, environmental, and economic issues. Her multidisciplinary background has led her to conduct a broad scope of research and consultancy projects in education, international development, gender, physical activity, and mental health in Africa, Southeast Asia, and Canada. The versatility of her research career is reflected in her peer-reviewed publications and book chapters. Not only her empirical work informs large parts of the book, but she is also to be credited for the book's hands-on approach that makes academic concepts actionable.

Hudson P. Silva cumulates 20 years of experience in the field of public policy and possesses a rare combination of research, teaching, and policy-making experience. Born in the State of Sao Paulo in Brazil, he holds a bachelor's degree in Economics, a master of science in Social and Labour Economics, a PhD in Public Health (University of Sao Paulo), and post-doctoral studies in Health Innovations (Université de Montréal). He is a senior research advisor with the In Fieri research program on RIH at the CReSP. He contributed to the theoretical foundations of RIH, devised rigorous methods and measures, which led to the development and validation of the RIH Assessment Tool, and conducted mixed-methods research with health innovation entrepreneurs on the development and social financing of RIH. Prior to this position, he was a Public Policy and Management professor at the State University of Campinas, worked as a technical advisor for the Brazilian Ministry of Health developing and assessing health innovation policies, was an associate researcher with the Department of Social and Preventative Medicine (University of Sao Paulo), and was a research assistant at the Center for Public Policy Studies (University of Campinas).

Abbreviations

AI:	Artificial Intelligence
CHUM:	Hospital Center of the Université de Montréal
CIHR:	Canadian Institutes of Health Research
CReSP:	Center for Public Health Research of the Université de Montréal
CO_2:	Carbon Dioxide
CSR:	Corporate Social Responsibility
DALY:	Disability-adjusted life years
ECG:	Electrocardiogram
ELSIs:	Ethical, Legal, and Social Issues
ÉTS:	École de technologie supérieure
FDA:	Food and Drug Administration
GDP:	Gross Domestic Product
GHDx:	Global Health Data Exchange
HFE:	Human Factors Engineering
ICU:	Intensive Care Unit
ISO:	International Organization for Standardization
IT:	Information and Technology
LED:	Light-emitting Diode
LGBTQ+:	Lesbian, Gay, Bisexual, Transgender, and Queer
NGO:	Non-governmental Organization
PDF:	Portable Document Format
QFD:	Quality Function Deployment
R&D:	Research and Development
RIH:	Responsible Innovation in Health
RRI:	Responsible Research and Innovation
SDGs:	Sustainable Development Goals

SHIFT: Sustainability, Help, Information, Frameworks/Findings, and Tools
SME: Small and Medium-Sized Enterprise
TTO: Technology Transfer Office
USB: Universal Serial Bus
WHO: World Health Organization
WTO: World Trade Organization
YLD: Years Lived with Disabilities
YLL: Years of Life Lost

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RIH Concepts

In this first part, five chapters gradually unpack the nine attributes of RIH to provide readers with a practice-oriented roadmap. We begin by underscoring the health sector's capacity to trailblaze an innovation path that delivers inclusive and sustainable solutions to twenty-first-century challenges (Chap. 1). We explain key RIH concepts and invite readers to tease out their initial health innovation design assumptions with our Responsible Design Compass (Chap. 2). Then, three chapters define in greater depth all nine RIH attributes. The logic is to first clarify how to generate ideas that can concurrently improve population health (*Health relevance*, *Health inequalities*) and strengthen health systems (*Responsiveness*, *Level and intensity of care*) (Chap. 3). Then, readers learn why it is important to mobilize at an early stage diverse stakeholders (*Inclusiveness*) when fleshing out a responsible enterprise (*Business model*) (Chap. 4). Lastly, we show how the design and production processes of a responsible product, service, or digital tool can be optimized (*Frugality*), its environmental impacts reduced throughout its lifecycle (*Eco-responsibility*), and its potential unintended consequences adequately mitigated (*Ethical, legal, and social issues*) (Chap. 5).

CHAPTER 1

Introduction

Abstract Is it possible to develop high-quality and safe health innovations that also strengthen health system equity, provide more value to users, use fewer resources, are good for the environment, and are economically viable? Though this may seem like a tall order, each of these demands represent significant twenty-first-century challenges to our health and well-being that innovators can no longer ignore. By drawing in some of the best minds, creative thinkers, and tinkerers, we believe that the health innovation sector has the capacity to trailblaze a new path of innovation development, one that delivers inclusive and sustainable solutions to twenty-first-century social, environmental, and economic challenges.

Keywords Responsible Health Innovation • Inclusive Health Innovation • Sustainable Health Innovation • Grand Challenges

OFF THE BEATEN PATH: MAKING WAY FOR RESPONSIBLE INNOVATION IN HEALTH

The healthcare sector is certainly among the most regulated industries, with countless quality and safety standards, regulatory agencies, ethical and legal requirements, and professional codes of conduct. Healthcare is also a global multi-billion-dollar industry that has developed myriad high-tech solutions. Within this highly institutionalized yet rapidly evolving

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context, *being* responsible when developing a health innovation and *making* a responsible one are two different things. While the former makes an appeal to individuals' commitment to follow established rules, the latter prompts innovation stakeholders to embark on a new path.

Since the late 1980s, the way health innovations have been designed, developed, and commercialized in industrialized countries has carved a particular pathway in which academic health centers, growth-oriented enterprises, and venture capital have played an increasingly influential role (Lehoux et al., 2016). Though this path has led to incredible advances worldwide, we are now witnessing its pitfalls. First, health technologies are mostly designed to support the work of medical specialists concentrated in large urban centers, which leaves general practitioners largely unequipped to attend to their patients' needs at the primary care level. Second, the development of medical devices and drugs has become increasingly labor- and capital-intensive, which translates into higher costs. For instance, gene therapies may come with a two-million-dollar price tag per patient per treatment. Such skyrocketing costs threaten the sustainability of all health-care systems, be they publicly or privately funded. Third, high-tech solutions reinforce geographical, financial, and cultural barriers experienced by patients who live in isolated, remote, or hard-to-reach communities. By ignoring what we already know about the broader determinants of health, we are missing a formidable opportunity to innovate. Forty years later, the context has changed: a new path where we can "innovate in innovation" is needed (Roy & King, 2016). Because it is by collectively "doing" responsibility that high rewards will be obtained, this book equips health innovators to make Responsible Innovation in Health (RIH).

The Need for Responsible Innovation in Health

Firmly anchored in the health and social care literature, RIH concepts draw attention to the value different innovations bring to population health and health systems, as well as to their economic, environmental, and organizational value (Fig. 1.1). RIH applies to the innovation *and* to the organization that develops it by addressing how for-profit and not-for-profit organizations can embed measurable responsibility attributes: into their business models, throughout a technology's lifecycle, and in view of the context where users are located (Silva et al., 2018).

Fig. 1.1 The five RIH value domains

The concept of responsibility promoted by RIH is grounded in the Responsible Research and Innovation (RRI) literature, which has gained momentum in the European innovation policy landscape in the past decade (Macnaghten et al., 2014). By "taking care of the future through collective stewardship of science and innovation in the present" (Stilgoe et al., 2013), RRI scholars aim to transform current innovation development pathways toward greater social, environmental, and economic responsibility (Owen et al., 2012).

To this end, RRI promotes four processes: anticipation, reflexivity, inclusion, and responsiveness (Stilgoe et al., 2013). Throughout the innovation development process, stakeholders are encouraged to:

1. Anticipate the risks and unintended consequences of the innovation
2. Reflect on the values, biases, and social norms that underlie and shape the innovation
3. Involve a variety of relevant stakeholders, including the publics, potential users, and other concerned parties when developing the innovation
4. Respond to emerging issues and shifting contexts of innovation use in a rapid and efficient manner

Because health innovation stakeholders (e.g., entrepreneurs, clinicians, healthcare managers, patients, regulators, and payors) need to address responsibility considerations that are particular to the health and social care sector when developing products, services, and digital solutions, our

research team saw the need to adapt RRI to this sector and further develop ways to materialize responsibility in health and social care. To this end, the five value domains of RIH (Fig. 1.1) are characterized by nine responsibility attributes, each comprising a measurable rating scale (detailed in Chaps. 2, 3, 4, 5, 6, 7, and 8). The domains, attributes, and rating scales aim to tackle social, environmental, and economic challenges without compromising the stringent quality, safety, and regulatory requirements specific to the health innovation sector.

Fostering Intersectoral Solutions to Health Challenges

As current challenges to our health and social well-being are increasingly globalized, RIH aims to align health innovation with worldwide movements addressing significant societal challenges, including the United Nations' Sustainable Development Goals (SDGs) (Box 1.1). Such movements provide direction to new research pathways. For instance, the 2021–2027 Horizon Europe funding program supports research and innovation on a range of challenges, including disaster-resilient societies, clean transport, sustainable food systems, and low carbon industries.

These global movements are typically calling for intersectoral actions across health and social care, education, climate action, and economic inclusion. One of our studies offers indications on how such intersectoral solutions to health challenges may bring multiple contributions. We

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Box 1.1   The United Nations' SDGs

1. No poverty
2. Zero hunger
3. Good health and well-being
4. Quality education
5. Gender equality
6. Clean water and sanitation
7. Affordable and clean energy
8. Decent work and economic growth
9. Industry, innovation, and infrastructure
10. Reduced inequalities
11. Sustainable cities and communities
12. Responsible consumption and production
13. Climate action
14. Life below water
15. Life on land
16. Peace, justice, and institutions
17. Partnerships for the goals
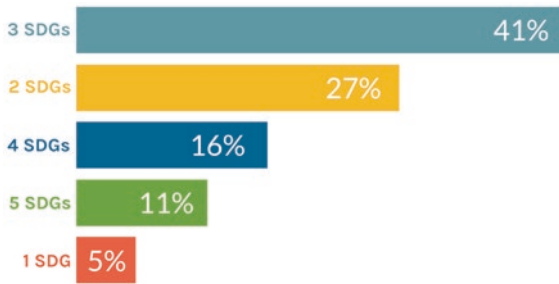
Fig. 1.2 Distribution of the innovations addressing from one to five SDGs

performed a horizon scanning using key words reflecting various responsibility features (e.g., affordability, eco-responsibility, and inclusiveness) (Lehoux et al., 2018).

Among the 105 innovations we identified, all were, of course, aligned with SDG-3 "Good health and wellbeing." They offered solutions, for instance, for newborn care, reduced mobility and limb amputation, infectious diseases, obstetrical care, or accessible care and drugs. Interestingly, these innovations also frequently addressed other SDGs, such as "Reduced inequalities" (87%), "No poverty" (15%), and "Quality education" (11%). A smaller yet sizeable portion addressed economic challenges such as "Sustainable cities and communities" (9%), or environmental challenges such as "Affordable and clean energy" (7%). Underscoring the potential of health innovations to simultaneously contribute to multiple SDGs, Fig. 1.2 shows that close to a third of the sample addressed two SDGs (27%) and 41% addressed three SDGs.

To further illustrate how social, environmental, and economic concerns can be combined, we summarize two examples from the sample. The first is a Canadian online platform that supports coordination among caregivers who attend to a vulnerable person (Box 1.2). It highlights how innovators can provide a responsive solution to a major health system challenge and adopt responsible governance practices, such as a B Corporation Certification. The latter requires carefully attending to the organization's impact on employees, suppliers, community, customers, and the environment.

> **Box 1.2   An Example from Canada**
>
> - More than 80% of Canadians offer unpaid voluntary health and social care assistance to family or community members (Cammack & Byrne, 2012).
> - The online platform can be used to archive documents, share news and photos, and synchronize a calendar with caregivers, family, and friends.
> - It can be adapted on demand to meet the needs of both individuals and institutions.
> - The platform is used by Saint Elizabeth Healthcare, Canada's largest non-profit nursing service providers.

The second example is a Brazilian not-for-profit enterprise that co-designed pediatric hearing aids using solar-powered rechargeable batteries with children and young adults with a hearing impairment (Box 1.3). Because it employs individuals living with a disability, it illustrates how responsibility can shape both the innovation and the organization. Entrepreneurs not only created a less environmentally harmful product sold at 20% of the market cost but also created an opportunity for vulnerable groups to earn stable revenues. This represents an important population health benefit because it improves their health and well-being through social and economic inclusion (Macaulay et al., 2018).

> **Box 1.3   An Example from Brazil**
>
> - The hearing aids using a solar energy charger were first developed in Botswana where the price of a battery with a one-week lifetime is $1 and where average revenues are between $1.25 and $2.50/day. The rechargeable batteries cost around $2.50 and last two to three years.
> - Though it remains difficult to estimate the environmental impact over the product's lifecycle, 200 million disposable batteries are discarded annually, a problem the solar charger mitigates.
> - In Brazil, the company's mission is to break the cycle of poverty in which many children with a hearing impairment are born and raised. By employing people living with a disability, it goes well beyond Corporate Social Responsibility (CSR) activities such as donating goods or raising funds (Levänen et al., 2015).

Ready to Embark on a New Path?

As we can see from the Canadian and Brazilian examples, the opportunity as well as the necessity to renew health innovation strategies are manifest in both mature and emerging economies. In many developed countries, a growing percentage of the Gross Domestic Product (GDP) is attributed to healthcare services, while an aging population, persistent health inequalities, and the need for thoughtful control of health spending coexist (Roncarolo et al., 2017). This threatens their capacity to tackle other pressing social, environmental, and economic concerns. Concurrently, the innovation capacities in emerging economies have steadily increased over the past decades. For instance, Brazil, India, and South Africa all have very large domestic markets for medical devices, digital tools, and artificial intelligence-based solutions. They are thus well positioned to engage in and bring to scale RIH.

The question readers may ask at this point is: "*How* can we develop high quality and safe health innovations that also: strengthen health system equity, provide more value to users, use fewer resources, are good for the environment, and are economically viable?" The answer is off the beaten path. Come and join us, we'll get you started!

References

Cammack, V., & Byrne, K. (2012). Accelerating a network model of care: Taking a social innovation to scale. *Technology Innovation Management Review, 2*(7), 26.

Lehoux, P., Roncarolo, F., Oliveira, R. R., & Silva, H. P. (2016). Medical innovation and the sustainability of health systems: A historical perspective on technological change in health. *Health Services Management Research, 29*(4), 115–123. https://doi.org/10.1177/0951484816670192

Lehoux, P., Silva, H. P., Pozelli Sabio, R., & Roncarolo, F. (2018). The unexplored contribution of Responsible Innovation in Health to Sustainable Development Goals. *Sustainability, 10*(11), 4015.

Levänen, J., Hossain, M., Lyytinen, T., Hyvärinen, A., Numminen, S., & Halme, M. (2015). Implications of frugal innovations on sustainable development: Evaluating water and energy innovations. *Sustainability, 8*(1), 4. https://doi.org/10.3390/su8010004

Macaulay, B., Mazzei, M., Roy, M. J., Teasdale, S., & Donaldson, C. (2018). Differentiating the effect of social enterprise activities on health. *Social Science & Medicine, 200*, 211–217. https://doi.org/10.1016/j.socscimed.2018.01.042

Macnaghten, P., Owen, R., Stilgoe, J., Wynne, B., Azevedo, A., De Campos, A., Chilvers, J., Dagnino, R., di Giulio, G., & Frow, E. (2014). Responsible inno-

vation across borders: Tensions, paradoxes and possibilities. *Journal of Responsible Innovation, 1*(2), 191–199. https://doi.org/10.1080/2329946 0.2014.922249

Owen, R., Macnaghten, P., & Stilgoe, J. (2012). Responsible research and innovation: From science in society to science for society, with society. *Science and Publich Policy, 39*(6), 751–760. https://doi.org/10.1093/scipol/scs093

Roncarolo, F., Boivin, A., Denis, J.-L., Hébert, R., & Lehoux, P. (2017). What do we know about the needs and challenges of health systems? A scoping review of the international literature. *BMC Health Services Research, 17*(1), 636. https://doi.org/10.1186/s12913-017-2585-5

Roy, V., & King, L. (2016). Betting on hepatitis C: How financial speculation in drug development influences access to medicines. *Bmj, 354*, i3718. https://doi.org/10.1136/bmj.i3718

Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J.-L. (2018). Introducing responsible innovation in health: A policy-oriented framework. *Health Research Policy and Systems, 16*(1), 90–103. https://doi.org/10.1186/s12961-018-0362-5

Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy, 42*(9), 1568–1580. https://doi.org/10.1016/j.respol.2013.05.008

CHAPTER 2

Getting Started

Abstract To get you and your team started to make Responsible Innovation in Health (RIH), this chapter clarifies the definition of RIH and presents the conceptual framework, which comprises the five value domains and nine responsibility attributes briefly introduced in Chap. 1. Then, we invite you and your team to work with our Responsible Design Compass, a novel design-thinking tool we developed based on the practical insights of health innovators. The objective of the Responsible Design Compass is to help you better grasp the RIH concepts and to tease out your own design assumptions before moving on to the RIH design brief detailed in Chaps. 3, 4, and 5.

Keywords Responsible Health Innovation • Health Equity • Sustainable Health Systems • Responsible Design Compass

What Is Responsible Innovation in Health

To define what is RIH, our team led an extensive review of the scientific literature on Responsible Research and Innovation (RRI), population health, health systems, bioethics, and innovation-based entrepreneurship, as well as an analysis of over 100 innovations illustrating various responsibility features (e.g., health equity, affordability, and sustainability) (Silva et al., 2018). Our definition explains *who* should be involved in the development of RIH, *what* they should do, *when*, and *why*. It is as follows:

Box 2.1   The Who, What, When, and Why of RIH

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

We use the term "sociotechnical solutions" rather than "technology" for two main reasons. First, the term encompasses solutions that go beyond what is usually understood as medical technologies (e.g., medical devices, drugs, vaccines, medical procedures, or information systems) and that address the broad range of social and environmental determinants of health (e.g., education, employment, gender, and physical environment). Second, it emphasizes how the use of every technology, from a simple syringe to a complex intensive care unit, requires *social* components, that is, the knowledge and know-how of various individuals and organizations. Sociotechnical thus reflects the fact that both human skills and technical means are intimately involved in any innovative solution.

The RIH definition also captures the entire innovation development process, including the design, financing, production, regulation, distribution, and, ultimately, the safe disposal of the innovation (Moultrie et al., 2016). Because of this, different stakeholders must collaborate throughout the RIH innovation process. These include innovators, entrepreneurs, investors, regulators, policymakers, healthcare providers and managers, patients, and civil society. While stakeholders pursue objectives that differ and sometimes conflict with each other, they do, nonetheless, possess complementary skills that are needed throughout the innovation pathway. Consequently, collaboration is essential for putting the ethical, economic, social, and environmental principles, values, and requirements of RIH into action. In this way, responsibility is shared across a large spectrum of individuals and organizations.

The RIH Conceptual Framework

Building on the aforementioned definition (Box 2.1), the RIH conceptual framework adopts a global perspective on population health and health

systems. It provides an integrated set of value domains and responsibility attributes through which stakeholders can support health system equity and sustainability by envisioning what types of innovations are needed, how they should be produced, and how they should be brought to market (Silva et al., 2018).

As illustrated in Fig. 2.1, the RIH conceptual framework comprises nine responsibility attributes, or features, that are organized into the five value domains presented in Chap. 1. The attributes are to be considered throughout the lifecycle of the innovation and in view of the context where users are located. Not only do individual and population health needs vary from one context to another (Sen, 2002), but different health systems experience different types of challenges (Roncarolo et al., 2017).

As Fig. 2.1 highlights, RIH takes into consideration the *processes* by which an innovation is being produced, its characteristics as a *product* as well as the *organization* that produces it and makes it available to end users. As readers may recall, by promoting anticipation, reflexivity, inclusion, and responsiveness in innovation development processes, RRI focuses on *how* innovation should be developed. Thus, to the process-oriented approach of RRI, the RIH framework adds: (1) the tangible responsibility features a health innovation should possess, that is, *what* should be delivered by health innovators; (2) the key purposes, that is, *why* this innovation is needed from a population health and health system
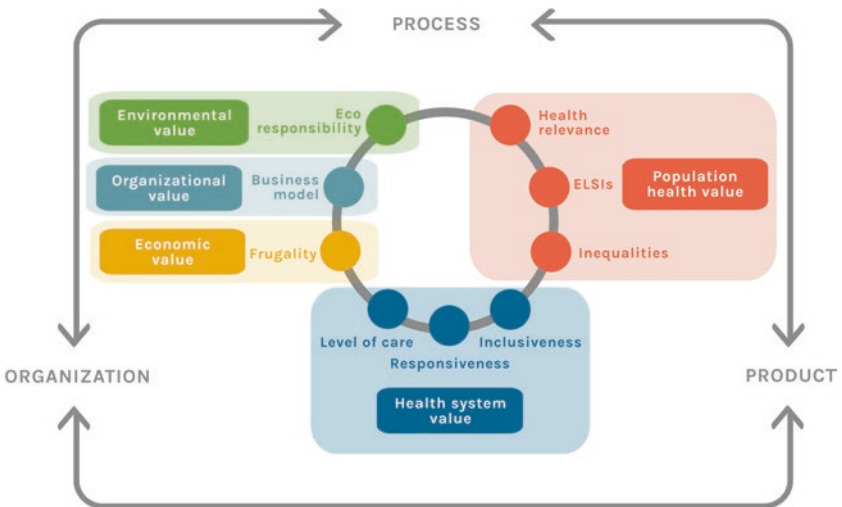
Fig. 2.1 The RIH conceptual framework

perspective; and (3) the entrepreneurial structure that produces and delivers the innovation, that is, *through what business model* the innovation is offered to end users (Lehoux et al., 2014).

Box 2.2 summarizes each value domain and the key question underlying their respective attributes.

Box 2.2   The RIH Value Domains and Attributes
Population health value. RIH should increase our ability to meet collective needs while addressing health inequalities.

- **Health relevance**: Does the innovation address a relevant health problem?
- **Ethical, legal, and social issues (ELSIs)**: Was the innovation developed by seeking to mitigate its ethical, legal, and/or social issues?
- **Health inequalities**: In what ways does the innovation reduce health inequalities?

Health system value. RIH should provide an appropriate response to system-level challenges.

- **Inclusiveness**: Were the innovation development processes inclusive?
- **Responsiveness**: Does the innovation provide a dynamic solution to a health system need or challenge?
- **Level and intensity of care**: Are the level and intensity of care required by the innovation compatible with health system sustainability?

Economic value. RIH should deliver affordable high-quality products.

- **Frugality**: Does the innovation deliver greater value to more people using fewer resources?

Organizational value. RIH should rely on business models through which more value is provided to society.

- **Business model**: Does the organization that produces the innovation seek to provide more value to users, purchasers, and society?

Environmental value. RIH should reduce as much as possible the environmental impacts of health innovations.

- **Eco-responsibility**: Does the innovation limit its negative environmental impact throughout its lifecycle as much as possible?

Teasing Out Your Design Assumptions with the Health Innovation Responsible Design Compass

The Responsible Design Compass is a novel design-thinking tool our team developed to help health innovators reflect on the design assumptions that guide their work. The objective is to prompt a dynamic discussion around responsibility issues that are not typically raised a priori in health innovation design. By engaging with these issues at the beginning of the ideation process, the Responsible Design Compass can help design teams collectively identify creative ways to break away from the current health innovation path. We describe how we built the Responsible Design Compass with the practical insights of health innovators and then explain how to work with it.

Building the Responsible Design Compass with Practical Insights from Health Innovators

We developed the Responsible Design Compass by drawing from scenario-based codesign methods (Abrassart et al., 2015) and from the empirical research we conducted with Canadian health innovators, including engineers, entrepreneurs, industrial designers, and clinical scientists. When discussing the five RIH value domains and sharing their perspectives on what they believed was and was not a responsible health innovation, the health innovators we interviewed identified practical challenges and tensions they believed might emerge when developing responsible health innovations (Rivard & Lehoux, 2020).

For example, though most interviewees agreed with the Inclusiveness attribute that promotes the inclusion of a variety of stakeholders during the design and development phases, many also raised practical challenges they must overcome to do so. Similarly, while the near majority agreed that environmental considerations are important in health innovation design, many saw a tension between meeting the Eco-responsibility attribute requirements as well as health requirements and stressed that the latter must remain the priority when designing health innovations (Rivard et al., 2020).

Based on these findings where interviewees saw RIH as both a matter of principle and a pragmatic issue, we formulated five questions that capture the practical tensions in the design of responsible health innovations around the five value domains. They are as follows:

- **Population health value tension**: Is it better to address the most prevalent population health needs or to fill key gaps in individual patient care (for instance, for those who suffer from rare or orphan diseases)?
- **Health system value tension**: Is it better to support solutions developed by end users or to ascribe greater importance to experts' abilities?
- **Economic value tension**: Is it better to aim for a higher degree of frugality or to exploit leading-edge technologies?
- **Organizational value tension**: Is it better to prioritize a lucrative business model or to prioritize health impacts for a greater number of people?
- **Environmental value tension**: Is it better to focus on health requirements or to take into consideration the environmental impact?

Our team then illustrated each question in the form of a continuum between two *equally* valid design objectives and placed each continuum to form a wheel (Fig. 2.2).
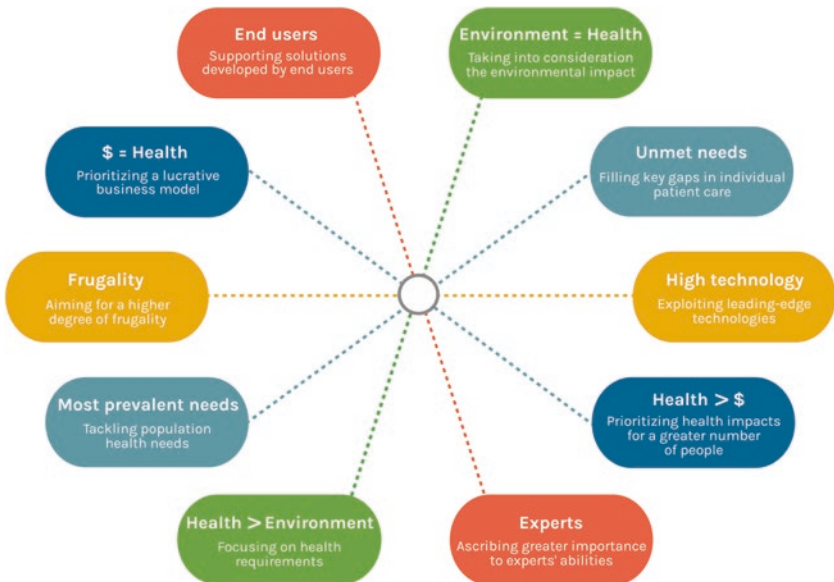
Fig. 2.2   The Responsible Design Compass for health innovators

The continuum between two contrasting but valid design objectives enables innovators to decide where they think a responsible health innovation should be positioned between the two poles. In this way, the design tensions serve as a sounding board to identify and discuss where one may stand along these continua and why. The purpose of discussing the tensions and where one positions health innovations along each continuum is to bring forward a variety of perspectives and issues in a more dynamic way and to make explicit the reasoning behind the selected positions on each continuum. As such, there are no right or wrong answers.

Working with the Responsible Design Compass

We conducted this activity with a group of 17 health innovation researchers and practitioners from various professional backgrounds, including engineering, clinical sciences, management, design, and communication. It prompted a lively discussion and created a fabulous learning space where many examples and design options were shared. We thus invite readers to either follow our activity format described further or to adapt it to their needs, as the time and space required are quite flexible. For a more dynamic discussion, we strongly recommend conducting this activity with a group of individuals with various backgrounds and experiences in health innovation design, production, management, and commercialization.

With the Responsible Design Compass projected onto a whiteboard, for instance, a moderator can read out each of the five questions capturing the practical tensions in the design of responsible health innovations. This person can then invite participants to react to each of the tensions successively, asking them to locate on the continuum where they believe the starting point for a responsible health innovation design should be positioned. After marking the position on the whiteboard with a red dot, the moderator should prompt the participant to explain their reasoning and offer concrete examples to support their reflection. The other participants can then jump in, share counterarguments as well as additional examples.

For instance, during our own activity, when discussing the health and environment continuum, some participants aimed to *equally* integrate eco-responsible requirements and health requirements when designing health innovations, while others preferred to *prioritize* health requirements while still integrating *some* environmental considerations (Fig. 2.3). This prompted a lively discussion on how different contexts of use impact responsibility considerations. A participant who placed their red dot closer
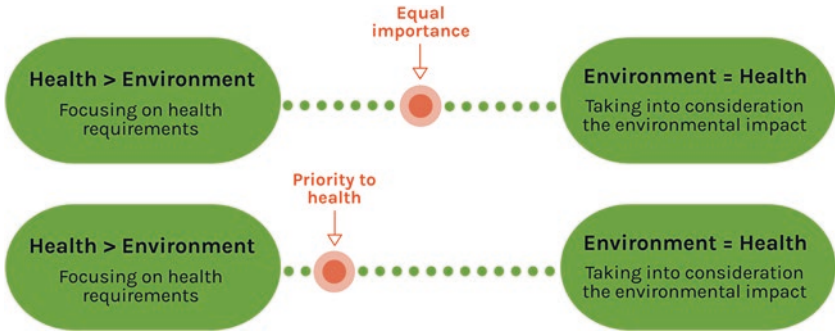
Fig. 2.3 Two positions on the Responsible Design Compass Environmental value tension

to the health requirements pole explained how the stringent infection control guidelines in hospital settings currently limit eco-friendly alternatives to disposable products. However, because these guidelines generate massive amounts of waste, participants agreed that hospitals still needed sustainable solutions. To stimulate the discussion "off the beaten path" and point toward potential ways of reconciling the "double burden" of health and environmental requirements, our moderator shared the oft-cited example inspired by biomimicry that offers a radically different approach to infection control: a coating that replicates the geometry of shark-skin scales as these inhibit the growth of bacteria (Rivard et al., 2020). Using counterexamples such as this one helps reframe the design problem and stimulate new ideas and approaches.

Our experience confirmed the value of using the Responsible Design Compass as a balanced yet powerful discussion tool. Health innovators can discuss as a group how their views regarding responsibility may vary according to the five sets of equally valid design objectives. They can bring out the practical issues that may justify a particular placement on the continuum for a certain innovation, but also break away from the tension points and look for innovative ways to reconcile them instead. This is why we invite you and your collaborators to get started with the Responsible Design Compass and tease out your own design assumptions before moving on to the RIH design brief described in the following chapters.

Both the notion of responsibility, which we see as a matter of degrees along a continuum, and the importance of identifying and reconciling

tensions between responsibility elements form the basis of the RIH design brief. In a stepwise fashion, this design brief will help you and your team think through ways to generate a responsible health innovation idea (Chap. 3), flesh out a venture that can responsibly tackle the problem (Chap. 4), and design a responsible solution (Chap. 5).

SUMMARY POINTS

Box 2.3 Chapter 2 Summary Points

- The RIH conceptual framework comprises nine responsibility attributes that define the value innovation brings to population health and health systems as well as its economic, organizational, and environmental value.
- Responsibility is considered throughout the lifecycle of the innovation and in view of the context where users are located.
- The Responsible Design Compass can help health innovation teams tease out their design assumptions before embarking on the RIH pathway.

REFERENCES

Abrassart, C., Gauthier, P., Proulx, S., & Martel, M. (2015). Le design social: une sociologie des associations par le design? Le cas de deux démarches de codesign dans des projets de rénovation des bibliothèques de la Ville de Montréal. *Lien social et Politiques* (73), 117–138.

Lehoux, P., Daudelin, G., Williams-Jones, B., Denis, J.-L., & Longo, C. (2014). How do business model and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs. *Research Policy, 43*(6), 1025–1038. https://doi.org/10.1016/j.respol.2014.02.001

Moultrie, J., Sutcliffe, L., & Maier, A. (2016). A maturity grid assessment tool for environmentally conscious design in the medial device industry. *Journal of Cleaner Production, 122*, 252–265. https://doi.org/10.1016/j.jclepro.2015.10.108

Rivard, L., & Lehoux, P. (2020). When desirability and feasibility go hand in hand: Innovators' perspectives on what is and is not responsible innovation in health. *Journal of Responsible Innovation, 7*(1), 76–95. https://doi.org/10.1080/23299460.2019.1622952

Rivard, L., Lehoux, P., & Miller, F. A. (2020). Double burden or single duty to care? Health innovators' perspectives on environmental considerations in health innovation design. *BMJ Innovations, 6*, 4–9. https://doi.org/10.1136/bmjinnov-2019-000348

Roncarolo, F., Boivin, A., Denis, J.-L., Hébert, R., & Lehoux, P. (2017). What do we know about the needs and challenges of health systems? A scoping review of the international literature. *BMC Health Services Research, 17*(1), 636. https://doi.org/10.1186/s12913-017-2585-5

Sen, A. (2002). Why health equity. *Health Economics, 11*(8), 659–666. https://doi.org/10.1002/hec.762

Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J.-L. (2018). Introducing responsible innovation in health: A policy-oriented framework. *Health Research Policy and Systems, 16*(1), 90–103. https://doi.org/10.1186/s12961-018-0362-5

Generating a Responsible Health Innovation Idea

Abstract With a grasp on the Responsible Innovation in Health (RIH) concepts and your design assumptions teased out with the Responsible Design Compass, you and your team are now ready to work with the RIH design brief covered in Chaps. 3, 4, and 5. After brief instructions on how to work with the design brief, we explain how to generate a responsible health innovation idea. The chapter is organized around the four RIH attributes that can align your innovation toward addressing a relevant health problem, providing a dynamic solution to a health system need, reducing health inequalities, and supporting the sustainability of health systems. The first two attributes—*Health relevance* and *Responsiveness*—guide teams toward the types of problems the innovation idea should target, while the remaining two attributes—*Health inequalities* and *Level and intensity of care*—explain for whom it should be developed. For each attribute, we begin by defining it and explaining why it matters. Then, we describe how to boost your idea's degree of responsibility and share an example of good practice. By working with four of the nine RIH attributes during the ideation phase, teams can increase their innovation's overall degree of responsibility right from the get-go.

Keywords Responsible Health Innovation • Health Relevance • Health System Responsiveness • Health Inequalities

Working with the RIH Design Brief

The objective of the RIH design brief is to enable teams to *do* responsibility by integrating the nine RIH attributes directly into the design, development, and commercialization of their innovation. Toward this end, we organized the nine RIH attributes briefly introduced in this text (Chap. 2) around three key innovation stages: ideation (Chap. 3), developing the organization that can bring the innovation to its intended end-users (Chap. 4), and designing the solution (Chap. 5). As the term "design brief" entails, our aim is to both inspire and challenge teams to consider a variety of responsibility elements and issues that are not always explored during early design and development phases. To do so, in addition to explaining the attributes and sharing examples of good practice, we also clarify what we mean by "degree of responsibility" and why rating scales should be used to guide decisions at the ideation stage. These scales can be regularly revisited as teams and their stakeholders iteratively progress along the innovation pathway.

As briefly mentioned in Chap. 1, each of the nine RIH attributes has its own measurable rating scale. The nine rating scales form part of the RIH Assessment Tool (Silva et al., 2021) and readers will learn more about how we developed them with the help of international experts in Chap. 8. Their purpose is to assess the degree of responsibility of an innovation: rather than assuming that a given innovation is either responsible or irresponsible, we define responsibility as a continuum. Each scale is made up of four levels ranging from A to D, where A implies a high degree of responsibility and D implies that there are no particular signs of responsibility. In this way, the lowest level of the scale does not measure *irresponsibility*, a point to which we will come back in Chap. 8.

For the purposes of the design brief, we invite innovation teams to work with the attributes and their four-level descriptive rating scales to stimulate and inform upstream decisions by determining which degree of responsibility they wish to aim for and why. In Chap. 7, we will further explore how teams can identify tensions between certain attributes that may arise in relation to the particularities of their innovation and how to leverage the synergies.

Because innovations come to life through iterative processes, myriad exchanges with stakeholders, as well as unpredictable circumstances, discrepancies between what teams set out to do and what they end up doing are simply to be expected. While a variety of elements will factor into the
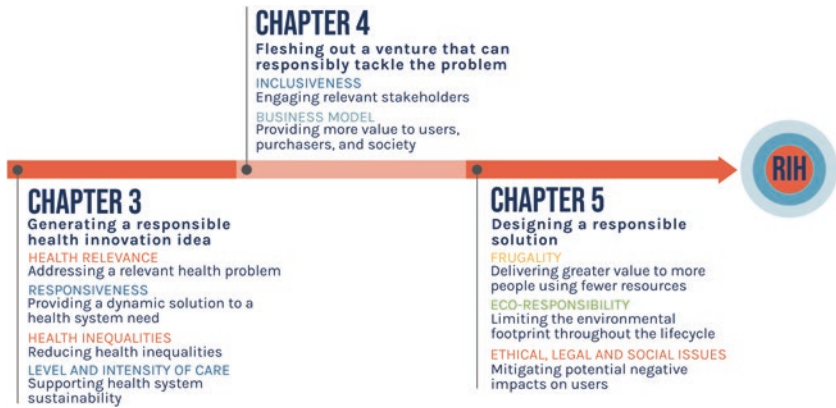
Fig. 3.1 The roadmap to discover the nine RIH attributes

decisions that lead to your end product, the RIH design brief offers a responsibility roadmap that you and your team can follow as you trace the path to make your responsible innovation.

With the idea of a roadmap in mind, we present the different attributes in a certain order and with a rationale behind the linear sequence (Fig. 3.1). Though we begin with the task of defining a responsible health innovation idea by focusing on four RIH attributes, this order is by no means set in stone. While the design brief represents a hypothetical "superhighway" from ideation to final product, we are well aware that innovation development is not a linear process, and we invite teams to take the routes and detours that work for them. As they travel through the innovation process, the attributes and their rating scales can serve as checkpoints that teams can first explore, decide, travel some more, and then come back to and adjust if need be.

Addressing a Relevant Health Problem

Briefly introduced in Chap. 2, the Health relevance attribute is part of the Population health value domain of RIH and asks the following question: does the innovation address a relevant health problem (Silva et al., 2018)? We invite teams to start the ideation process with this question as tackling a relevant health problem will increase the potential impact of the innovation. In the Responsible Design Compass, we captured the practical design

tension of whether it is better to address the most prevalent population health needs or to fill key gaps in individual patient care, including patients who suffer from rare or orphan diseases. While both objectives are equally valid and important, we help teams navigate through this tension by proposing a set of metrics that assess the relevance of a health problem.

For RIH, a health problem is relevant when it addresses a significant portion of the overall burden of disease in the region where the intended users of the innovation are located. To assess the burden of a disease in a certain region, the following elements are typically taken into consideration: the causes of death (mortality), the causes of injury and disability (morbidity), and the associated risk factors. As such, the burden of a disease can significantly differ per region. For example, malaria is associated to a very high burden of disease in South Asia and in Sub-Saharan Africa (top quarter) but has a limited impact in Europe and North America (bottom quarter). Inversely, cocaine use disorders are very significant in North America but are associated to a lesser burden of disease in low-income regions (Global Burden of Disease Collaborative Network, 2020).

While burden of disease measurements may be limited due to a lack of robust data or differing classifications across countries, the Global Burden of Disease Study of the Institute of Health Metrics and Evaluation from the University of Washington works with the following five metrics:

- The number of deaths
- Disability-adjusted life years (DALY)
- Years lived with disabilities (YLD)
- Years of life lost (YLL)
- The prevalence and incidence rates

The Global Health Data Exchange (GHDx) and data from the Global Health Observatory can help you and your team better understand the overall burden of the health problem you wish to tackle. The Institute of Health Metrics and Evaluation runs the GHDx, a free online tool that calculates these five metrics for 364 diseases on a yearly basis, across the globe and multiple regional levels, as well as for both sexes and all age groups. The diseases are categorized into communicable, maternal, neonatal, and nutritional diseases, noncommunicable diseases (including mental illnesses), and injuries. The Global Health Observatory of the World Health Organization (WHO) also provides global health estimates on the leading causes of DALYs, YLLs, and YLDs from 2000 to 2019. Data can be

downloaded for free by region or by country and is organized by year, cause, age, and sex. Because of the way data is presented, variations to the burden of diseases can be observed across time, regions, ages, and sexes.

Boosting Your Innovation Idea's Degree of Responsibility

Working with the metrics of the Global Burden of Disease Study listed earlier, the rating scale of the Health relevance attribute breaks down the burden of the disease into four levels. Specifically, we look at whether the innovation addresses a cause of death, injury or disability, or a risk factor that falls within:

  A. The top quarter of all causes of death, injury or disability, or risk factors of the region where the intended users are located (75% and above)
  B. The upper middle quarter (50% to 74%)
  C. The lower middle quarter (26% to 49%)
  D. The bottom quarter (the lowest 25%)

To increase the degree of responsibility of your innovation idea, you and your team can follow these steps:

  1. Use the GHDx to calculate the burden of the disease your team aims to tackle. This can be measured in terms of the cause of death, injury or disability, or a risk factor in the region where the intended users are located. Alternatively, you may look for rigorous data from a respectable source that describes: the number of people affected by the targeted disease, for how long, and with what sorts of consequences for a given geographical region.
  2. Determine which quarter the burden of the disease falls within the above Health attribute rating scale (A to D).
  3. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation idea or if adjustments can be made to increase it (i.e., closer to an A).

Box 3.1 summarizes an example of an innovation that addresses a relevant health problem in North America. Like for other real-world examples found across this book, the experts who shared the information appear at the bottom of the box.

Box 3.1   The KneeKG System from Emovi

Addressing a relevant health problem: The KneeKG System from Emovi

Osteoarthritis is a degenerative disease of joint cartilage that can affect aging populations. The cartilage that prevents bones from rubbing against each other gradually deteriorates causing pain and limitations in activities of daily living. The Public Health Agency of Canada (2020) reports that knee osteoarthritis affects 13.6% of Canadians—approximately 3.9 million people—and the disease falls within the top quarter of all causes of disabilities in North America (Global Burden of Disease Study, 2017). As such, knee osteoarthritis in North America corresponds to an A on the RIH Health relevance attribute rating scale.

Current diagnostic tools for knee osteoarthritis are limited in their capacity to identify knee biomechanical markers, which are directly associated with disease progression and patient symptoms. Doctors mainly rely on static X-rays, self-administered questionnaires, and observations to confirm the diagnosis, but these have limited value when defining treatment.

To address this issue, the KneeKG system was developed by researchers from the École de technologie supérieure (ÉTS), the Hospital Center of the Université de Montréal (CHUM), and the Université TÉLUQ in Quebec. It assesses the movements of the knee and presence of biomechanical markers both in real time and in 3D. It therefore enables a precise and objective functional assessment of the knee and helps healthcare providers to detect biomechanical alterations. Using artificial intelligence (AI), it suggests personalized treatments and exercises to address these markers. Its value in osteoarthritis management was confirmed in a clinical effectiveness study with over 300 doctors and 800 patients (Cagnin et al., 2020).

Source: Nicola Hagemeister, PhD, Biomedical Engineer and Full Professor, ÉTS

With your innovation idea aligned toward tackling a relevant health problem, the next step is to take a closer look at what the health system needs to refine your targeted problem.

Providing a Dynamic Solution to a Health System Need

Part of the Health system value domain, the Responsiveness attribute looks at whether the innovation provides a dynamic solution to a health system need or challenge that is documented as being important in the region where the intended users are located (Silva et al., 2018). After determining which relevant health problem your innovation targets, the next question you and your team can ask is: what are the most pressing challenges of the local health system in providing care for the targeted health problem? These can also include challenges that occur outside of health services facilities, for instance, preventive interventions or home-based care challenges.

To identify system-level challenges where innovations can have a significant impact, Roncarolo et al. (2017) conducted a review of the international literature on the challenges of health systems worldwide. They analyzed 292 scientific articles and identified a total of 1590 reported challenges. The latter were categorized following an established health system components framework and the countries where these challenges were reported were grouped according to the Human Development Index (2012). Though the nature and magnitude of the systemic challenges varied across countries, the following four categories of challenges, which accounted for three quarters of the total reported challenges, are a good place for innovation teams to start their exploration:

- **Human resources challenges**, including training and education, supervision, staff distribution, and workforce retention
- **Service delivery challenges**, including access to care (affordability, acceptability, geography, etc.), quality (reliability, wait times, etc.), and patient centeredness (continuity of care, safety, stigma, etc.)
- **Knowledge and information challenges**, including data acquisition, analysis, and interpretation (at the patient level and at the service provision level), development and implementation of knowledge-based tools (decision aids, clinical guidelines), and health information systems
- **Leadership and governance challenges**, including intersectoral collaboration (affordable housing, literacy, healthy foods, etc.), coordination within public services and between private and public services, accountability, and community partnerships (empowerment of local communities, etc.)

Other challenges to consider can include the way a region's demographic profile is changing (aging, birth rate, immigration) or epidemiological shifts that indicate changes in the prevalence of infectious and chronic diseases over time.

Boosting Your Innovation Idea's Degree of Responsibility

The rating scale of the Responsiveness attribute looks at the level of importance of the health system challenge the innovation addresses in the targeted region, that is, whether it is of:

A. High importance
B. Moderate importance
C. Low importance
D. No specific system-level challenge

To increase the degree of responsibility of your innovation idea, you can do the following:

1. Identify which system-level challenge you aim to tackle with your innovation.
2. Search for and review credible sources of information that explain how important the challenge is for the region where the intended users are located.
3. Assess whether the challenge is documented as being of high, moderate, or low importance and whether it is on the rise or being addressed through other means.
4. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation idea or if adjustments can be made to increase it.

In Box 3.2, we describe how a new model of health and social care is envisioned to provide a dynamic solution to a health system need.

Box 3.2   Envisioning a Responsive Solution for Polyimpaired Individuals at the CHUM

Providing a dynamic solution to a health system need: A new model of health and social care delivery for polyimpaired individuals and their families

Polyimpairment is a severe motor deficit and intellectual disability that considerably reduces mobility and autonomy. Polyimpaired individuals and their families require specialized physical, psychological, social, and financial support. In the Quebec provincial health and social care system, there is currently a significant service delivery gap as the system lacks a proper network of resources, standards of practice, and facilitated transitions from pediatric to adult care.

Consequently, parents of polyimpaired individuals lack information about available services, are forced to find resources on their own, and must deal with several specialized centers for care. As navigating through the cracks of the system is arduous and time-consuming, exhaustion, work absenteeism, or needing to leave the workforce altogether places families of polyimpaired individuals at high risk of financial as well as physical and mental health problems.

To tackle these problems, the CHUM, the Centre Philou (a community organization), and their multiple partners are cocreating a new model of health and social care for polyimpaired individuals and their families that is built along the life care pathway. It will offer services that are lacking, propose ways to support patients and their families, and leverage existing resources. Cocreators of the new model include: parents of patients, doctors, nurses, primary, secondary, and tertiary care providers, psychosocial professionals, school representatives as well as government health, social, and economic representatives.

Source: Kathy Malas, M.P.O., GCHlthMgt, Speech-Language Pathologist, Practitioner- Researcher, and Associate to the President & Chief Executive Officer, Pole of Innovation & Artificial intelligence in Health, Executive Office, CHUM

Once your innovation idea addresses a relevant health problem and provides a timely solution to a health system need, the next step is to define for whom the innovation should be developed.

Reducing Health Inequalities

Part of the Population health value domain, the Health inequalities attribute looks at whether an innovation helps to reduce or exacerbates disparities in health status that result from diverse social factors (Silva et al., 2018). Health inequalities occur when the health of an individual or a group is negatively impacted by social factors, including socioeconomic status, social position, or capabilities (skills, knowledge, perceived self-efficacy, social network, etc.) (Sen, 2002). As such, individuals or groups can suffer from greater rates of mortality or morbidity as a result of who they are (e.g., a visible minority group), where they grow up or where they live (e.g., deprived urban or rural areas), and where they work (e.g., precarious employment and work-related safety hazards) (Silva et al., 2021). These social factors therefore increase the relative risk individuals face as well as the cumulated life-long impact different health problems have on certain populations (Marmot, 2015; Marmot & Bell, 2012).

Here are a few examples of groups whose social factors can increase their risk of health problems:

- **In relation to employment**: subsistence farmers, long-term unemployed, seasonal/daily workers, and so on.
- **In relation to living conditions**: people living in deprived urban or rural areas, living in poverty, experiencing homelessness, living with disabilities, living with mental illnesses, and so on.
- **In relation to social status**: visible minority groups, asylum seekers, refugees, socially marginalized groups (e.g., lesbian, gay, bisexual, transgender, and queer [LGBTQ+]), single parents, older people, children, and so on.

Because health innovations are designed, developed, commercialized, and used within societal structures and established power dynamics, they are not immune to the social factors that create or exacerbate health inequalities. Innovators can better address such inequalities by being aware of how these factors affect health. For instance, the online Health Inequalities Data Tool developed by the Canadian Government makes it easy to visualize inequalities data in relation to various social determinants of health (website listed at the end of the chapter).

Boosting Your Innovation Idea's Degree of Responsibility

The rating scale of the Health inequalities attribute looks not only at who benefits from the innovation but also at whether the ability to benefit from the innovation varies across society. It draws attention to whether the innovation:

A. Reduces existing inequalities by catering to the specific needs of a vulnerable group that are not met by current solutions
B. May contribute to the reduction of inequalities since the ability to benefit from the innovation is not affected by one's socioeconomic status, social position, or capabilities
C. May contribute to the increase of inequalities since the ability to benefit from the innovation is affected by one's socioeconomic status, social position, or capabilities
D. Increases inequalities by catering the specific needs of groups whose socioeconomic status, social position, or capabilities are among the highest

To increase the degree of responsibility of your innovation idea, you can do the following:

1. Determine if your innovation idea aims to meet the needs of a vulnerable group.
2. Closely examine whether one's socioeconomic status, social position, or individual capabilities (knowledge, perceived self-efficacy, social network, etc.) can negatively impact the capacity to benefit from the innovation. Keep in mind that the capacity to benefit includes but goes beyond financial accessibility. To identify and better understand potential issues, discuss with a diversity of relevant stakeholders, including public health experts, community-based health and social care providers, or social scientists doing research on health inequalities.
3. Assess whether your innovation idea corresponds to an A, B, C, or D on the rating scale.
4. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation idea or if adjustments can be made to increase it.

In Box 3.3, we present a digital platform ecosystem developed in India that supports a vulnerable group and addresses several determinants of health.

Box 3.3   A Digital Platform Ecosystem for Waste Collectors in India
Reducing health inequalities: A digital platform ecosystem for waste collectors in India

Informal waste collectors in India are a marginalized population often exploited by organizations that pay low and irregular wages. Although they provide an essential public health service, they are often stigmatized by local communities. In many cities, government services are limited to collecting household waste and bringing it to various sites. In a city with mass migration due to a growing information and technology (IT) sector, this service became inadequate, creating an unhealthy urban environment (Ahuja & Chan, 2020).

To tackle this problem, a non-governmental organization (NGO) decided to formalize waste collection, management, and recycling and to foster the social inclusion of waste collectors through a dignified and well-paid livelihood. They created small waste collection centers across the city with the help of the local government as well as a digital platform ecosystem that brings together representatives from the government, NGOs, waste pickers, and community volunteers. The technology for the platform was provided by a local IT company via its Corporate Social Responsibility (CSR) funds.

The platform connects waste collectors with clients and is specifically tailored to cater to the needs and constraints of collectors, many of whom own inexpensive non-touchscreen phones. Consisting of several apps, a dashboard, and social media components, the platform is not only accessible on affordable low-end smartphones, but the apps are available in eight languages and collectors with low levels of literacy can use voice messages instead of text messages to communicate with clients.

Households are geotagged to facilitate collectors' work and clients receive an automated text message reminder prior to collection. Because waste collectors wear an official uniform and possess an identification card, many have reported feeling respected when interacting with residents. Their daily income stabilized, and for many, it "doubled or tripled" (Ahuja & Chan, 2020).

Though the development, implementation, and maintenance of the platform is necessarily an iterative process fraught with challenges, this solution addresses several determinants of health simultaneously: the income, social status, employment, and working conditions of waste collectors have significantly improved and the physical environment of citizens is healthier.

Source: Suchit Ahuja, PhD, Management Information Systems, Assistant Professor, Concordia University—John Molson School of Business

After determining how social factors may affect the ability to benefit from your innovation, the final step is to determine who will use it within the health and social care system. As briefly mentioned earlier, the Health system value domain also includes care that is delivered outside of health services facilities. We further elaborate on this point in the next section.

Supporting Health System Sustainability

The Level and intensity of care attribute of the Health system value domain looks at who uses the innovation and in what context (Silva et al., 2018). Similarly to the way in which the Health inequalities attribute aims to reduce rather than exacerbate existing inequalities, the Level and intensity of care attribute aims to strengthen rather than weaken the health system's capacity to deliver quality care in a sustainable manner. This attribute focuses on the long-term capacity of a given health system to provide the care and services needed by its population, as many face shortages as well as skyrocketing costs (Roncarolo et al., 2017). Environmental sustainability is addressed by the Eco-responsibility attribute presented in Chap. 5.

For RIH, health system sustainability can be supported by innovations that generate high-quality care outcomes while reducing labor intensity. Toward this end, we consider the level of healthcare specialization that is required by the innovation. When it is possible to do so *effectively* and *safely*, the objective is for an innovation to support the most decentralized unit in the health system, or in other words, the least specialized level of care rather than the most specialized level of care, as the latter is often the least accessible and more costly level of care.

The idea is to generate a solution targeted at the right level of care, one where a care provider can be empowered to attend safely and effectively to patient needs. Within a similar logic, empowering patients and their relatives to take care of the health problem in a safe and effective manner strengthens the sustainability of the health system. Although innovations for specialized hospitals are valuable, they rarely reduce labor intensity and therefore do not contribute to health system sustainability. By empowering the capacity for self-care in an everyday environment and facilitating the work of general practitioners and social care providers, health innovators can help to reduce or altogether avoid unnecessary interventions at the most specialized level of care.

Boosting Your Innovation Idea's Degree of Responsibility

The rating scale of the Level and intensity of care attribute looks at whether the innovation was designed to be used mostly under the care of:

A. The patient, an informal caregiver, or a health and social care provider operating in a non-clinical environment
B. The patient, an informal caregiver, or a health and social care provider operating in a primary healthcare facility
C. Health and social care providers operating in a secondary or intermediate level of care facility
D. Health and social care providers at the most specialized level of care within the health system

To increase the degree of responsibility of your innovation idea, you can do the following:

1. Identify the safety and efficacy issues raised by the use of the innovation.
2. Determine who will *mainly* use the innovation: patient, informal caregiver, healthcare provider, social care provider, or specialist.
3. Determine in which context and for how long the innovation will be *mainly* used: non-clinical environment, primary healthcare facility, secondary or intermediate level of care facility, or specialized level of care.
4. Assess whether your innovation idea corresponds to an A, B, C, or D on the rating scale.
5. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation idea or if adjustments can be made to increase it.

Box 3.4 describes a solution that increases access to rehabilitation services for patients living outside large urban centers while supporting system-level sustainability.

Box 3.4   The OpenTeraPlus Platform from the Université de Sherbrooke

Supporting health system sustainability: A customized solution for home-based telerehabilitation

In the Quebec provincial health system, patient access to rehabilitation services is often impeded by long wait times. With the aim of reducing delays, a research team has been researching and developing different solutions since 2003 to provide remote rehabilitation services for diverse patient populations. Its approach to telerehabilitation has evolved over time: from a traditional videoconferencing system using the patient's television, to a touchscreen set up with a controllable camera, and to the computer, tablet, or smartphone of the patient.

Its latest solution is named OpenTeraPlus. It is a highly secure open-source system designed to be flexible and user-friendly for both patients and healthcare providers. The platform supports audio and video telehealth sessions through a user interface adapted to different contexts of care. Telerehabilitation functionalities include a chronometer and countdown, the measurement of angles, fixed and remote-controlled cameras, sensors to measure patients' activity level in between sessions, and a scheduling calendar accessible to both the patient and the clinician.

By its open-source nature and software structure, the platform can evolve and enable the addition of new functionalities over time. This is important when the aim is to provide a solution that is responsive to systemic needs, which are not static and largely influenced by the available workforce. It is currently available in many private and public clinics in Quebec and in France, and is used by clinicians to provide remote care for diverse patient populations.

Source: Michel Tousignant, PhD, Full Professor, Université de Sherbrooke; François Michaud, PhD, Full Professor, Université de Sherbrooke; Simon Brière and Mathieu Hamel, M.Sc., Research Engineers, Research Center on Aging; Dominic Létourneau, M.Sc., Research Engineer, Interdisciplinary Institute for Technological Innovation; Catherine Pagé, M.Sc., Research Coordinator, ESTRAD
https://github.com/introlab/opentera   and   https://www.telereadaptation.com/en/technologies/

Summary Points

Box 3.5   Chapter 3 Summary Points

- This chapter describes in greater detail four RIH attributes that offer key guidance at the ideation stage.
- Health relevance and Responsiveness bring your attention to the types of problems a responsible health innovation should target, whereas Health inequalities and Level and intensity of care ask you to consider for whom your solution should be developed and where it will be mostly used.
- A relevant health problem represents a significant portion of the overall burden of disease in the region where intended users are located.
- A responsive innovation provides a dynamic solution to an important health system need or challenge in the region where intended users are located.
- An innovation that addresses health inequalities considers the social groups for whom it is being developed as well as the social factors that may influence the ability to benefit from it.
- When it is possible to do so effectively and safely, an innovation should support the least specialized level of care because the most specialized level of care is often the least sustainable level of care.

Websites Mentioned in the Chapter

GHDx
http://ghdx.healthdata.org/gbd-results-tool
Global Health Observatory
https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/global-health-estimates-leading-causes-of-dalys
Health Inequalities Data Tool of the Canadian Government
https://health-infobase.canada.ca/health-inequalities/data-tool/index

References

Ahuja, S., & Chan, Y. (2020, December 13–16). *From waste to inclusive growth: A digital platform for 'Ragpickers' in India*. Paper presented at the International Conference on Information Systems, India.

Cagnin, A., Choinière, M., Bureau, N. J., Durand, M., Mezghani, N., Gaudreault, N., & Hagemeister, N. (2020). A multi-arm cluster randomized clinical trial of the use of knee kinesiography in the management of osteoarthritis patients in a primary care setting. *Postgraduate Medicine, 132*(1), 91–101.

Global Burden of Disease Collaborative Network. (2020). *Global burden of disease 2019 results*. Retrieved from Institute for Health Metrics and Evaluation (IHME), Seattle, USA: http://ghdx.healthdata.org/gbd-results-tool

Global Burden of Disease Study. (2017). https://ghdx.healthdata.org/gbd-2017

Human Development Report. (2012). United Nations, New York, USA. ISBN: 9789211263404.

Marmot, M. (2015). The health gap: The challenge of an unequal world. *The Lancet, 386*(10011), 2442–2444.

Marmot, M., & Bell, R. (2012). Fair society, healthy lives. *Public Health, 126*, S4–S10.

Public Health Agency of Canada. (2020). Osteoarthritis in Canada.

Roncarolo, F., Boivin, A., Denis, J.-L., Hébert, R., & Lehoux, P. (2017). What do we know about the needs and challenges of health systems? A scoping review of the international literature. *BMC Health Services Research, 17*(1), 636. https://doi.org/10.1186/s12913-017-2585-5

Sen, A. (2002). Why health equity. *Health Economics, 11*(8), 659–666. https://doi.org/10.1002/hec.762

Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J.-L. (2018). Introducing responsible innovation in health: A policy-oriented framework. *Health Research Policy and Systems, 16*(1), 90–103. https://doi.org/10.1186/s12961-018-0362-5

Silva, H. P., Lefebvre, A.-A., Oliveira, R. R., & Lehoux, P. (2021). Fostering responsible innovation in health: An evidence-informed assessment tool for innovation stakeholders. *International Journal of Health Policy and Management, 10*(4), 181–191. https://doi.org/10.34172/ijhpm.2020.34

Fleshing Out a Venture That Can Responsibly Tackle the Problem

Abstract After generating a responsible health innovation idea, you and your team can flesh out the responsibility characteristics of your venture. Toward this end, this chapter is organized around two Responsible Innovation in Health (RIH) attributes: Inclusiveness and Business model. We begin by describing the importance of mobilizing at an early stage relevant stakeholders through accountable methods and ensuring that their inputs are integrated throughout the innovation process. We then clarify what business model characteristics should be emphasized for ventures, whether not-for-profit or for-profit, to deliver more value to end users, purchasers, and society.

ENGAGING RELEVANT STAKEHOLDERS

Within the RIH conceptual framework (Chap. 1), the Inclusiveness attribute is part of the Health system value domain and asks the following question: were the innovation development processes inclusive? More specifically, this attribute refers to whether and how a variety of relevant stakeholders were engaged during the design, development, and pilot stages of an innovation (Silva et al., 2018). The premise here is that involving at an

early stage a diverse and relevant set of stakeholders through an account-able method is likely to improve the innovation and the venture's rapport with end users. Hence, RIH makes explicit the rationale and scope of the stakeholder engagement process as well as its impact on the innovation's design.

The goal of this requirement is to bring forward an innovation's various social, political, ethical, and economic implications that the innovation team may not be able to identify on its own (Stilgoe et al., 2013). Stakeholder inclusion therefore considers: which stakeholders are involved, whether they are representative of the targeted user group, when they are involved in the innovation process, and whether their inputs impact design decisions in a meaningful manner (Lubberink et al., 2017). In this way, the engagement of stakeholders goes far beyond simply consulting with a small group of users (Brand & Blok, 2019).

The main categories of stakeholders to consider are:

- patients, caregivers, and patient advocacy organizations;
- clinicians and their professional associations;
- institutional healthcare providers, such as hospital systems and health clinics;
- government departments and agencies;
- purchasers and payers, such as employers and public and private insurers;
- healthcare industry representatives;
- healthcare policymakers at the federal, provincial/state, and local levels;
- healthcare researchers and research institutions;
- supply chain actors (e.g., material suppliers, service providers, distributors, retailers);
- experts on the problem to be tackled and/or on the type of innovation to be designed;
- innovation managers of intermediating platforms;
- non-government organizations; and
- the wider public (Cottrell et al., 2014; Lubberink et al., 2017).

To engage with these stakeholders, various methods can be used, ranging from low to high levels of involvement (see Table 4.1).

To explore and choose which methods are best adapted to which stakeholder group, a very useful resource is the Engage2020 Action Catalogue.

Table 4.1 Overview of low- and high-involvement stakeholder engagement methods

Consultation (lower involvement)	Engagement (higher involvement)
• Advisory committee, board/council	• Charrette
• Community or public meetings	• Citizens' juries or panels
• Focus groups	• Consensus or search conferences
• Interviews	• Constituent assembly
• Issue conferences	• Deliberative polling
• Online discussion groups	• Delphi process
• People's panel	• Pilot testing and user assessment
• Polling	• Retreats
• Public hearings and seminars	• Round tables
• Questionnaires	• Study groups or circles
• Surveys and other feedback mechanisms	• Sustainable community development
• Workshops	• Think tanks

Adapted from (Health Canada, 2010)

This is an online decision support tool that enables those who want to conduct inclusive research and innovation development find the method that is best suited for their specific project. The catalog comprises 57 methods, and you can search the database by selecting 32 different criteria, such as objectives, levels of stakeholder involvement, geographical scope, and skills required to properly apply the method, as well as weigh the importance of each criterion. Results are presented either in a prioritized list of the methods that fit the selected criteria or in a visual overview with the relevance of each method corresponding to its size. Figure 4.1 illustrates the results of a search for methods that give direct decision-making power to stakeholders in a local project on health, demographic challenges, and well-being.

In Chap. 6, we discuss in greater detail examples of tools to engage stakeholders during the innovation design process because it is important that you and your team develop a good command of engagement methods to increase the responsibility of your solution. At this point in the design brief, we mainly emphasize that stakeholder groups can also help to increase the responsibility of your venture.

Fig. 4.1 Using the Engage2020 Action Catalogue to identify engagement methods. (Source: Screen capture from http://actioncatalogue.eu/search)

Boosting Your Venture's Degree of Responsibility

The rating scale of the Inclusiveness attribute assesses three interconnected aspects (Fig. 4.2): the engagement of stakeholders, the methods used to engage them, and the impact of their participation on the innovation. It thus draws attention to whether those who developed the innovation:

A. Engaged a diverse and relevant set of stakeholders through a formal method and explained how their input was integrated in the design process

Fig. 4.2 Aspects covered in the Inclusiveness attribute rating scale

   B. Engaged a diverse and relevant set of stakeholders through a formal method, but did not explain how their input was integrated in the design process

   C. Engaged a limited set of stakeholders or did not explain the method used

   D. Did not engage stakeholders

To increase your venture's degree of responsibility, you and your team can follow these steps:

   1. Identify which stakeholders are relevant to your project. The following methods are frequently used in the health innovation field to identify potential stakeholders:

- Review of the literature, policy documents, press articles, or social media
- Individual or group interviews followed by snowballing (e.g., asking for additional contacts)
- Research team discussions and brainstorming
- Surveys and questionnaires (Franco-Trigo et al., 2020)

2. Determine whether your identified stakeholders form a diverse group. To do so, you can:

   - Classify stakeholders according to the degree (low, moderate, high) that they can affect or be affected by the health and social care problem you are addressing
   - Use geographical criteria (e.g., where your venture will operate and where users are located)
   - Use demographic criteria (e.g., age, gender, nationality)

3. Discuss which methods can help you work with your stakeholders. Ensure that the methods are feasible for your project and that they offer a high-level of involvement for participating stakeholders.

4. Reflect on how stakeholders will influence the decision-making process. You can use the following questions to help guide your reflection:

   - Will you adopt formal procedures for deliberation?
   - What information will you share with stakeholders?
   - How will their interests be equally considered?
   - How will decision-making power be allocated to stakeholders?
   - How will you explain what will be done with their input?

5. Discuss as a team whether you are satisfied with the current degree of responsibility of your venture or if adjustments can be made to increase it.

Box 4.1 illustrates how a digital dashboard for Intensive Care Units (ICUs) was developed with relevant stakeholders at a leading mother and child hospital center in Canada.

Box 4.1   A Digital Dashboard for a Pediatric ICU
Engaging relevant stakeholders: The TVL-HSJ from the Sainte-Justine Mother and Child University Hospital Center

The TVL-HSJ is a digital dashboard that displays in real-time key patient information for the caregivers working in the pediatric ICU. As an organizational tool, the dashboard ensures safer care monitoring by helping the clinical team distribute patients to available ICU beds and stations that adequately meet their needs, summarizing key patient information in a confidential manner, and coordinating the work of caregivers.

The dashboard was collaboratively designed within a digital health innovation ecosystem over the course of six years. The project began in 2016 when Dr. Philippe Jouvet, head of the pediatric ICU, and his team anticipated disruptions in care monitoring resulting from the retirement of several senior nurses who possessed institutional knowledge on care monitoring and the reliance on an obsolete hand-written monitoring tool that had become unreadable due to the increasing amount of information being shared.

A team of five clinicians and seven engineers designed the beta version of the TVL-HSJ and won a prize at the 2016 Cooperathon organized by Hacking Health. The beta version was piloted in the hospital for six months during which users identified several imperfections. The hospital's information and technology (IT) team then developed a web version that was implemented and iteratively refined several times over the years.

When the COVID-19 pandemic hit in March 2020, the dashboard needed to handle a potential increase in patients. In collaboration with Philippe Doyon Poulin, Assistant Professor in the Department of Mathematical and Industrial Engineering at Polytechnique Montréal, a new version was developed to include additional visual indicators. Because inclusive design processes require an iterative user-centered assessment approach, a clinical workflow integration evaluation of these visual indicators is underway (Hébert-Lavoie et al., 2021).

(continued)

Box 4.1   (continued)
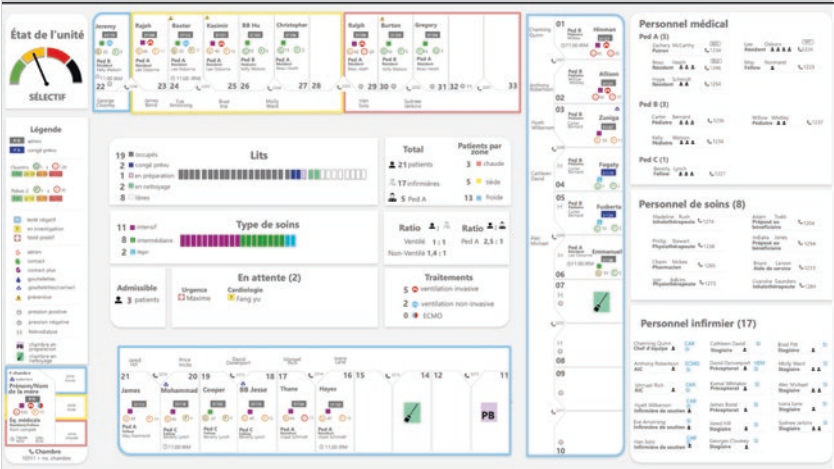
Source: Philippe Jouvet, MD, PhD, MBA, Pediatric Intensivist and Full Professor, Université de Montréal; Patricia Monnier, MD, PhD, Obstetrician-gynecologist and Associate Professor, McGill University.

Once you have covered the three aspects of responsible stakeholder engagement (diversity, accountable method, and impact of participation), the next step is to examine the business model characteristics that can enhance the value your venture will provide to users, purchasers, and society.

Providing More Value to Users, Purchasers, and Society

The Business model attribute is part of the Organizational value domain. It examines whether the business model of the venture that produces the innovation provides more value to users, purchasers, and society. In the Responsible Design Compass (Chap. 2), we highlighted a tension many entrepreneurs face when developing their new ventures: is it better to prioritize a lucrative business model or to prioritize health impacts for a greater number of people? Although there are no right or wrong answers

to this question, we describe a set of responsibility characteristics that can be integrated into your business model to resolve this tension in a way that meets the aims, needs, and constraints of your project.

What is a business model? Simply put, it describes how a firm "does business," that is, the "rationale of how it creates, delivers and captures value" (Osterwalder & Pigneur, 2010). It articulates different components through which an organization offers a new *value proposition*, that is, a novel service and/or product that meets the needs of specific *market segments* while enabling revenues to be generated. While it is through its *value chain* that the organization creates, produces, and distributes the innovation, its *value network* includes suppliers, partners, and "complementors." Given the value proposition and the value chain structure, its *cost structure and profit potential* of producing the solution are estimated. Finally, the *competitive strategy* defines how to "gain and hold advantage over rivals" (Chesbrough & Rosenbloom, 2002). Business models thus include both external factors (e.g., supply chain, competitors, customers) and internal factors (e.g., conditions of service provision/value creation).

Typically, a business model entails a tension between value capture, that is, the redistribution of financial returns to the shareholders of the organization, and value creation, that is, the provision of a high-quality product or service. Although business models were historically shaped in a commercial market context, their value logic is applicable to all types of organizations, including hybrid organizations such as social purpose businesses, cooperatives, and enterprising non-profits (Santos et al., 2015). These hybrid organizations develop business models that not only are commercially viable but also generate positive impacts on society and the environment. They differ from traditional commercial enterprises in at least three ways:

- They adopt explicit goals to address social and/or environmental change.
- Their relationships with suppliers, employees, and customers are sustainable and mutually beneficial.
- Their interactions with the market, competitors, and other institutions aim to benefit society as a whole (Haigh & Hoffman, 2011).

While traditional commercial enterprises may contribute to economic development and offer valuable innovations, organizations that adopt alternative business models can better support RIH. To provide more value to users, purchasers, and society, RIH defines several responsibility characteristics that business models should aim to possess. They are as follows:

- Pursue a social and/or environmental mission, operate on a not-for-profit basis, or reinvest the majority of the revenues in their mission (e.g., social enterprises).
- Make the innovation freely usable or exploitable by others (e.g., open-source, product licensing waivers, do-it-yourself).
- Adopt a pricing scheme based on ability to pay or a redistributive logic (e.g., customers who "buy one, give one").
- Employ people with particular needs (e.g., low literacy, disabilities).
- Comply with social responsibility programs (e.g., Certified B Corporation, SA8000 standard for decent work, ISO26000 for social responsibility) (Silva et al., 2018).

Boosting Your Venture's Degree of Responsibility

The rating scale of the Business model attribute considers the number of responsibility characteristics the organization that produces the innovation possesses to provide more value to users, purchasers, and society:

- A. Three of the characteristics described or more
- B. Two of the characteristics described
- C. One of the characteristics described
- D. None of the characteristics described

To increase your venture's degree of responsibility, you and your team can follow these steps:

1. Design a preliminary version of your venture's business model by:

   - Articulating the value proposition (value created for users by the innovation)
   - Identifying a market segment (users for whom the solution is useful and for what purpose)
   - Specifying the mechanism(s) that will generate revenue
   - Defining the structure of the value chain required to create and distribute the solution and determining the complementary assets that are needed to support the venture's position in this chain
   - Estimating the cost structure and profit potential of producing the solution

- Describing the position of the venture within the value network linking suppliers and customers, including the identification of potential "complementors" and competitors
- Formulating your competitive strategy

2. Closely examine which responsibility characteristics of the Business model attribute your venture can adopt to provide more value to users, purchases, and society.
3. Assess whether the number of selected characteristics corresponds to an A, B, C, or D on the rating scale.
4. Discuss as a team whether you are satisfied with the current degree of responsibility of your venture or if adjustments can be made to increase it.

To help you think creatively about the way an organization may strike a balance between revenue generation and the creation of social and environmental value for society, Box 4.2 describes a unique business model that comes from the digital industry.

Box 4.2 Ecosia's Business Model

Adopting a responsible business model: Ecosia—the search engine that plants trees

Founded in 2009, Ecosia is a not-for-profit, social mission enterprise whose business model is quite unique. The company created a search engine to enable internet users fight climate change: it directs about 80% of its surplus revenues to plant and protect trees in South America, Africa, and Asia where they absorb carbon dioxide (CO_2) from the atmosphere.

It was the first German company to obtain a B Corp Certification in 2014. While its revenues mostly come from selling digital advertising, it refuses contracts from companies that generate negative social and environmental impacts.

Ecosia cannot be sold and does not pay out dividends to its owners. Surplus revenues stay within the company and are used for tree planting or invested to finance environmental projects (e.g., regenerative agriculture, solar power plants).

Box 4.2   (continued)

Evolving in the largely unregulated digital industry, Ecosia has a strong competitive strategy. To earn and maintain users' trust, its privacy policy is stringent. It does not sell data to advertisers, it quickly anonymizes searches, it does not use external tracking tools to prevent access by third-parties, and its "do not track" option is easy to locate.

In 2019, Ecosia was the first company from the digital sector to become carbon negative, producing twice as much renewable energy as it consumes, and it had supported more than 9000 reforestation sites in 2021.

Its monthly financial report shows how revenues generated from searches are spent, and a blog provides readers with key information about the communities with whom it works. In November 2021, Ecosia earned EUR 2,167,344 as total income, financed the planting of 2,346,969 trees, and paid EUR 618,496 in taxes and social security benefits. Though reforestation alone is not sufficient to fight climate change, staying clear of tax evasion as well as contributing to local communities is part of Ecosia's business vision.

Source: https://blog.ecosia.org/ecosia-financial-reports-tree-planting-receipts/

Summary Points

Box 4.3   Chapter 4 Summary Points

- Two RIH attributes—Inclusiveness and Business model—help flesh out a responsible venture.
- Involving at an early stage a diverse and relevant set of stakeholders through an accountable method can increase the responsibility of both the solution and the organization that brings it to end users.
- Non-conventional economically viable business models can support RIH by generating positive impacts on society and the environment.

References

Brand, T., & Blok, V. (2019). Responsible innovation in business: A critical reflection on deliberative engagement as a central governance mechanism. *Journal of responsible innovation, 6*(1), 4–24.

Chesbrough, H., & Rosenbloom, R. S. (2002). The role of the business model in capturing value from innovation: Evidence from Xerox Corporation's technology spin-off companies. *Industrial and Corporate Change, 11*(3), 529–555.

Cottrell, E., Whitlock, E., Kato, E., Uhl, S., Belinson, S., Chang, C., Hoomans, T., Meltzer, D., Noorani, H., & Robinson, K. (2014). Defining the benefits of stakeholder engagement in systematic reviews.

Franco-Trigo, L., Fernandez-Llimos, F., Martínez-Martínez, F., Benrimoj, S. I., & Sabater-Hernández, D. (2020). Stakeholder analysis in health innovation planning processes: A systematic scoping review. *Health Policy, 124*(10), 1083–1099. https://doi.org/10.1016/j.healthpol.2020.06.012

Haigh, N., & Hoffman, A. J. (2011). Hybrid organizations: the next chapter in sustainable business. *Organizational Dynamics, 41*(2), 126–134.

Health Canada. (2010). *The Health Canada policy toolkit for public involvement in decision making*. Ottawa, Canada: https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-canada-policy-toolkit-public-involvement-decision-making.html#a13

Hébert-Lavoie, M., Ung, K., Boudreault, L., Mahmoudi, C., Vu, Q., Jouvet, P., & Doyon-Poulin, P. (2021). *Remote design of a pediatric intensive care unit dashboard in time of pandemics*. Paper presented at the Congress of the International Ergonomics Association.

Lubberink, R., Blok, V., Van Ophem, J., & Omta, O. (2017). Lessons for responsible innovation in the business context: A systematic literature review of responsible, social and sustainable innovation practices. *Sustainability, 9*(5), 721.

Osterwalder, A., & Pigneur, Y. (2010). *Business model generation: A handbook for visionaries, game changers, and challengers* (Vol. 1). John Wiley & Sons.

Santos, F. M., Pache, A.-C., & Birkholz, C. (2015). Making hybrids work: Aligning business models and organizational design for social entreprises. *California Management Review, 57*(3), 36–58. https://doi.org/10.1525/cmr.2015.57.3.36

Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J.-L. (2018). Introducing responsible innovation in health: A policy-oriented framework. *Health Research Policy and Systems, 16*(1), 90–103. https://doi.org/10.1186/s12961-018-0362-5

Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy, 42*(9), 1568–1580. https://doi.org/10.1016/j.respol.2013.05.008

Designing a Responsible Solution

Abstract After covering the responsibility characteristics of your venture, you are now ready to design a responsible solution by integrating three Responsible Innovation in Health (RIH) attributes—Frugality; Eco-responsibility; and Ethical, legal, and social issues (ELSIs). We start this chapter by describing how frugality characteristics may increase the economic value of RIH. We then examine what eco-responsibility concerns may contribute to limiting the environmental footprint of health innovations throughout their lifecycle. Finally, we clarify the importance of anticipating and mitigating the potential negative impacts of an innovation on end users.

Keywords Frugal Innovation • Affordable Health Innovation • Sustainable Health Innovation • Ethical, Legal, and Social Issues in Health Innovation • User-Centered Design

Delivering Greater Value to More People Using Fewer Resources

The RIH conceptual framework (Chap. 1) emphasizes, through the Economic value domain and its corresponding Frugality attribute, that responsible health innovations should deliver affordable high-quality products (Silva et al., 2018). The following question is asked: does the

innovation deliver greater value to more people using fewer resources such as capital, materials, energy, and labor time? In order to meet this objective, designers of frugal innovation aim to substantially reduce the costs of production and use of an innovation, focus on the core functionalities its users require, and optimize its performance level considering the intended purpose and context of use (Weyrauch & Herstatt, 2016).

Frugal innovations "are robust, easy to use, and environmentally friendly, as well as strongly associated with sustainability concerns" (Hossain, 2020). In addition to the usual economic impacts stemming from conventional solutions (e.g., revenue, novel products and services, employment), frugal innovations generate many other positive outcomes, such as:

- Affordable products that address local problems and unserved communities
- New markets and new sources of revenue
- Local entrepreneurship and empowerment of local partners
- New business models and new forms of employment
- Lower resource needs and use of local and/or recycled materials and/or materials from sustainable sources
- Development of associated infrastructure
- Organizational learning
- Inclusion and democratization
- Mindset change of high-income customers toward inexpensive sustainable products (Hossain, 2018)

Although frugal innovations are often considered for low-resource settings where high-tech solutions are too expensive, unavailable, or impossible to use, sophisticated technologies can be frugal. Examples include: a portable ultrasound machine comprising a laptop computer with sophisticated software and associated probe; a compact, efficient car developed to minimize unnecessary features; and a portable underwater electric robotic system that can operate at a depth of 300 meters (Rao, 2017).

The development of frugal innovation is particularly prominent in the healthcare sector, which accounted for one-third of the cases documented in peer-reviewed literature (Hossain, 2017). They can be grouped into four main subtypes:

- Simplification of existing techniques or technologies (e.g., portable electrocardiogram [ECG] machine)

- Use of modern technologies to tackle "old problems" (e.g., 3D-printed prosthetic hands)
- Diversion of existing tools for completely different purposes (e.g., paper clips in surgery)
- Use of low-tech approaches to solve local unmet needs (e.g., solar disinfection of water) (Tran & Ravaud, 2016)

Frugality may increase the economic value of RIH by incorporating three characteristics:

- **Affordability**, which may result from optimized innovation production processes and/or lower maintenance needs
- **Focus on core functionalities and ease of use** to meet the requirements of a larger number of users (e.g., in remote or resource-poor settings, at home)
- **Optimized performance**, which maximizes the fit between an innovation's characteristics and its context of use (e.g., robustness if used in difficult climatic conditions, transportability if used in remote settings, economies of scale if used in large centers)

Boosting Your Innovation's Degree of Responsibility

The rating scale of the Frugality attribute takes into consideration the three characteristics described earlier. It thus draws attention to whether the innovation incorporates:

A. Three characteristics of frugal innovation
B. Two characteristics of frugal innovation
C. One characteristic of frugal innovation
D. No characteristics of frugal innovation

To increase the degree of responsibility of your innovation in the Economic value domain, you and your team can follow these steps:

1. To provide an affordable, low-cost solution for end users, think about how you can optimize the production processes of your innovation and reduce its maintenance needs.
2. Identify the essential functions your innovation must have to meet users' needs and increase ease of use.

3. Examine what level of performance and quality is required to maximize the fit between your innovation's characteristics and its context of use.
4. Determine how many frugality characteristics your innovation will integrate.
5. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation or if adjustments can be made to increase it.

An illustration of a frugal innovation in health is provided in Box 5.1.

Box 5.1   The kindestCup
Delivering greater value to more people using fewer resources: The kindestCup

The kindestCup is a 3-in-1 breastfeeding milk catcher designed to offer an affordable and easy-to-use alternative to conventional breastfeeding pumps. Rather than pumping milk through an electric device, the kindestCup is a cup made from 100% pure food-grade silicon designed to catch hand expressed breastmilk and milk that naturally leaks when breastfeeding. It can also be used to cup feed babies.

By reconceptualizing milk removal from a purely mechanical process to one that leverages the natural physiology of milk production, this solution radically departs from the main design features of pumps to optimize the quantity and quality of milk extraction in several ways.

Mechanical pumps are relatively inefficient at removing colostrum or mature milk from the human breast. Because many women rely on pumps, that is, when they go back to work, this design flaw affects their capacity to continue breastfeeding. By relying on hand expression instead, a skill that has been used for millions of years and is easy to develop, the kindestCup helps users maintain a stable milk supply. Furthermore, hand expression produces 50% more milk that contains twice as much fat than pumped milk, making it healthier for the baby (Morton et al., 2012).

Pumps generally come with large bottles, which are sometimes difficult to fill as the quantity of milk produced varies. Because perceived

Box 5.1   (continued)

inadequate milk supply is the number one reason why women stop breastfeeding (Gatti, 2008), the kindestCup has a tapered reservoir that fills up faster and no volume scale. Milk ejection is an oxytocin-based system and feeling that milk production is adequate helps women release more milk.

Pumps rely on electricity and comprise several parts that need to be regularly disassembled and disinfected. This impacts when and where women can pump. In contrast, the kindestCup can be easily carried in a bag, washed with soap and water, and used in multiple settings. While the kindestCup may not align with the preferences of all women, priced at CAD 29.95 at the time of writing, it is much less expensive than a pump, it can be reused as a snack cup, and/or be shared with other women.

Source: Melanie Scholz, PhD in biomechanics, Designer of the kindestCup, Research Technology Specialist, Kinesiology and Health Sciences, University of Waterloo

https://kindestcup.com/

After considering how the concept of frugality may help you provide more value to more people using fewer resources, the next step is to examine how to reduce the negative environmental impacts of your innovation.

LIMITING THE ENVIRONMENTAL FOOTPRINT THROUGHOUT THE LIFECYCLE

The Eco-responsibility attribute is part of the Environmental value domain of the RIH conceptual framework. It acknowledges the importance of healthcare's carbon footprint and emphasizes the environmental impacts of health innovations throughout their lifecycle (Moultrie et al., 2016). This attribute aims to reduce an innovation's negative impacts on the environment through the adoption of eco-responsibility concerns at key stages throughout its lifecycle.

This objective represents a planetary health research priority (Whitmee et al., 2015) because the healthcare sector is responsible for a large share

of the global carbon footprint, that is 4.4% of greenhouse gases, 2.8% of particulate matter, and about 3.5% of air pollutants (Lenzen et al., 2020). By contributing to climate change, the healthcare sector also increases the risks of various diseases, which, in turn, generates more healthcare costs and greenhouse gas emissions. Furthermore, activities inside and around hospitals consume a lot of energy and raw resources and produce a range of hazardous materials that may be dangerous, infectious, toxic, or radioactive. Examples of such materials include discarded materials and equipment, expired or unused pharmaceutical products, drugs and vaccines, and chemicals generated through disinfecting procedures or cleaning processes, which have a negative impact on human health (Chartier et al., 2014).

RIH can be supported by attending to eco-responsibility concerns at key stages in the lifecycle of an innovation (Fig. 5.1):

- **Raw material sourcing**: product or hardware made of recycled or renewable content materials, free of substances such as latex, metals, or chemicals that are of major public health concern or harmful and toxic to ecosystems (e.g., arsenic, asbestos, benzene, bisphenol A, bromine- and chlorine-based compounds, cadmium, chromium, dioxin and dioxin-like substances, lead, mercury, phthalate, PVC)
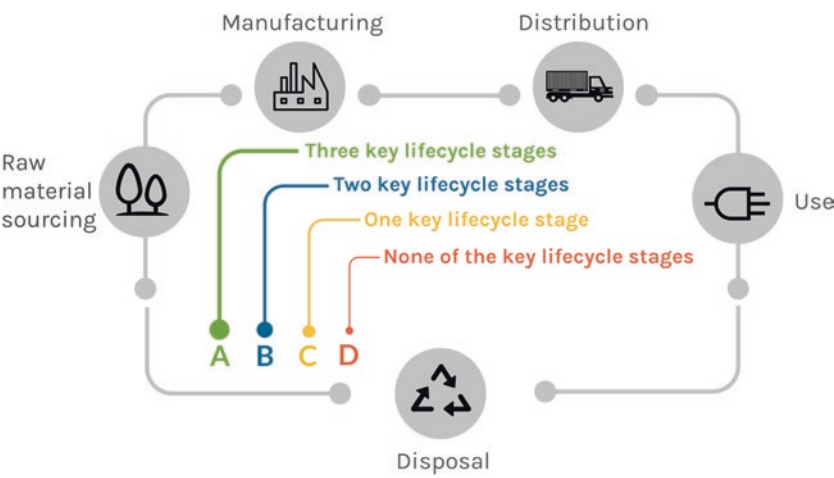
Fig. 5.1   Key lifecycle stages for eco-responsibility concerns

- **Manufacturing**: efficient energy consumption, compliance with national or international environmental regulations, reduced solid or water waste, and so on
- **Distribution**: packaging, transportation, and so on
- **Use**: efficient energy consumption, reusability, durability, and so on
- **Disposal**: product or hardware designed to be recycled, disassembled, remanufactured, composted, or biologically degraded, and so on

Boosting Your Innovation's Degree of Responsibility

The rating scale of the Eco-responsibility attribute takes into consideration whether eco-responsibility concerns are integrated at:

A. Three key lifecycle stages or more
B. Two key lifecycle stages
C. One key lifecycle stage
D. None of the key lifecycle stages

We suggest the following steps to increase the degree of eco-responsibility of your innovation:

1. Determine whether the parts of your innovation can be made of recycled or renewable material and whether they are free of substances that are of major public health concern or harmful and toxic to ecosystems.
2. Identify the eco-responsibility concerns that can be integrated in the manufacturing, distribution, and use of the innovation.
3. Examine whether your innovation can be easily recycled, reused, remanufactured, composted, or biologically degraded when it reaches its end of life.
4. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation or if adjustments can be made to increase it.

Box 5.2 presents an innovation that limits its environmental footprint throughout its lifecycle.

Box 5.2   The Etrëma Masks by Frëtt Solutions

Limiting the environmental footprint throughout the lifecycle: The etrëma masks by Frëtt Solutions

With the SARS-CoV-2 pandemic, demand for disposable single-use face masks exploded across the world. At the time of writing, over 2 trillion disposable masks had been used and thrown away, with 50,000 more being used per second.

Frëtt Design, a Canadian enterprise specializing in eco-responsible clothing, took on the challenge of designing a protective mask without sacrificing the environment. Its research and development (R&D) branch, Frëtt Solutions, developed the ëncore technology, which layers several ultralight and breathable technical fabrics that filter submicronic particles and aerosols (0.02 to 3 μm) and ensures a stable performance. It was tested for 100 washes "without loss of efficiency."

Built with this technology, the etrëma masks comply with the American Society for Testing and Materials standard specification for barrier face coverings F3502-21 (for workplaces) and are recommended by the US Center for Disease Control and the International Society for Respiratory Protection.

Aligned with their longstanding eco-responsibility mission in the clothing industry, Frëtt Solutions set up a "production line that respects strong environmental practices." The masks are manufactured in Canada using recycled fabrics, and materials neither are treated nor contain any toxic additives or coatings. They are reusable and highly durable. One mask saves up to 200 disposable masks, which, in turn, "saves 97.8% of materials used in production." All masks are recovered through Frëtt Solutions' Zero Waste box where "components are entirely recycled or reused."

Sources: https://www.frettdesign.ca/en/home and https://solutions.frettdesign.ca/en/?v=3e8d115eb4b3

After limiting your innovation's environmental footprint, the final step in the RIH design brief is to anticipate and mitigate its potential negative impacts on users.

Mitigating Potential Negative Impacts on Users

The Ethical, legal, and social issues (ELSIs) attribute is part of the Population health value domain and raises the following question: was the innovation developed by seeking to mitigate its ethical, legal, and/or social issues? More specifically, this attribute refers to an innovation's positive and negative impacts on the moral and sociocultural well-being of individuals and groups and to the legal and regulatory issues its use raises. It thus acknowledges that "health care is a moral endeavour" and that "the vast potential of technology poses complex moral challenges" (Hofmann, 2008).

ELSIs that underlie the development, distribution, and use of health technologies may negatively impact users. For instance, a mobile application may share personal data to third parties and not preserve users' anonymity, a genetic test may not be delivered following an appropriate data stewardship framework, or an assistive device may exacerbate social stigma associated to disability.

Although ELSIs cannot entirely be identified in advance, RIH calls for a careful examination of the mitigation strategies that are needed considering the context in which the innovation will be used (Table 5.1). The following examples illustrate the means that should be made available to mitigate negative impacts for each of the three types of issues:

- If a home-based treatment requires the assistance of a caregiver, the means to mitigate the discrimination against individuals living alone is to offer an alternative resource for such individuals.
- If a medical device relies on digital components, means to mitigate risks include the respect of regulatory frameworks in effect in the region where intended users are located. These frameworks generally cover data collection, use, archiving, sale, or sharing with third parties.

Table 5.1 Examples of means to mitigate ELSIs

For ethical issues	*For legal and regulatory issues*	*For social issues*
• Patient decision-aids • Psychological support • Group empowerment • Ethical guidelines	• Laws and regulatory frameworks regarding individual rights, privacy, confidentiality, discrimination (health insurance, the workplace), adverse event monitoring, data stewardship	• Stigma-reduction programs • Caregiver support • Community-led educational forums • Return to work strategies

- If values or cultural preferences can potentially impact the perception or the use of a diagnostic test, means to mitigate these negative effects include the use of culturally sensitive communication tools.

Boosting Your Innovation's Degree of Responsibility

The rating scale of the ELSIs attribute looks at the availability of mitigation strategies in the region where the users of the innovation are located. It draws attention to whether means to mitigate the negative impacts of the innovation are available for:

A. Nearly all applicable ELSIs
B. Several of the applicable ELSIs
C. Few of the applicable ELSIs
D. None of the applicable ELSIs

To increase the degree of responsibility of your innovation, you can follow these steps:

1. Identify the probable impacts of the innovation for each of the three types of issues: ethical, legal, and social.
2. Examine whether means to mitigate the negative impacts are available in the region where intended users are located.
3. When means to mitigate negative impacts are not available for all applicable ELSIs, assess what mitigation strategies you can develop to close this gap.
4. Discuss as a team whether you are satisfied with the current degree of responsibility of your innovation or if adjustments can be made to increase it.

An example of mitigation strategies is presented in Box 5.3.

In Chap. 6, we provide examples of tools that can help deliver greater value to more people using fewer resources, limit the environmental footprint throughout the innovation's lifecycle, and mitigate potential negative impact on users.

Box 5.3   The Mentallys App Project
Mitigating potential negative impacts on end users: The Mentallys app project

Pathways to mental healthcare across different public, private, and frontline community services are long, labyrinthine, and discouraging. This compromises access to proper care for individuals with a mental health condition and their caregivers. Though difficulties in accessing mental healthcare have been documented for years, they are persistent.

The Mentallys project aims to improve, simplify, and unify access to mental healthcare via an app entirely codesigned with patients, families, caregivers, and clinicians. The Mentallys app will equip healthcare providers, patients, and family caregivers with a shared tool to navigate more easily and effectively care pathways.

While there is a lack of regulation and legislation for health apps in general, the development team knows that identifying and mitigating potential ELSIs is crucial to the success of the project. One key concern is the protection of users' privacy. Data generated through an app for mental health patients is highly sensitive and the commercial value of such data is a major concern (Torous et al., 2018).

Risks to data privacy include data leaks through security breaches or hacking as well as the disclosure of navigation information to third party data brokers (who mainly work for the advertisement industry). This generally occurs by accessing unencrypted metadata of communication exchanges taking place on the app and through tracking end users' activities via other apps installed on their smartphones.

To mitigate these negative impacts, the Mentallys app integrates a privacy by design approach as well as strict cybersecurity measures. In opposition to the current trend of digital phenotyping where passive data is collected in the background even if the user is not using the app (Benoit et al., 2020), the strategy is to reduce the quantity of data generated through the app. It will also be important to use sound privacy enhancing and/or data anonymization strategies to make data inaccessible or unusable if leaked or hacked.

Source: Stéphane Vial, PhD, Research Chair in Design for e-Mental Health, Associate Professor of Design, Université du Québec à Montréal (UQAM)

Summary Points

Box 5.4   Chapter 5 Summary Points
- Affordability, focus on core functionalities and ease of use, and optimized performance are frugality characteristics that can help the innovation provide greater value to more people using fewer resources.
- The adoption of eco-responsibility concerns at key lifecycle stages helps to limit the environmental footprint of the innovation.
- Means to mitigate the negative impacts of ELSIs should be made available in the regions where intended users of the innovation are located.

References

Benoit, J., Onyeaka, H., Keshavan, M., & Torous, J. (2020). Systematic review of digital phenotyping and machine learning in psychosis spectrum illnesses. *Harvard Review of Psychiatry, 28*(5), 296–304.

Chartier, Y., Emmanuel, J., Pieper, U., Pruess, A., Rushbrook, P., Stringer, R., Townend, W., Wilbum, S., & Zghondi, R. (2014). *Safe management of wastes from health-care activities* (2nd ed.). World Health Organization (WHO).

Gatti, L. (2008). Maternal perceptions of insufficient milk supply in breastfeeding. *Journal of nursing scholarship: An official publication of Sigma Theta Tau International Honor Society of Nursing, 40*(4), 355–363. https://doi.org/10.1111/j.1547-5069.2008.00234.x

Hofmann, B. M. (2008). Why ethics should be part of health technology assessment. *International Journal of Technology Assessment in Health Care, 24*(4), 423–429. https://doi.org/10.1017/s0266462308080550

Hossain, M. (2017). Mapping the frugal innovation phenomenon. *Technology in Society, 51*, 199–208. https://doi.org/10.1016/j.techsoc.2017.09.006

Hossain, M. (2018). Frugal innovation: A review and research agenda. *Journal of Cleaner Production, 182*, 926–936. https://doi.org/10.1016/j.jclepro.2018.02.091

Hossain, M. (2020). Frugal innovation: Conception, development, diffusion, and outcome. *Journal of Cleaner Production, 262*, 121456. https://doi.org/10.1016/j.jclepro.2020.121456

Lenzen, M., Malik, A., Li, M., Fry, J., Weisz, H., Pichler, P.-P., Chaves, L. S. M., Capon, A., & Pencheon, D. (2020). The environmental footprint of health care: A global assessment. *The Lancet Planetary Health, 4*(7), e271–e279. https://doi.org/10.1016/S2542-5196(20)30121-2

Morton, J., Wong, R. J., Hall, J. Y., Pang, W. W., Lai, C. T., Lui, J., Hartmann, P. E., & Rhine, W. D. (2012). Combining hand techniques with electric pumping increases the caloric content of milk in mothers of preterm infants. *The Journal of Perinatology, 32*(10), 791–796. https://doi.org/10.1038/jp.2011.195

Moultrie, J., Sutcliffe, L. F. R., & Maier, A. M. J. J. o. C. P. (2016). A maturity grid assessment tool for environmentally conscious design in the medical device industry. *Journal of Cleaner Production, 122*, 252–265.

Rao, B. C. (2017). Advances in science and technology through frugality. *IEEE Engineering Management Review, 45*(1), 32–38. https://doi.org/10.1109/EMR.2017.2667219

Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J.-L. (2018). Introducing responsible innovation in health: A policy-oriented framework. *Health Research Policy and Systems, 16*(1), 90–103. https://doi.org/10.1186/s12961-018-0362-5

Torous, J., Nicholas, J., Larsen, M. E., Firth, J., & Christensen, H. (2018). Clinical review of user engagement with mental health smartphone apps: evidence, theory and improvements. *Evidence-Based Mental Health, 21*(3), 116–119.

Tran, V.-T., & Ravaud, P. (2016). Frugal innovation in medicine for low resource settings. *BMC Medicine, 14*(1), 102. https://doi.org/10.1186/s12916-016-0651-1

Weyrauch, T., & Herstatt, C. (2016). What is frugal innovation? Three defining criteria. *Journal of Frugal Innovation, 2*(1), 1. https://doi.org/10.1186/s40669-016-0005-y

Whitmee, S., Haines, A., Beyrer, C., Boltz, F., Capon, A. G., de Souza Dias, B. F., Ezeh, A., Frumkin, H., Gong, P., Head, P., Horton, R., Mace, G. M., Marten, R., Myers, S. S., Nishtar, S., Osofsky, S. A., Pattanayak, S. K., Pongsiri, M. J., Romanelli, C., … Yach, D. (2015). Safeguarding human health in the Anthropocene epoch: Report of The Rockefeller Foundation—Lancet Commission on planetary health. *The Lancet, 386*(10007), 1973–2028. https://doi.org/10.1016/S0140-6736(15)60901-1

Tools to Make and Measure RIH

In Part II, in addition to discovering how tools borrowed from different fields of practice can be adapted to materialize the nine RIH attributes introduced in Part I, you will also learn how to measure whether you are meeting key responsibility targets by using the RIH Assessment Tool. First, we describe and illustrate with examples the tools and approaches that can be leveraged to fulfill RIH attributes (Chap. 6). Then, we contextualize the synergies and tensions underlying RIH by clarifying how you can identify the tensions that may exist between some RIH attributes and also search for design variations that can concurrently satisfy multiple attributes (Chap. 7). Lastly, we explain how to consolidate the basis upon which design decisions are made while increasing transparency throughout the process (Chap. 8).

Making RIH

Abstract This chapter describes innovation design tools and approaches to equip teams as they set out to make a responsible health innovation. We begin by explaining why and how, with the input of health innovation researchers and practitioners, we put together a toolbox that draws from different disciplines and areas of expertise. Then, we present 15 tools and approaches that can be leveraged to fulfill five Responsible Innovation in Health (RIH) attributes, that is to engage with relevant stakeholders (*Inclusiveness*); provide more value to users, purchasers, and society (*Business model*); deliver greater value to more people using fewer resources (*Frugality*); limit the environmental footprint throughout an innovation's lifecycle (*Eco-responsibility*); and mitigate potential negative impacts on end users (*Ethical, legal, and social issues*). By no means exhaustive, our toolbox is a starter kit to guide and inspire innovation teams as they search for tools and approaches that are or can be aligned toward making a responsible health innovation.

Keywords Responsible Health Innovation • Interdisciplinarity in Health Innovation • Health Innovation Design Tools • Redesign • Wearable Robotic Exoskeleton

A Multidisciplinary Toolbox for RIH

Health innovation design and development is an endeavor that mobilizes stakeholders with varying needs, viewpoints, and expertise, including engineers, designers, clinicians, patients, and entrepreneurs. Over the past decades, myriad innovation design and management tools have been developed and tested to tap into and bring together their knowledge and know-how. While RIH may be new, making a responsible health innovation does not necessarily require new tools. Existing tools developed within and outside of the health innovation field can be leveraged to support the design, development, or commercialization of a responsible health innovation. By working with the nine RIH attributes early in the design process, as proposed by the RIH design brief (Chaps. 3, 4, and 5), teams may look for and apply tools that can help to fulfill the different responsibility objectives. Indeed, widely known tools may already correspond to an attribute, while others may be used in their original form but oriented toward an RIH goal.

To illustrate how teams may work with existing tools to meet RIH objectives, we propose a starter kit toolbox comprising 15 tools and approaches from different fields of practice. The toolbox is the result of a study we conducted with health innovation researchers and practitioners.

Drawing on the Insights of Innovation Researchers and Practitioners

We conducted a codesign-inspired study to identify practice-oriented tools that can support the design and management of innovations that meet the requirements of RIH. A total of 17 health innovation researchers and practitioners working in Canada and from various professional backgrounds (engineering, clinical sciences, management, design, and communication) took part in the study. The participants were split across eight teams of their own making with an overall balanced representation of professional backgrounds, years of experience, and genders.

To help participants bridge the gap between the high-level concepts of RIH (Chap. 2) and the project-level tools used by innovation designers and managers, we asked participants to conceptually *redesign* an existing innovation to make it more responsible. Participants worked with a concrete example but still had creative space to imagine what a responsible

version of this innovation might look like if its designers were to start over and what tools or approaches could help them to achieve this goal.

Using the RIH Assessment Tool, which is discussed in greater depth in Chap. 8, we evaluated the degree of responsibility of a commercialized wearable robotic exoskeleton powered at the knees and hips to help patients with spinal cord injuries stand and walk. Participants were notified that we do not endorse the technology nor have any personal, financial, or commercial interests in its redesign. Using the nine RIH attributes' scores as a baseline, that is an A, B, C, or D, participants searched for tools or approaches that could increase the score of each attribute, for instance, from a C to a B, or a D to an A. Because the selected model received a low score on most attributes, it offered a wide range of possible redesigns. Each team was randomly assigned five RIH attributes. We limited the number of attributes so that the task could be accomplished within a reasonable amount of time.

To prepare for this task, participants first attended a half-day event organized by our team that brought together health innovation experts, practitioners, and academics from the Quebec health innovation ecosystem (management, industrial design, entrepreneurship, and clinical care). We introduced RIH and facilitated critical discussions on the levers and barriers to implementation in different fields of practice. Afterward, a focus group session was held with participants to explain the redesign task and to engage in a dynamic discussion around health innovation responsibility with the Responsible Design Compass (Chap. 2). Teams then worked independently over the course of two months. They presented their work during a half-day session and discussed potential formats and uses of an RIH toolbox.

Leveraging Existing Tools and Approaches

Our participants identified a total of 34 tools and approaches from a broad variety of disciplines and areas of expertise. To be concise, we present a selection of ten tools and approaches based on participants' appraisals, as well as five additional tools we came across in the course of our research that we believe can inspire teams to rethink health innovation design. The websites to access these tools and approaches are listed at the end of the chapter. The selection is summarized in Table 6.1 and applies to five RIH attributes: Inclusiveness; Business model; Frugality; Eco-responsibility; and Ethical, legal, and social issues (ELSIs). We discuss the remaining four

Table 6.1 Summary of tools and approaches

RIH attribute	Tool or approach
Inclusiveness	Applying human factors and usability engineering to medical devices
	House of quality diagram
	Photojournal
Business model	Business model canvas
	B impact assessment
	Cross-subsidy
Frugality	Modular design
	3D printing
	Ishikawa diagram
Eco-responsibility	SHIFT platform
	Guidelines for incorporating ecodesign
	Ecodesign assessment
Ethical, legal, and social issues	Data ethics framework
	Privacy guide for businesses
	Framework for systematic identification of ethical aspects of healthcare technologies

attributes, that is, Health relevance, Responsiveness, Health inequalities, and Level and intensity of care, in Chap. 7, where we explain how tools and approaches can help to fulfill many attributes simultaneously.

As a starter kit toolbox, our selection is by no means exhaustive. The toolbox is meant to encourage teams to examine whether their preferred tools are or can be aligned toward fulfilling RIH attributes and to search for similar tools that are adapted to their own region or country. Toward this end, we gathered additional information about each tool and approach to provide readers with a general description, and we draw from the exoskeleton example to briefly illustrate how they can help to rethink health innovation design.

Readers should note that we do not critically review or officially endorse the tools and approaches. We are aware that they each come with their limitations and that the latter can vary significantly according to project objectives, needs, and contexts. What makes them valuable is their ability to make RIH concepts actionable.

Tools to Engage with Relevant Stakeholders

To fulfill the Inclusiveness attribute (Chap. 4), teams should employ a formal method to engage with a diverse and relevant set of stakeholders throughout the design and development phases and explain how the contributions of stakeholders influenced the final product, service, or solution. The following tools can serve as a formal method to engage stakeholders. They respectively come from the fields of medical devices, engineering, and human-centered design.

Applying Human Factors and Usability Engineering to Medical Devices (FDA)

Developed by the US Food and Drug Administration (FDA), this practical guide explains how to apply human factors engineering (HFE) throughout the innovation design process to maximize the security and efficacy of medical devices. Also known as usability engineering, HFE is:

> the application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use. (U.S. Food and Drug Administration, 2016)

Freely available from the FDA's website, the guide specifies which and how many stakeholders should take part in human factors validation testing, different data collection methods as well as the rationale for doing so. The FDA invites innovators to "evaluate and understand the characteristics of all intended user groups" that could affect how they interact with the device (U.S. Food and Drug Administration, 2016). Innovators should describe how variability and limitations among users were taken into consideration during the medical device development process.

The guide was proposed by a team of engineer participants who appreciated its structured and regulated approach to HFE and how it enables innovators to study users' interactions with the prototype. In the case of the exoskeleton redesign, studying users' interactions with the device to capture and adapt to their variability and limitations could significantly improve the exoskeleton's capacity to meet the needs of a greater variety of users. Indeed, even if each exoskeleton model differs in terms of general

configuration, weight, autonomy of the battery, cost, and functions (Hill et al., 2017), the models reviewed by Kandilakis and Sasso-Lance (2019) could only be used by individuals who met specific requirements in terms of weight, height, health of their skin and bones, and the capacity to execute certain movements. By working with a broader variety of users throughout the design process, innovators can rethink their original design objectives.

House of Quality Diagram (QFD)

The House of Quality diagram is a product design tool that translates users' needs and priorities into technical engineering measures and requirements (Dias et al., 2019). First developed in the 1960s by the industrial sector in Japan and largely adopted later by the medical device sector, the House of Quality diagram is part of the Quality Function Deployment (QFD) approach. The latter is comprised of four phases that are built in a sequential and incremental manner: House of Quality, Parts Deployment, Process Planning, and Production Planning (Dias et al., 2019). To complete the House of Quality diagram, users' needs and priorities can be identified through a variety of methods, including "questionnaires, comment cards, individual interviews, focus groups [and] product in use" (Dias et al., 2019).

While the House of Quality diagram is not without criticism (Neira-Rodado et al., 2020; Zhang et al., 2020), it enables innovators to work with stakeholders early in the innovation design process to capture, understand, and work with their needs in a structured and "more transparent process" (Dias et al., 2019). Numerous books, websites, software programs, and training courses are offered on the QFD approach and the House of Quality diagram.

In the context of our redesign study, a team of participants with expertise in health innovation management suggested this tool for its capacity to consider the priorities of users as well as the priorities of the organization that develops the innovation. They also put forward the tool's capacity to question the reasons underlying design decisions. As such, the House of Quality diagram can help innovators meet users' actual needs and priorities. In the case of the exoskeleton, for instance, William Peace, a wheelchair user and blogger, argued that for the price of one exoskeleton (between USD 70,000 and USD 100,000 at the time of writing), he would rather purchase an ergonomic chair and comfortable cushion for

everyday use, a variety of sporting equipment (e.g., handcycle, sit ski, racing chair) that would allow for an active lifestyle, as well as invest in adapted transportation and housing (Peace, 2013). By applying the House of Quality diagram, innovators can thus consider how various design scenarios could meet the most pressing everyday needs of wheelchair users.

Photojournal (IDEO.org)

Stemming from the social sciences, qualitative research methods developed around the use of photography have significantly grown in popularity since the 2000s and now rely on a robust scholarship (Alves et al., 2021). Typically, individuals take photographs of objects, people, and/or environments that speak to their lived experiences of or perspectives on a particular issue or problem (Wang & Burris, 1997). A multitude of different methods exist with varying degrees of user or stakeholder involvement—from consultation to more active participation (Gervais & Rivard, 2013).

IDEO.org, a world-renowned American not-for-profit design studio, includes the Photojournal in its human-centered design toolkit. Comprising five steps, the tool is applied during the first phase of the design process—inspiration—and is used in preparation for the interview between the designer and the person for whom they are designing a product or service. The objective is "to go beyond an in-person interview to better understand a person's context, the people who surround them, community dynamics, and the journey through how they use a product or service." IDEO.org's Photojournal tool is freely available from their website.

Also proposed by the team of participants with expertise in health innovation management, photo-based methods can help users capture and share with innovators their needs that may be less obvious at first sight as well as their social environments, including their everyday social interactions and how they perceive their use of the innovation in different social contexts (e.g., public transportation, professional setting, casual setting with friends). For the exoskeleton redesign, the user's day-to-day social context is essential to understand as, at the time of writing, the FDA requires users to be accompanied by a trained attendant when using an exoskeleton, thereby largely influencing when and how individuals can use the technology (Fritz et al., 2019).

Tools to Provide More Value to Users, Purchasers, and Society

The Business model attribute (Chap. 4) encourages organizations to develop products, services, or solutions that not only meet users' needs but also provide more value to users, purchasers, and society. The following tools and approaches come from the fields of entrepreneurship and social entrepreneurship.

Business Model Canvas (Osterwalder and Pigneur)

The Business Model Canvas comes from Alexander Osterwalder and Yves Pigneur's highly influential book *Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers* published in 2010. The Business Model Canvas helps to design business models along nine essential building blocks: customer segments, value propositions, channels, customer relationships, revenue streams, key resources, key activities, key partnerships, and cost structure (Osterwalder & Pigneur, 2010). Presented like "a painter's canvas," the tool aims to generate "understanding, discussion, creativity, and analysis" and also includes a specific section on "how the Canvas can drive business model innovation in the public and nonprofit sectors" (Osterwalder & Pigneur, 2010). A 72-page book preview is freely available online and the book can be purchased from major retailers.

This tool was selected by a team of study participants in design and communication because it is a widely known and used tool that has been adopted by both new and seasoned entrepreneurs (Parry, 2014). The Business Model Canvas has also been adapted to different business sectors and inspired many other tools including, for instance, sustainable business models (Joyce & Paquin, 2016), the Social Enterprise Model Canvas (Sparviero, 2019), and the Ecocanvas adapted to a circular economy objective (Daou et al., 2020).

As such, the Business Model Canvas can help develop mission-oriented business models, and in this way, help to meet responsibility characteristics of the Business model attribute, that is, to pursue a social and/or environmental mission, operate on a not-for-profit basis, or reinvest the majority of the revenues in the organization's mission. When applied to the exoskeleton redesign exercise, it opens up opportunities to rethink the

shareholder model of many of the companies developing and commercializing the technology.

B Impact Assessment (Certified B Corporation)

Another responsibility characteristic of the Business model attribute is for an organization to comply with social responsibility programs. One example of such a program is the international Certified B Corporation program. Established since 2007 and administered by the non-profit B Lab, its objective is for businesses to be "purpose-driven" and to create "benefit for all stakeholders, not just shareholders." Toward this end, the B Corp Certification evaluates the product or service as well as the "overall positive impact of the company that stands behind it," that is, it's "entire social and environmental performance." B Lab publishes a yearly ranking of the "Best for the World" businesses in the B Corp Certification's five impact areas: community, customers, environments, governance, and workers.

The B Impact Assessment tool, a free confidential online platform, evaluates how an organization's operations and business model impact workers, community, environment, and customers through transparent and accountable requirements. The questions are "tailored to a company's size, sector, and geography" and are "overseen by B Lab's independent Standards Advisory Council." The results of the assessment help organizations "to create a roadmap for improved performance year-over-year or quarter-by-quarter."

A link to sample questions is provided at the end of the chapter. For instance, the following question from the Community impact area is not only highly relevant for the exoskeleton redesign, but is also aligned with another Business model attribute responsibility criteria, that is, to employ people with particular needs, including disabilities: "What % of management is from underrepresented populations? This includes women, minority/previously excluded populations, people with disabilities, and/or individuals living in low-income communities."

Cross-Subsidy

The cross-subsidy business model was proposed by the team of study participants with expertise in health innovation management to fulfill one of the attribute's characteristics: adopting a pricing scheme based on ability to pay. With the cross-subsidy business model, "support for one product

or service comes from revenues generated from another product or service" (Jahani & West, 2015). To do so, pricing structures can, for example, "offer the same product to all customers, with differential pricing based on customer type or general ability to pay," "offer a higher-priced upgraded product to cover the cost of providing discounted or free products," or "offer entirely different products and rely on one product to subsidize the other" (Jahani & West, 2015). This model is gaining popularity in emerging economies to increase access to health and social care services, including health technologies (Angeli & Jaiswal, 2016). It has also been found to successfully provide health and social care in more mature economies (Cicellin et al., 2019).

In the case of the exoskeleton redesign, for example, an organization that produces a variety of assistive devices and products for occupational and physical therapy clinics could increase access to an exoskeleton by subsidizing the technology at near-cost with the profits generated through an exclusive services agreement with the clinics.

Tools to Deliver Greater Value to More People Using Fewer Resources

The three objectives of the Frugality attribute (Chap. 5) are to substantially reduce the costs of production and use of an innovation, focus on the core functionalities its users require, and optimize its performance level considering the intended purpose and context of use. Teams should therefore aim to make an affordable, easy-to-use, and high-performing innovation. We propose tools and approaches that come from engineering, design, and management fields of practice that can be oriented toward fulfilling a frugality objective.

Modular Design

Proposed by a team of engineer participants, modular design is "the process of producing units that perform discrete functions, then connecting the units together to provide a variety of functions" (Kamrani & Nasr, 2010). As engineers know well, this design approach is at "the core of many innovative technologies across engineering" as it allows for "rapid, efficient, and reproducible construction and maintenance of complex systems" while reducing costs and facilitating customization (Garcia & Trinh, 2019). The modular approach is also used to design digital platforms in a more frugal way (Ahuja & Chan, 2019).

A modular design approach to the exoskeleton could entail, for example, assembling through a "soft" structure a series of uniform multifunction mechanical components to support either the hip, the knee, or the ankle to reduce manufacturing costs. When combined with 3D printing, modular design also opens up innovative redesign opportunities, as presented in the following section.

3D Printing

Another team of engineers who took part in our study turned to 3D printing as a tool to fulfill the Frugality attribute. Also known as additive manufacturing, the use of 3D printing in the health field is growing exponentially with wide ranging applications, from prosthetics (Manero et al., 2019) to personalized medication (Aquino et al., 2018) and tissue engineering (Poomathi et al., 2020) just to name a few examples. As 3D printers are largely made available in fab labs and makerspaces (Rayna & Striukova, 2021), the technology is rapidly breaking new ground.

In the context of our redesign study, the team of engineers argued that 3D printing could increase the frugality of the exoskeleton through the customization of certain key pieces. Following a modular design approach, they proposed separating the pieces that are closest to the body from the rest of the exoskeleton. This would allow for customized 3D-printed pieces that are more comfortable for the user as well as an outer structure designed to be shared among several users. The participants envisioned a rehabilitation program where a care professional assists several patients at home using the same exoskeleton outer structure. In this way, the customized pieces would be cheaper and easier to replace while the outer structure would be lighter to manipulate and travel with for the care professional. The customized and shareable model would reduce costs while increasing access.

Ishikawa Diagram

The Ishikawa diagram, also known as the Fishbone or Cause and Effect diagram, "is a practical widely used tool for a group to organize its understanding of the causes and variation in the outcome of their work" (Best & Neuhauser, 2008). Developed by Kaoru Ishikawa in Japan in the 1960s, the Ishikawa diagram is part of seven technical tools for quality control. Along with seven management tools, Ishikawa's "company-wide quality control stressed the entire life cycle from design to after-sale service" (Best & Neuhauser, 2008).
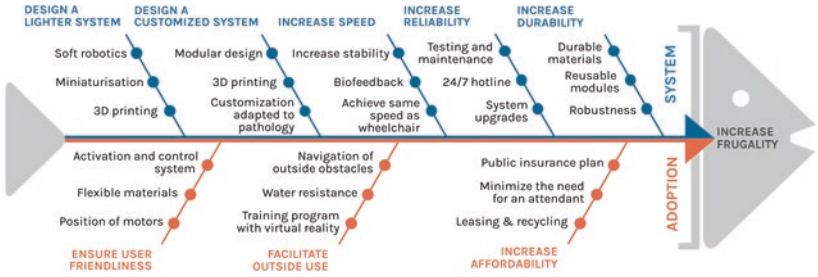
Fig. 6.1   An example of an Ishikawa diagram examining the Frugality attribute

In the health field, Health Quality Ontario offers a free Portable Document Format (PDF) worksheet that explains how to use the tool, the materials needed, and how to analyze the data generated during discussions. The tool can "help your team create a common understanding of the potential sources (root causes) that most significantly contribute to the problem in question" and in this way, ensure that team members can "focus improvement efforts on true causes rather than symptoms" (Health Quality Ontario).

A team of study participants with expertise in biomedical engineering and healthcare management produced an Ishikawa diagram for all five of their assigned attributes, including Frugality. As we can see in Fig. 6.1, the diagram is shaped like a fishbone, with the quality problem on the far right (increasing frugality) and categories of redesign objectives on the left.

Tools to Limit the Environmental Footprint Throughout the Lifecycle

To reduce the negative environmental impacts of a health innovation, the Eco-responsibility attribute (Chap. 5) invites teams to integrate eco-responsibility concerns during three or more of the following key lifecycle stages: raw material sourcing, manufacturing, distribution, use, and disposal.

In the context of our redesign study, strategies to reduce the environmental footprint of the exoskeleton varied widely across teams depending, for instance, on the functions (e.g., motorized or not) or the type of components they had envisioned (e.g., with or without electronics). We present next tools from the fields of management and design that can inform

the design of a broad range of health innovations, without referring to the exoskeleton example.

SHIFT Platform (MIT Sloan School of Management)

Led by the Sustainability Initiative at MIT Sloan School of Management, the SHIFT platform is a free "search engine for business sustainability resources." SHIFT is an acronym for Sustainability, Help, Information, Frameworks/Findings, and Tools. The objective of the platform is to help businesses "navigate the sea of sustainability tools and carve out [their] pathway to implementation" by finding, comparing, and choosing the tools that work best for them. It is developed and curated by "a community of practitioners working together to review tools based on their own experiences" in order to "make it easier for leaders of all stages of development to 'hardwire' sustainability into their organizations." Contributors of resources cover a very broad variety of sectors and areas of expertise.

Searches can be conducted by sector (e.g., Healthcare), issue (e.g., Environmental), and job function (e.g., product design, entrepreneur, management) and refined according to resource type (e.g., app, template, questionnaire, guidelines, course, article), reviews (3 to 5 stars), access (free, freemium, or paid), and whether it is public or proprietary. Results can also be organized by the following categories: clarify strategy; engage and build business case; measure and value; implement; and communicate.

Guidelines for Incorporating Ecodesign (ISO 14006:2020)

Well-known by innovators and managers worldwide, standards produced by the International Organization for Standardization (ISO) can also be useful for making RIH. Standard 14006 helps organizations implement environmental considerations in the design and development of their product (including both goods and services) to reduce adverse environmental impacts throughout the entire lifecycle. The lifecycle stages covered by the standard are: "material acquisition, design and development; manufacturing; delivery and installation; use (including reuse, maintenance, repair, remanufacturing, refurbishing, and upgrading); end-of-life treatment; and disposal."

The standard "is applicable to any organization regardless of its type, size or product(s) provided" and "gives guidelines for assisting

organizations in establishing, documenting, implementing, maintaining and continually improving their management of ecodesign as part of an environmental management system." It is available for a fee.

Ecodesign Assessment (Estonian Design Centre)

Developed by the Estonian Design Centre, the Ecodesign Assessment for products is part of the Circular Design Toolkit freely available online. For the Estonian Design Centre, circular design is a multidisciplinary endeavor that:

> can unveil new dimensions of sustainable business by exploiting underlying needs and behavioural patterns and creatively translating environmental and social responsibilities into profitable business opportunities.

Because the circular economy aims to "re-invent how products are designed, manufactured, used, sold, refurbished and recycled," "products need to be designed for upgradeability, repairability and new specifications related to sharing or other service based business models." In this way, circular design represents "a totally new dimension of sustainability."

In addition to the business model, the Ecodesign Assessment for products covers six phases: design, resources, manufacturing, distribution, use, and after use. A series of questions are asked for each phase and answered along a five-level rating scale. The final score highlights the strengths and areas for improvement. The tool is available for free.

Tools to Mitigate Potential Negative Impacts on Users

Finally, to meet the responsibility objectives of the Ethical, legal, and social issues (ELSIs) attribute (Chap. 5), teams should first identify potential negative impacts of their innovation on users as well as appropriate means to mitigate them. The latter may already exist (e.g., personal data management law) or may have to be developed and implemented by competent authorities (e.g., patient decision aid). We present two tools developed by governmental organizations and one tool developed by a health technology assessment agency.

Data Ethics Framework (Government of the United Kingdom)

The Data Ethics Framework was developed by the Central Digital & Data Office of the Government of the United Kingdom to "help public servants understand ethical considerations, address these within their projects, and encourage responsible innovation." Though the framework is intended for individuals who work in the public sector directly or indirectly with data, it defines specific actions along three ethical principles that have gained wide acceptance in the digital and artificial intelligence (AI) field: transparency, accountability, and fairness. As such, the framework can inform good practice for a broad variety of innovations.

The framework defines the three ethical principles and provides guiding questions as well as specific actions to help teams: "define and understand public benefit and user need;" "involve diverse expertise;" "comply with the law;" "review the quality and limitation of the data;" and "evaluate and consider wider policy implications." In addition, the framework includes a self-assessment scoring scale to help innovators identify the aspects of their project that need further reflection and work. It is available for free.

Privacy Guide for Businesses (Government of Canada)

Developed by the Office of the Privacy Commissioner of the Government of Canada, the Privacy Guide for Businesses explains "what Canadian businesses need to know to comply with federal privacy law." In accessible and non-legal terms, the guide describes the ten fair information principles underlying the law, the responsibilities of organizations in respect with each principle, how to fulfill them, as well as tips and related links.

While innovation teams should look for practical guides that help businesses comply with their own federal laws, the ten fair information principles described for the Canadian context can be relevant to other countries as they point to generalized issues of concern: accountability, identifying purposes, consent, limiting collection, limiting use, disclosure and retention, accuracy, safeguards, openness, individual access, and challenging compliance. The guide is available for free.

Framework for Systematic Identification of Ethical Aspects of Healthcare Technologies (Swedish Agency for Health Technology Assessment)

The Swedish Agency for Health Technology Assessment developed a framework to help health technology assessors as well as non-ethicists

identify an innovation's ethical and social issues. The framework is comprised of twelve questions (with detailed sub-questions) that examine an innovation's health impact, compatibility with ethical values, structural and resource factors, professional values, special interests, and long-term ethical consequences (Heintz et al., 2015).

The open-ended questions aim to guide innovation teams as they reflect on relevant issues that impact patients, patient groups, healthcare professionals, healthcare systems, third parties, as well as broader social impacts. The following scientific article explains how the framework was put together (Heintz et al., 2015).

Summary Points

The RIH toolbox covers a broad scope of tools and approaches from multiple fields of practice. The wide array of well-known tools indicates that, though RIH sets new objectives for health innovation design, a responsible health innovation can be made with existing and commonly used tools and approaches.

After looking for the tools and approaches that can help you and your team fulfill your responsibility objectives, the following step is to bring it all together by making strategic design decisions that best suit your project's needs and constraints.

Box 6.1   Chapter 6 Summary Points

- While RIH may be new, making a responsible health innovation does not require new tools or approaches.
- The RIH toolbox is a starter kit comprising 15 tools and approaches from different fields of practice (engineering, management, entrepreneurship, design).
- The RIH toolbox was built by researchers and practitioners who worked with the RIH design brief to conceptually redesign an existing innovation.
- Innovation teams can look for existing and commonly used tools and approaches that correspond to or can be aligned toward fulfilling the responsibility objectives they set for their project with the RIH design brief.

Websites Mentioned in the Chapter

Applying human factors and usability engineering to medical devices
https://www.fda.gov/media/80481/download
Photojournal
https://www.designkit.org/methods/photojournal
Business Model Generation free preview
https://assets.strategyzer.com/assets/resources/business-model-
   generation-book-preview-2010.pdf
B Impact Assessment
https://bimpactassessment.net/how-it-works/assess-your-impact#
   see-sample-questions
Ishikawa diagram—Health Quality Ontario tool
http://www.hqontario.ca/Portals/0/Documents/qi/qi-fishbone-
   instruction-sheet-ac-en.pdf
SHIFT platform
https://shift.tools/
Guidelines for incorporating ecodesign (ISO 14006:2020)
https://shop.standards.ie/preview/627027251089.pdf?sku=
   875581_SAIG_NSAI_NSAI_2816383
Ecodesign Assessment (product)
https://circulardesign.tools/
https://circulardesign.tools/wp-content/uploads/2021/04/EDC_
   EcodesignAssessment-Product-1.pdf
Data Ethics Framework
https://www.gov.uk/government/publications/data-ethics-framework/
   data-ethics-framework-2020
Privacy Guide for Businesses
https://www.priv.gc.ca/media/2038/guide_org_e.pdf
**Swedish Agency for Health Technology Assessment and Assessment
   of Social Services**
https://www.sbu.se/en/method/

References

Ahuja, S., & Chan, Y. E. (2019). Frugal innovation and digitalisation: A platform ecosystem perspective. In *Frugal innovation* (pp. 89–107). Routledge.

Alves, K. Y. A., Rodrigues, C. C. F. M., & Salvador, P. T. C. de O., & Fernandes, S. D. de M. (2021). Use of photography in qualitative research in the health area: Scoping review. *Ciência & Saúde Coletiva, 26*, 521–529.

Angeli, F., & Jaiswal, A. K. (2016). Business model innovation for inclusive health care delivery at the bottom of the pyramid. *Organization & Environment, 29*(4), 486–507.

Aquino, R. P., Barile, S., Grasso, A., & Saviano, M. (2018). Envisioning smart and sustainable healthcare: 3D printing technologies for personalized medication. *Futures, 103*, 35–50.

Best, M., & Neuhauser, D. (2008). Kaoru Ishikawa: From fishbones to world peace. *BMJ Quality & Safety, 17*(2), 150–152.

Cicellin, M., Scuotto, A., Canonico, P., Consiglio, S., & Mercurio, L. (2019). Understanding the low cost business model in healthcare service provision: A comparative case study in Italy. *Social Science & Medicine, 240*, 112572.

Daou, A., Mallat, C., Chammas, G., Cerantola, N., Kayed, S., & Saliba, N. A. (2020). The ecocanvas as a business model canvas for a circular economy. *Journal of Cleaner Production, 258*, 120938.

Dias, P. A., João, I. M., & Lourenço, J. C. (2019). *Patients' requirements prioritization on the house of quality: The case of glucose monitoring devices in young adults with type 1 diabetes.* Paper presented at the 2019 IEEE 6th Portuguese Meeting on Bioengineering (ENBENG).

U.S. Food and Drug Administration. (2016). *Applying human factors and usability engineering to medical devices: Guidance for industry and Food and Drug Administration staff.* Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usabilityengineering-medical-devices

Fritz, H., Patzer, D., & Galen, S. S. (2019). Robotic exoskeletons for reengaging in everyday activities: Promises, pitfalls, and opportunities. *Disability and Rehabilitation, 41*(5), 560–563.

Garcia, S., & Trinh, C. T. (2019). Modular design: Implementing proven engineering principles in biotechnology. *Biotechnology Advances, 37*(7), 107403.

Gervais, M., & Rivard, L. (2013). 'SMART' Photovoice agricultural consultation: Increasing Rwandan women farmers' active participation in development. *Development in Practice, 23*(4), 496–510.

Heintz, E., Lintamo, L., Hultcrantz, M., Jacobson, S., Levi, R., Munthe, C., … Sandman, L. (2015). Framework for systematic identification of ethical aspects of healthcare technologies: The SBU approach. *International Journal of Technology Assessment in Health Care, 31*(3), 124–130.

Hill, D., Holloway, C. S., Ramirez, D. Z. M., Smitham, P., & Pappas, Y. (2017). What are user perspectives of exoskeleton technology? A literature review. *International Journal of Technology Assessment in Health Care, 33*(2), 160–167.

Jahani, M., & West, E. (2015). Investing in cross-subsidy for greater impact. *Stanford Social Innovation Review*. Retrieved January 9, 2017, from https://ssir.org/articles/entry/investing_in_cross_subsidy_for_greater_impact

Joyce, A., & Paquin, R. L. (2016). The triple layered business model canvas: A tool to design more sustainable business models. *Journal of Cleaner Production, 135*, 1474–1486.

Kamrani, A. K., & Nasr, E. A. (2010). Modular design. In *Engineering design and rapid prototyping* (pp. 57–86). Springer US.

Kandilakis, C., & Sasso-Lance, E. (2019). Exoskeletons for personal use after spinal cord injury. *Archives of Physical Medicine and Rehabilitation, 102*(2), 331–337. https://doi.org/10.1016/j.apmr.2019.05.028

Manero, A., Smith, P., Sparkman, J., Dombrowski, M., Courbin, D., Kester, A., … Chi, A. (2019). Implementation of 3D printing technology in the field of prosthetics: Past, present, and future. *International Journal of Environmental Research and Public Health, 16*(9), 1641.

Neira-Rodado, D., Ortiz-Barrios, M., la Hoz-Escorcia, D., Paggetti, C., Noffrini, L., & Fratea, N. (2020). Smart product design process through the implementation of a fuzzy Kano-AHP-DEMATEL-QFD approach. *Applied Sciences, 10*(5), 1792.

Osterwalder, A., & Pigneur, Y. (2010). *Business model generation: A handbook for visionaries, game changers, and challengers* (Vol. Vol. 1). John Wiley & Sons.

Parry, Z. (2014). Book review: Business model generation: A handbook for visionaries', game changers, and challengers. *The International Journal of Entrepreneurship and Innovation, 15*(2), 137–138. https://doi.org/10.5367/ijei.2014.0149

Peace, W. (2013). ReWalk: A plea for common sense. https://badcripple.blogspot.com/2013/04/rewalkplea-for-common-sense.html

Poomathi, N., Singh, S., Prakash, C., Subramanian, A., Sahay, R., Cinappan, A., & Ramakrishna, S. (2020). 3D printing in tissue engineering: A state of the art review of technologies and biomaterials. *Rapid Prototyping Journal, 27*(7), 1313–1334.

Rayna, T., & Striukova, L. (2021). Fostering skills for the 21st century: The role of fab labs and makerspaces. *Technological Forecasting and Social Change, 164*, 120391.

Sparviero, S. (2019). The case for a socially oriented business model canvas: The social enterprise model canvas. *Journal of Social Entrepreneurship, 10*(2), 232–251.

Wang, C., & Burris, M. A. (1997). Photovoice: Concept, methodology, and use for participatory needs assessment. *Health Education & Behavior, 24*(3), 369–387.

Zhang, X., Li, J., Fan, K., Chen, Z., Hu, Z., & Yu, Y. (2020). Neural approximation enhanced predictive tracking control of a novel designed four-wheeled rollator. *Applied Sciences, 10*(1), 125.

Bringing It All Together

Abstract After setting your nine responsibility objectives with the Responsible Innovation in Health (RIH) design brief (Chaps. 3, 4, and 5) and looking for tools and approaches that can help you meet them with the RIH toolbox (Chap. 6), the next step in the path to RIH is to bring it all together by making strategic design decisions. In this chapter, we help teams navigate through this decision-making process while keeping RIH as their "North Star." Depending on the particularities of your project, some responsibility objectives may be achievable in tandem, while others may conflict with one another. Working with the synergies and tensions early in the design process enables you and your team to make informed decisions that best suit your project's needs and constraints, while aiming for an overall degree of responsibility. Toward this end, we share steps and tools to help teams find and leverage the synergies and tensions between their responsibility objectives. For inspiration, we also share examples of innovations that fulfill several RIH attributes simultaneously.

Keywords Responsibility Tensions • Health Innovation Trade-offs • Design Decision-making

Making Upstream Strategic Design Decisions to Fulfill RIH

Throughout the previous chapters, our overall aim has been to inspire and equip teams to fulfill all nine RIH attributes, as they are equally important to make health innovations that tackle twenty-first-century challenges. In the RIH design brief, we introduced each attribute separately, described its particular importance for health innovation, and invited innovation teams to work with each rating scale to set the responsibility objectives that best suit their project (Chaps. 3, 4, and 5). However, we are well aware that many innovation teams may encounter difficulties in meeting the highest responsibility scores for all attributes, that is, an "A" or a "B" on the rating scales.

As innovators know well, each project comes with its own constraints, limitations, and unforeseen circumstances that require making compromises and trade-offs. An RIH project is no different in that, depending on the particularities of an innovation, there may be responsibility elements that are in conflict. In other words, contextual factors, constraints, or demands may be difficult to reconcile and lessen the degree of responsibility the innovation team originally set for a certain attribute.

To help you and your team make strategic design decisions, we propose a three-step reflection process that can be applied after you have set your responsibility objectives and looked for tools and approaches to meet them. The purpose of the reflection process is to identify the synergies and tensions that may arise between your responsibility objectives and to use this information to help you decide on which compromises and trade-offs best suit your project.

Step 1: Finding the Synergies

Begin by closely examining the nine responsibility objectives you have set for your project to see if there are some objectives that can be achieved in tandem or that have a combined effect. In other words, by meeting one objective, you can easily meet another or several others. For instance, meeting the need of a vulnerable group in a safe and effective manner may *require* a solution that is affordable, easy to use, and optimized for a home setting. As such, this innovation would simultaneously score an "A" on the rating scale of three RIH attributes: Health inequalities, Frugality, and Level and intensity of care. See Box 7.1 for an example.

Box 7.1   An Innovation That Synergizes Three RIH Attributes
A frugal innovation for energy poor households and communities

   The innovation: A solution made with plastic bottles, solar panels, and light-emitting diode (LED) lamps to light energy poor households and communities.

   Health inequalities: In many countries worldwide, people living in poverty or in deprived areas lack access to electricity and to non-polluting sources of light. This can directly impact their health and safety.

   Level and intensity of care: A lighting solution is designed specifically to light up a household room while another is designed to light up a public space where public services do not provide lampposts.

   Frugality:

- *Affordability*: The solution is developed by a global open-source movement that provides lighting free of charge.
- *Focus on core functionalities and ease of use*: The solution is designed to produce light for one room or to function as an off-grid lamppost and integrates universal serial bus (USB) charging ports for cellphones.
- *Optimized functionality*: The solution produces over 12 hours of light. Many energy poor households and communities are located in geographical areas that receive, on average, 12 hours of darkness per day.

By finding the synergies between your responsibility objectives during the early stages of innovation design, you can select tools and approaches that can fulfill several RIH attributes concurrently. This strategy was used by several health innovation researchers and practitioners who took part in our exoskeleton redesign study (Chap. 6). For example, the team of study participants who produced an Ishikawa diagram for the Frugality attribute presented in Chap. 6, also applied this tool to the Health inequalities attribute as well as the Level and intensity of care attribute. By fleshing out the causes and desired effects in relation to each targeted attribute, this tool can be used to highlight concurring design elements.

   Other tools in the RIH toolbox are also applicable to many RIH attributes. The Photojournal, for instance, not only is aligned with the

Inclusiveness attribute but may also help to fulfill other attributes by bringing forward end users' needs and everyday context of use, including Health inequalities (needs), Ethical, legal, and social issues (social context of use), Level and intensity of care (non-clinical environment), and Frugality (ease of use and optimized performance for the context of use). A mission-oriented Business Model Canvas was also promoted by a team of study participants as capable of bringing together multiple RIH attributes. In addition to fulfilling the Business model attribute, an organization working with a mission-oriented Business Model Canvas can integrate key responsibility elements under its mission umbrella, including health system sustainability (Responsiveness and Level and intensity of care) and environmental sustainability (Eco-responsibility).

Box 7.2 describes an example of an innovation that integrates six RIH attributes simultaneously.

Box 7.2   An Innovation That Integrates Six RIH Attributes
A creative innovation for pediatric patients

The innovation: An educational booklet that explains 160 oncology terms related to the disease and treatment procedures in a clear, objective, visually appealing, and optimistic manner for pediatric patients and their informal caregivers.

Health relevance: When we consider the set of all types of cancer most prevalent in children (e.g., leukemia, non-Hodgkin's lymphomas, neuroblastomas, soft tissue sarcomas), the disease ranks in the top quarter of all causes of death, injury or disability, or risk factors of the region where the intended users are located.

Responsiveness: As a patient-centered tool adapted to the specific needs of pediatric patients, the innovation addresses an important service delivery gap.

Level and intensity of care: As a visually appealing booklet for children, the innovation was designed for its use to take place mostly under the care of the patient, an informal caregiver, or a health and social care provider operating in a non-clinical environment (e.g., bedtime reading at home). However, it can also be used by healthcare providers operating at the most specialized level of care to explain certain procedures as children undergo treatment.

Inclusiveness: The booklet was developed by patients, parents, doctors, and nurses. The doctors provided the technical explanation

Box 7.2   (continued)

of the terms, the innovation team adapted the descriptions in child-friendly language, and the booklet was reviewed by multidisciplinary healthcare professionals as well as end users.

Business model: The booklet is produced by a not-for-profit entity that adopts a pricing scheme based on the ability to pay. While the booklet can be purchased online by those who can afford it, it is also distributed for free to public healthcare facilities and patients.

Frugality:

- *Affordability*: The cost of production and use of the booklet are very low.
- *Focus on core functionalities and ease of use*: The language and visual elements of the booklet are child-friendly.
- *Optimized performance*: The booklet is highly portable and fit for use in multiple clinical and non-clinical contexts.

Step 2: Finding the Tensions

After finding the synergies between your responsibility objectives, look for the tensions. Closely examine the objectives to see if there are some that conflict with one another. In other words, by meeting one objective, it becomes difficult to meet another or several others as certain contextual constraints may impose design limitations that impact the intended degree of responsibility.

For instance, fulfilling the Eco-responsibility attribute can represent a particular challenge in the health field where strict infection control guidelines often favor disposable solutions (Rivard, Lehoux, & Miller, 2020b). As an example, an innovation that targets the needs of aging patients (Responsiveness) in a primary healthcare facility (Level and intensity of care) may be distributed with green packaging, be reusable, and recyclable (Eco-responsibility) but ultimately rejected by the healthcare facility because the staff do not have the time or resources to wash and disinfect it after each use.

The digital health field may also pose certain challenges to some RIH attributes (Rivard, Lehoux, & Alami, 2020a). For instance, an innovation team who developed a solution through participatory workshops with relevant stakeholders (Inclusiveness) living with a debilitating chronic disease (Health relevance and Responsiveness) in a local fab lab may have set out to make the solution freely usable or exploitable by others with an open-source model (Business model attribute), but the platform through which it is shared does not respect health data privacy and confidentiality laws (Ethical, legal, and social issues).

Another type of tension could arise if innovation teams get too enthusiastic about a particular RIH attribute and neglect the "distorting" impact their willingness to fulfill this attribute may have on other RIH attributes. For example, choosing to develop a frugal wheelchair is not automatically conducive to the development of an environmentally sustainable wheelchair or to a wheelchair that reduces inequalities. A similar distortion could be caused if innovation teams a priori choose to limit their design scenarios to solutions meant to be used by patients themselves (Level and intensity of care), an approach that may unduly shift the burden of care on their shoulders. We therefore suggest that innovation teams always keep an eye on the relationships between the nine RIH attributes.

Step 3: Deciding on the Trade-Offs and Compromises

When tensions between responsibility objectives occur, we invite innovation teams to work with the nine attributes in a holistic manner. By this we mean that, after zooming into each attribute and setting your nine responsibility objectives separately, the next step is to zoom out and look at the responsibility objectives as working together to bring your innovation to the highest possible *overall* degree of responsibility. In other words, your original responsibility objectives for each RIH attribute can be "tweaked" in response to emerging challenges, and in so doing, your team can identify trade-offs adapted to your project.

For instance, let's say that your responsibility objective for the Frugality attribute is an "A" on the rating scale, that is, you aim for your innovation to be affordable, easy to use, and optimized for its context of use, and that your responsibility objective for the Business model attribute is a "C," as you aim to fulfill one characteristic of the attribute: complying with a social responsibility program. However, in the early stages of your project,

you encounter challenges that will increase the intended cost of the innovation for the end users and reduce its performance level in its context of use. As a result, your responsibility score for the Frugality attribute will "fall" to a "C." In response to this anticipated change in degree of responsibility, you can look to the other RIH attributes to see if there are responsibility elements that can be leveraged. For example, to compensate for the increase in cost to the end user, you can look to the Business model attribute and decide to offer a "buy one, give one" option to your customers. By doing so, you not only enable greater access to your innovation for end users negatively affected by the increase in cost but also boost your score for this attribute to a "B" by fulfilling two characteristics instead of one. While your individual objectives for the Frugality and Business model attributes change—from an "A" to a "C" and a "C" to a "B"—your overall degree of responsibility remains the same.

To identify and work through some of these tensions, a team of study participants with expertise in design and communication recommended that innovation teams assemble a multi-stakeholder steering committee to map and resolve tensions throughout the innovation design and development process. Following a participatory approach, the steering committee can engage stakeholders in mapping exercises to highlight anticipated tensions between responsibility objectives and then support the emergence of creative solutions. If tensions are too difficult to resolve, the steering committee can help team members arrive at a collective consensus on compromises that can be made.

Although for some projects it may not be feasible to fulfill many RIH attributes, such innovations can still significantly contribute to forging the RIH pathway. Because they may represent "off the beaten path" solutions for their specific field of practice, innovations such as these are necessary to break new ground and open up new possibilities for future projects. This may especially be the case in areas of practice where the consideration of certain RIH attributes is relatively new, including environmental considerations as well as ethical, legal, and social issues in the rapidly evolving digital health field.

For example, Box 7.3 describes an innovative ecological solution for pharmacists. While the solution only fulfills four of the nine RIH attributes, the eco-friendly solution represents a radical break from

Box 7.3   Setting a New Path in the Drug Distribution and Retail Industry

An innovative ecological solution for pharmacists

   The innovation: Eco-friendly medication vials.

   Inclusiveness: The vials were designed in collaboration with relevant stakeholders from the pharmaceutical ecosystem and the local recycling authorities.

   Level and intensity of care: Made for pharmacists, patients, and informal caregivers, the innovation is used outside of a healthcare facility.

   Frugality:

   - *Affordability*: The vials are 20% less expensive than conventional models.
   - *Optimized functionality*: The eco-friendly model does not require a separate cap.

   Eco-responsibility:

   - *Raw material sourcing*: The vials contain up to 35% less plastic than conventional vials.
   - *Manufacturing*: The production process generates up to 100 times less carbon dioxide (CO_2).
   - *Distribution*: The vials are packaged in boxes without plastic bags.
   - *Disposal*: The vials are 100% recyclable.

conventional design practices in the drug distribution and retail ecosystem. It therefore sets a new path for future innovations in this field.

Finding the synergies and tensions that occur between the responsibility objectives you and your team have set for your innovation will help you make informed strategic design decisions on the trade-offs and compromises that will align your project toward a targeted overall degree of responsibility.

Once your project is finalized and the innovation is made available to end users, the RIH Assessment Tool presented in the following chapter will help to evaluate the overall degree of responsibility of your innovation in an objective, systematic, and rigorous manner.

SUMMARY POINTS

Box 7.4   Chapter 7 Summary Points

- Depending on the particularities of your project, some responsibility objectives may be achievable in tandem, while others may conflict with one another.
- Synergies between responsibility objectives can help to fulfill several RIH attributes simultaneously.
- When tensions occur between responsibility objectives, other RIH attributes may be leveraged to identify potential trade-offs and maintain an overall degree of responsibility.
- Innovations that only fulfill a few RIH attributes can still help to set new paths for future responsible innovations.

REFERENCES

Rivard, L., Lehoux, P., & Alami, H. (2020a). 'It's not just hacking for the sake of it': A qualitative study of health innovators' views on patient-driven open innovations, quality and safety. *BMJ Quality & Safety, 30*(9). https://doi.org/10.1136/bmjqs-2020-011254

Rivard, L., Lehoux, P., & Miller, F. A. (2020b). Double burden or single duty to care? Health innovators' perspectives on environmental considerations in health innovation design. *BMJ Innovations, 6*, 4–9. https://doi.org/10.1136/bmjinnov-2019-000348

Assessing the Degree of Responsibility of a Health Innovation

Abstract This chapter describes how the Responsible Innovation in Health (RIH) Assessment Tool supports a rigorous assessment of a health innovation's degree of responsibility. We begin by explaining why we developed this tool and how it differs from existing Responsible Research and Innovation (RRI) evaluation tools. We summarize the stepwise process of its development where the validity of its constructs was established with international experts in RRI, health technology assessment, engineering, and bioethics, and the reliability of its results thoroughly measured. Then we explain how to correctly use the RIH Assessment Tool within a formal evaluation process and how to interpret its results. After discussing findings from the application of the Tool to a cohort of 16 enterprises in Canada and Brazil, we describe how it can be used to inform decisions at an early stage in the development of a wide range of health and social care solutions.

Keywords Responsible Health Innovation • Responsible Research and Innovation • Health Technology Assessment • Responsibility Measurement • Responsibility Scorecard • Corporate Social Responsibility

Measuring the Degree of Responsibility of Health Innovations

In Part I of the book, we invited readers to work with the RIH attributes and their corresponding rating scales to generate a health innovation idea (Chap. 3), develop a responsible venture (Chap. 4), and design a responsible solution (Chap. 5), as these tangible four-level scales can inform creative reflections to increase the innovation's degree of responsibility. In Part II, we provided an example of how innovators and entrepreneurs can work with the attributes' rating scales, where we described a study with health innovation researchers and practitioners who conceptually *redesigned* an existing wearable robotic exoskeleton to increase its degree of responsibility (Chap. 6). Readers were then invited to apply existing tools and approaches that can be leveraged to fulfill RIH attributes, while attention was given to potential synergies and tensions between their responsibility objectives (Chap. 7).

In this last chapter of Part II, we focus on the next step in the RIH pathway, which is to assess the overall degree of responsibility of a health innovation by applying the RIH Assessment Tool in a rigorous manner. Comprising the nine RIH attributes discussed so far, this Tool supports an evidence-informed judgment to distinguish innovations that possess key responsibility features from those with no particular signs of responsibility. While the latter are not necessarily considered "irresponsible," the former are by design more likely to generate greater social, economic, and environmental value (Silva et al., 2021).

The RIH Assessment Tool: Its Premises, Validity, and Reliability

In 2015, confronted with the question of how we should assess whether a given health innovation is responsible, we performed a comprehensive search of RRI evaluation tools. We found that the efforts made by the RRI community to support the implementation of RRI principles were diversified and substantial, but the RRI tools available for innovators and entrepreneurs suffered from a lack of studies on their validity, reliability, and applicability. Furthermore, these tools typically adopted a *formative* evaluation approach that primarily aims to foster *internal* reflections, learning, and/or ongoing improvement processes within an organization or a team of innovators (Flipse & Yaghmaei, 2018; Jarmai et al., 2020; Kuhlmann et al., 2016).

Such a formative approach largely relies on self-reflective tools with open-ended questions that may not provide innovators and entrepreneurs with clear practical guidance. In addition, it produces results that are not meant to be publicly disclosed. The tools that include measurable indicators often emphasize self-assessed indicators, that is, data generated by and for each organization's or team's own purposes (Lehoux et al., 2020). One key problem with this approach is that it cannot generate a solid, comparable, and openly accessible empirical basis allowing scholars and practitioners to assess how, in practice, different innovations integrate responsibility considerations.

Seeking to bridge this gap, we developed and validated the RIH Assessment Tool, which adopts a *summative* evaluation approach that primarily aims to measure in a transparent manner the extent to which a health innovation fulfills the nine RIH attributes (Silva et al., 2021). Informed by a set of guiding principles (Box 8.1), the RIH Assessment Tool entails an *external* evidence-informed evaluation process. An external evaluation is performed by individuals who do not hold a stake in the innovation being assessed. Such an evaluation approach is widely used and valued in the healthcare sector. To increase objectivity, the application of the RIH Assessment Tool relies on scientific studies and publicly available documents. To increase transparency, its scoring system supports an accountable reporting of the results.

Box 8.1   RIH Assessment Tool Guiding Principles
RIH Tool guiding principles

- Consistent with current knowledge;
- Able to discriminate what is and what is not RIH at an early stage;
- Easy to understand;
- Easy to apply by people who possess research skills;
- Transparent, valid, reliable, and accountable;
- Applicable to a broad spectrum of health and social care solutions;
- Freely available and usable with proper academic citation.

Source: Adapted from (Silva et al., 2018)

To develop the Tool, we adopted an iterative stepwise process that combined conceptual and empirical research activities conducted at an international level (Silva et al., 2021):

- A review of the scientific literature on RRI to identify the key concepts, dimensions, and indicators that could apply to RIH
- A review of the health services and policy research literature and bodies of knowledge relevant to health innovations (e.g., health technology assessment, ethical, legal, and social issues [ELSIs], determinants of health, health economics, medical device industry)
- A web-based horizon scanning to identify the various responsibility features of a large set of existing health and social care innovations
- A pre-test of preliminary versions of the tool with graduate students in public health and biomedical engineering as well as feedback from health innovation scholars and practitioners

These iterative efforts to develop the Tool's constructs and measures led us to clarify important premises that condition how we understand and approach responsibility in health innovation, that is, with an emphasis on health equity and health system sustainability:

1. *The Tool adopts a population health perspective*. Although an innovation that provides individual health benefits is valuable, RIH should first and foremost increase our ability to attend to collective needs and challenges.
2. *The overall responsibility of a given innovation is intimately linked to how and where it is used*. This means that the degree of responsibility of an innovation must be appraised in view of its context of use, which includes infrastructures; human resources; ethical and legal frameworks; and financial, geographical, and/or cultural barriers to health and social care.
3. *The Tool was not designed to assess an innovation against a standard option* (e.g., gold standard) because such a comparator may not exist. However, it generates an overall RIH score that may be used to compare the respective value of different innovations.
4. *The Tool is meant to be used when an innovation can be made available for use in the region where its intended users are located*. A number of aspects may still be unknown at this stage (e.g., reimbursement by third-party payers, long-term effects), but effectiveness and safety

studies are more likely to have been conducted. As explained below, one of our screening criteria posits that if an innovation's effectiveness and safety have not been demonstrated, there is little point in applying the Tool because safety and effectiveness are prerequisites to RIH.

5. *Because the Tool provides evidence-informed results, it must be applied by individuals who possess research skills and are able to retrieve and critically read scientific literature.* We suggest the following requirements: (a) holding formal training in an applied discipline with a focus in health and social care; (b) experience working within an interdisciplinary research team; and (c) having access to relevant bibliographic databases and search engines for retrieving scientific peer-reviewed journals.

Construct Validity of the RIH Tool

To ensure the *construct validity* of the RIH Tool, that is, whether its criteria, attributes, and scales are adequately defined (i.e., in congruence with current knowledge) and whether these components do capture the concepts proposed to measure responsibility in health innovation, we conducted a two-round Delphi study with international experts in RRI, health technology assessment, biomedical engineering, and bioethics. The Delphi method is a group facilitation technique designed to anonymously gather the opinions of experts and iteratively establish consensus "in the face of complex problems, expensive endeavours, and uncertain outcomes" (Grime & Wright, 2016). The four expert groups we recruited were well positioned to critically appraise a preliminary version of the Tool and provide insightful suggestions to improve its construct validity. They shared more than 300 comments and consensus was achieved for 80% of the survey questions after the second Delphi round. This work confirmed the importance, clarity, and appropriateness of the Tool's criteria, attributes, and scales (Silva et al., 2018).

Reliability of the RIH Tool

To ensure that the RIH Tool provides consistent results when applied by different evaluators to the same set of innovations, we conducted an inter-rater reliability assessment study where two raters applied the Tool to a

diversified sample of health innovations (n = 25) (Silva et al., 2021). Innovations included diagnostic tests, medical devices, therapeutic procedures, digital solutions, and mobile care units. We used three reliability measures to determine agreement between raters (percentage of agreement, Gwet's coefficient, and Pearson's *r*), while the strength of the agreement was interpreted using an established benchmark scale (Landis & Koch, 1977). Findings were statistically significant and provided strong evidence that the Tool is reliable:

- A complete agreement (100%) was observed for all four screening criteria (described further).
- An "almost perfect" agreement was obtained for seven attributes and the overall RIH score (ranging from 0.81 to 0.96).
- A "substantial" agreement was achieved for two attributes (0.63 for Health inequalities, and 0.74 for Inclusiveness).

We summarize how the RIH Tool should be applied to rigorously assess the degree of responsibility of health innovations. To facilitate the application of the Tool, we developed an online User Guide that includes supporting material and examples to illustrate each attribute. We strongly suggest reading the User Guide before applying the Tool because one has to search for and assemble specific sources of information on the innovation that is to be assessed. The User Guide, as well as a video that introduces the RIH framework and tool, is freely available in English, Portuguese, and French (see websites listed at the end of this chapter).

Applying the RIH Assessment Tool: A Three-Step Evidence-Informed Process

The RIH Tool is an eight-page document accessible as a free supplementary material to a peer-reviewed article we published and it was developed to be applied by individuals who possess research skills and have access to scientific literature databases (Silva et al., 2021). Box 8.2 illustrates the overall structure of the Tool using the Inclusiveness attribute as an example. First, we define the attribute and explain why it is important for RIH. Then, we indicate potential sources of information that can be used for assessing this attribute and present the scale that is specific to the attribute.

Box 8.2   The Structure of the RIH Assessment Tool
Attribute definition and rationale
Inclusiveness: Refers to the degree of stakeholder engagement in the design, development, and pilot stages of an innovation. Different methods (e.g., codesign, interviews, citizen juries, focus groups, workshops, pilot testing, user assessment, feedback) can be used to engage different types of stakeholder (e.g., health and social care practitioners, decision makers, patients, relatives, community, society representatives).

Involving at an early stage, a diverse and relevant set of stakeholders through an accountable method is likely to improve an innovation. Hence, RIH makes explicit the rationale and scope of the stakeholder engagement process and its impact on the innovation design and delivery.

Potential information sources for the assessment

- Type 1 information describing who was involved, why, how, when, and with what impact.
- Type 2 or Type 3 information analyzing who was involved, why, how, when, and with what impact.

Four-level scale
Those who developed the innovation (*only one option should be selected in light of the available information*):

A. Engaged a diverse and relevant set of stakeholders through a formal method and explained how their input was integrated in the design process.
B. Engaged a diverse and relevant set of stakeholders through a formal method, but did not explain how their input was integrated in the design process.
C. Either engaged a limited set of stakeholders or did not explain the method used.
D. Did not engage stakeholders.

The RIH Tool does not assign the same quality value to all types of information sources. Because independent organizations and peer-reviewed publications are more likely to be objective in their reporting, they are classified as being of better quality for the Tool's assessment purposes:

- **Type 1. Low quality** (1 point): Technical documentation made available by the organization that produces the innovation. Although newspaper articles, social media, and blog posts fall within this category, they are not recommended.
- **Type 2. Moderate quality** (2 points): Reports by multilateral organizations, governments, regulatory agencies, certification bodies or independent not-for-profit organizations that monitor and report on human and labor rights, animal welfare, and environmental regulation.
- **Type 3. High quality** (3 points): Peer-reviewed scientific articles and systematic reviews of the scientific literature, including health technology assessments and Cochrane reviews.

Figure 8.1 summarizes the three-step application process of the RIH Assessment Tool.

The first step is to screen the innovation using four dichotomous (yes/no) inclusion and exclusion criteria to quickly identify whether it may potentially qualify as a responsible health innovation and therefore worth evaluating. The inclusion criteria select *novel solutions* that *safely and effectively address a determinant of health*. The exclusion criteria exclude innovations that are *not available* to intended users or that are produced by

Fig. 8.1 The three-step process of the RIH Assessment Tool

organizations involved in *irresponsible corporate actions*. For example, if credible public sources indicate that the organization producing the innovation has committed illegal corporate actions that can harm people, animals, or the environment, the innovation is excluded from the assessment. This exclusion criterion derives from the fact that RIH applies to both the innovation and the organization.

The second step assesses the presence of responsibility features through the nine RIH attributes described in Chaps. 3, 4, and 5. As you recall, each attribute comes with a four-level scale, ranging from A to D. The assessment of each attribute assigns a number of points to each level of the scale as follows:

A. High degree of responsibility: 5 points
B. Moderate degree of responsibility: 4 points
C. Low degree of responsibility: 2 points
D. No particular signs of responsibility: 1 point

The third step rates the availability and the quality of the information sources used to score each attribute, and the presence of RIH features. A scorecard (Fig. 8.2) is used to report this information as well as extracts from sources that justify the score of each attribute.

Value domains & Attributes	Availability & Quality of information sources				Assessment of the attributes			
	Available?	High 3 pts	Moderate 2 pts	Low 1 pt	A 5 pts	B 4 pts	C 2 pts	D 1 pt
Population health value								
1. Health relevance	☐	③	②	①	⑤	④	②	①
2. EL&S issues	☐	③	②	①	⑤	④	②	①
3. Health inequalities	☐	③	②	①	⑤	④	②	①
Health system value								
4. Inclusiveness	☐	③	②	①	⑤	④	②	①
5. Responsiveness	☐	③	②	①	⑤	④	②	①
6. Level and intensity of care	☐	③	②	①	⑤	④	②	①
Economic value								
7. Frugality	☐	③	②	①	⑤	④	②	①
Organisational value								
8. Business model	☐	③	②	①	⑤	④	②	①
Environmental value								
9. Eco-responsibility	☐	③	②	①	⑤	④	②	①
Number of attributes documented:		Quality mean score:			RIH features mean score:			

Interpretation	Interpretation	Interpretation
≥ 7/9 →Covers key aspects of RIH < 7/9 →Compromised by missing information	≥ 2 → Based on superior quality sources < 2 → Compromised by inferior quality sources	4.1-5.0: Almost all RIH features are present 3.1-4.0: Many RIH features are present 2.1-3.0: Few RIH features are present 1.0-2.0: Almost no RIH features are present
When one of the above two requirements is not met, the overall score is not meaningful		

Fig. 8.2   The RIH Tool scorecard

Evaluators should report (1) the number of attributes with available information, (2) the mean score of the quality of the sources used to perform the assessment (if more than one type of sources is used to score an attribute, the source of highest quality is reported), and (3) the mean score of the responsibility features. To facilitate the application of the Tool, we developed an Excel version of the scorecard programmed with automatic calculations (see the websites listed at the end of this chapter). Detailed instructions on how to fill in the scorecard are explained in the file.

Overall RIH Score and Its Conservative Interpretation

Because health innovations are multifaceted and value-laden, it is important that the RIH Tool be applied by an interdisciplinary team. We recommend that the team be composed of a minimum of two evaluators and a maximum of five. Team members should independently judge each criterion and attribute in light of the available information. This implies that no one should speculate about the characteristics of the innovation, how it was developed or the quality of the organization that brings it to end users. In addition, the information sources used should reflect the region where users are located. If differences in individual scores occur, team members should deliberate to resolve differences and establish the innovation's final overall score in light of the available evidence.

The overall RIH score of the innovation is determined by calculating the mean value of the points obtained, that is, the sum of the points obtained for each attribute divided by the number of attributes with available information. The overall RIH score ranges from 1.0 to 5.0 and its interpretation relies on a four-level interval rating that follows the logic of the scale used to assess the degree of responsibility for each attribute (ranging from 1 point to 5 points). The intervals are as follows:

- 4.1–5.0: Almost all RIH features are present
- 3.1–4.0: Many RIH features are present
- 2.1–3.0: Few RIH features are present
- 1.0–2.0: Almost no RIH features are present

Then, to determine whether the overall RIH score is meaningful, two results must be considered concurrently. First, the assessment must be conducted on at least seven of the nine attributes to cover key aspects of

RIH. When the number of attributes documented is less than seven, the assessment is compromised by missing information. Second, the assessment must be based on information sources that are of superior quality. When the quality mean score is inferior to 2.0, the assessment is compromised by information sources of inferior quality.

Thus, as Fig. 8.3 shows, the RIH Tool comes with a conservative interpretation rule: the overall RIH score is considered meaningful *only* if the assessment relies on ≥7/9 documented attributes *and* information sources with a mean score ≥2 points.

By applying such a conservative interpretation rule, evaluators will avoid either over- or under-rating the responsibility of the innovation. In
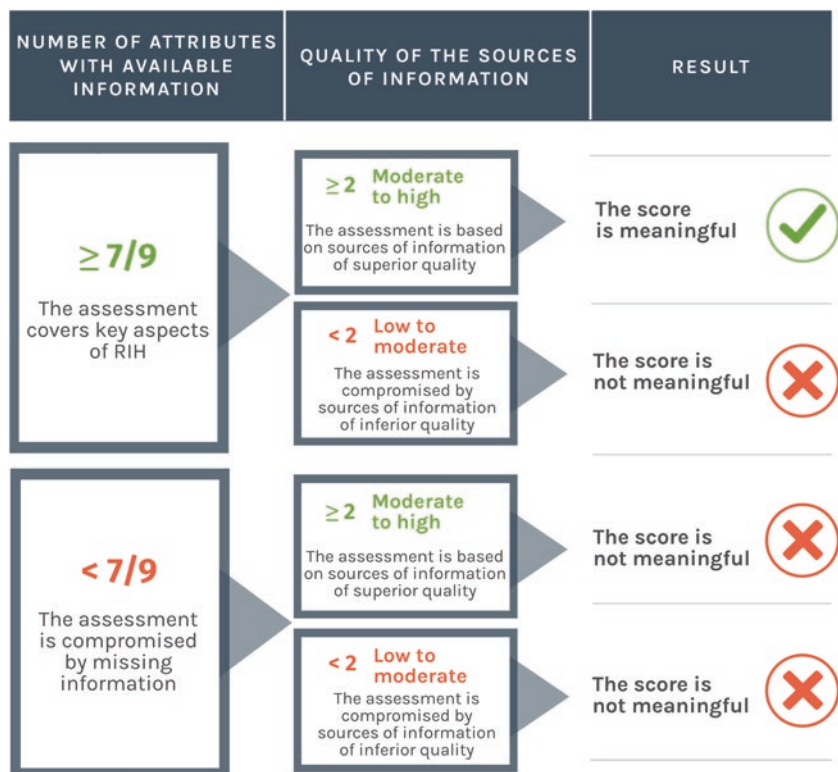

Fig. 8.3 Conditions for the overall RIH score to be considered meaningful

the long run, researchers should be encouraged to generate additional evidence and entrepreneurs to report information that covers all nine RIH attributes (Lehoux et al., 2020).

FINDINGS FROM THE APPLICATION OF THE RIH TOOL TO A DIVERSIFIED SAMPLE

As part of a longitudinal case study started in 2017, we applied the RIH Tool to a sample of 16 small and medium-sized enterprises (SMEs) that produce responsible health innovations in different regions of Brazil and Canada (Lehoux et al., 2020). The goal of the case study is to better understand why and how SMEs can develop and bring to market responsible health innovations. The application of the RIH Tool to this sample is instructive because of its diversity. It includes both for-profit and not-for-profit organizations that developed different types of innovation (e.g., diagnostic tools, assistive devices, community-based solutions, patient-oriented tools, artificial intelligence-based and digital solutions).

Findings from the application of the RIH Tool are summarized in Table 8.1. More than half of the innovations obtained an "A" for five attributes. This result confirms the feasibility of simultaneously achieving the highest level of the scale for several attributes. However, more than half of the sample received a "C" for (1) Ethical, legal, and social issues (ELSIs) and (2) Inclusiveness. According to the publicly available information we gathered, means to mitigate ELSIs were only available for a few

Table 8.1   RIH scores obtained by a sample of 16 SMEs

Assessment step	A	B	C	D	N	Mean score
Responsiveness	12 (86%)	0 (0%)	1 (7%)	1 (7%)	14	4.5
Health relevance	13 (81%)	0 (0%)	1 (6%)	2 (13%)	16	4.3
Frugality	8 (50%)	6 (38%)	2 (13%)	0 (0%)	15	4.3
Level & intensity of care	11 (73%)	0 (0%)	4 (27%)	0 (0%)	15	4.2
Health inequalities	7 (54%)	4 (31%)	2 (15%)	0 (0%)	13	4.2
Eco-responsibility	2 (40%)	1 (20%)	2 (40%)	0 (0%)	5	3.6
Business model	6 (38%)	3 (19%)	5 (31%)	2 (13%)	16	3.4
ELSIs	1 (7%)	3 (20%)	11 (73%)	0 (0%)	15	2.6
Inclusiveness	2 (14%)	2 (14%)	9 (64%)	1 (7%)	14	2.6
Rating step	4.1–5.0	3.1–4.0	2.1–3.0	1.0–2.0	N	Mean score
Interval/mean	5 (31%)	8 (50%)	3 (19%)	0 (0%)	16	3.8

Source: Adapted from Lehoux et al. (2020)

issues and entrepreneurs either engaged a limited set of stakeholders or did not explain the method used to do so.

When interviewing the entrepreneurs, we came to understand that the scope of the ELSIs they addressed varied according to their understanding of the practical ethical, legal, or regulatory tools available in health and social care to mitigate ELSIs. The fact that seven innovations among our sample targeted vulnerable groups also increased the challenge of securing means to mitigate several or all applicable ELSIs, as is required to obtain a "B" or an "A" on the rating scale. For the Inclusiveness attribute, though several entrepreneurs did work collaboratively with users, communities, and partners, their methods of engagement were not always fully described in publicly available documentation, as is required to obtain a higher score on the scale.

Lastly, as highlighted in Table 8.1, information on the Eco-responsibility attribute was available for only 5 of the 16 innovations. This signals a pressing need for more studies on the environmental impact of health technologies.

Using the RIH Assessment Tool to Inform Decisions and Practices

The RIH Assessment Tool can support decisions of a variety of innovation stakeholders who influence either the emergence of health innovations, such as entrepreneurs, investors, engineers, or digital technology developers, or their adoption, such as regulators, clinicians, patients, or healthcare managers (Silva et al., 2021). The Tool may in fact inform practices both at an early or later stage in the development of health and social care solutions.

For instance, Technology Transfer Offices (TTOs) that seek to match, at an early stage, academic research discoveries that have commercial potential with investors and entrepreneurs who can further develop and bring to market a new product based on these findings can use the Tool to increase responsibility. Within such a university–industry collaboration, the RIH Tool will broaden the basis upon which decisions are made. TTOs could expand their outreach efforts to entrepreneurs who pursue a social and/or environmental mission and aim to address health and social care needs in a sustainable and equitable way. The Tool also provides research funders with operational definitions of responsibility features to include in calls for research-oriented proposals. This practice is already adopted by research funding agencies concerned with the integrity and societal benefits of the research they support (Davis & Laas, 2014).

If applied at a later stage to guide the adoption of more mature technologies, the RIH Tool can support a value-based approach in procurement processes. Here, the aim would be to broaden how value is defined by considering economic and environmental impacts, social preferences, and suppliers' business practices (Miller et al., 2019). Lastly, the Tool could be used to foster productive discussions among clinicians, patients, informal caregivers, and health and social care managers on the priorities that the health system should pursue at the regional and local levels.

Summary Points

Box 8.3   Chapter 8 Summary Points

- The RIH Assessment Tool was developed to rigorously assess the degree of responsibility of health innovations in a transparent and accountable manner.
- The formal application of the RIH Tool requires research skills because it adopts an evidence-informed assessment approach.
- It should be applied by an interdisciplinary team comprising two to five evaluators who first independently score each attribute and then reach consensus in light of the available information.
- The overall RIH score measures the presence of responsibility features and should be interpreted in view of the number of attributes documented and of the quality of information sources used to assess the innovation.
- Results of the RIH Tool can inform the decisions of key innovation stakeholders, at an early or later stage in the development of health and social care innovations.

Websites Mentioned in the Chapter

The RIH Assessment Tool

- English version: https://bit.ly/2WsJlMt
- French version: https://bit.ly/3DZEyDv
- Portuguese version: https://bit.ly/2X9SqdC

User Guide

- English version: https://bit.ly/3gJZbcL
- French version: https://bit.ly/2XaO0Dl
- Portuguese version: https://bit.ly/3E2wYI9

Video introducing Responsible Innovation in Health

- English version: https://youtu.be/aaY2vMBnEC0
- French version: https://youtu.be/nmUboDPUtRc
- Portuguese version: https://youtu.be/2EIDN7perBM

Excel version of the scorecard

- English version: https://bit.ly/3hhAeG1
- French version: https://bit.ly/2YyhIT8
- Portuguese version: https://bit.ly/3E2k0ug

References

Davis, M., & Laas, K. (2014). 'Broader impacts' or 'responsible research and innovation'? A comparison of two criteria for funding research in science and engineering. *Science and Engineering Ethics, 20*(4), 963–983. https://doi.org/10.1007/s11948-013-9480-1

Flipse, S. M., & Yaghmaei, E. (2018). The value of 'measuring' RRI performance in industry. In F. Ferri (Ed.), *Governance and sustainability of responsible research and innovation processes*. SpringerBriefs in Research and Innovation Governance.

Grime, M. M., & Wright, G. (2016). *Delphi method*. Wiley StatsRef: Statistics Reference Online, 1–6. https://doi.org/10.1002/9781118445112.stat07879

Jarmai, K., Tharani, A., & Nwafor, C. (2020). Responsible innovation in business. In K. Jarmai (Ed.), *Responsible innovation* (pp. 7–17). Springer.

Kuhlmann, S., Edler, J., Ordóñez-Matamoros, G., Randles, S., Walhout, B., Gough, C., & Lindner, R. (2016). Responsibility navigator. Retrieved from Karlsruhe, Germany. https://responsibility-navigator.eu/

Landis, J., & Koch, G. (1977). The measurement of observer agreement for categorical data. *Biometrics, 33*(1), 159–174.

Lehoux, P., Silva, H. P., Oliveira, R. R., & Rivard, L. (2020). The responsible innovation in health tool and the need to reconcile formative and summative ends in RRI tools for business. *Journal of Responsible Innovation, 7*(3), 646–671. https://doi.org/10.1080/23299460.2020.1844974

Miller, F. A., Lehoux, P., Peacock, S., Rac, V. E., Neukomm, J., Barg, C., … Krahn, M. (2019). How procurement judges the value of medical technologies: A review of healthcare enders. *International Journal of Technology Assessment in Health Care, 35*(1), 50–55. https://doi.org/10.1017/S0266462318003756

Silva, H. P., Lehoux, P., & Hagemeister, N. (2018). Developing a tool to assess responsibility in health innovation: Results from an international Delphi study. *Health Policy and Technology, 7*(4), 388–396.

Silva, H. P., Lefebvre, A.-A., Oliveira, R. R., & Lehoux, P. (2021). Fostering responsible innovation in health: An evidence-informed assessment tool for innovation stakeholders. *International Journal of Health Policy and Management, 10*(4), 181–191. https://doi.org/10.34172/ijhpm.2020.34

A Sustainable Path for RIH

In this last part of the book, readers are invited to envision RIH within the broader innovation ecosystem where innovation managers can directly support responsible health and social care initiatives and where both health policymakers and innovation policymakers must create a sustainable path for RIH. The following chapters examine how leaders of what we call "intermediating platforms" (e.g., innovation hubs, technology transfer offices, accelerators) can orchestrate RIH (Chap. 9), what obstacles are to be expected along the RIH path, and what drivers can be leveraged (Chap. 10). The take-home message is that RIH cannot solely result from individual responsible innovators' efforts: trailblazing innovation managers, health and social care managers, and other stakeholders should together boldly forge a rewarding twenty-first-century health innovation pathway (Chap. 11).

Orchestrating RIH

Abstract This chapter reviews the ways in which "intermediating platforms" (innovation hubs, incubators, accelerators, living labs, and technology transfer offices) can orchestrate Responsible Innovation in Health (RIH) by working with the concepts and tools described in Parts I and II of the book. We turn our attention to the key role played by innovation managers and the way they can better support responsible innovators. Like a maestro conducting an orchestra, we envision the role of those who lead and manage intermediating platforms as coordinating the work of diverse stakeholders to bring RIH to life. Toward this end, we begin by describing how such platforms can grow and nurture RIH projects. Then, through a stepwise approach that is informed by our research in Quebec, Ontario, and Brazil, we propose a series of activities for platform leaders and innovation managers that link directly to the concepts and tools presented in each chapter. These activities can serve as their maestro baton as they guide responsible entrepreneurs along a new "partition" that will create a sustainable RIH pathway.

Keywords Responsible Innovation Management • Innovation Ecosystem • Incubators • Accelerators • Health Innovation Pathway • Responsible Entrepreneurship

The Role of Intermediating Platforms in Growing and Nurturing RIH

In the past decades, several types of "intermediating platforms" have been created across different industry sectors to foster innovation, including innovation hubs, incubators, accelerators, living labs, and technology transfer offices (TTO) (Galbraith et al., 2019). Though they operate under different names, they all seek to provoke interactions through which innovative projects are competently and creatively brainstormed, structured, and eventually brought to market. Most of them explicitly bring together academia and the private sector.

Intermediating platforms do not operate according to a single, clear-cut model because they are accountable to different sponsors (e.g., universities, governments, industry, philanthropic foundations) (Hausberg & Korreck, 2020). For instance, the MaRS Discovery District, the largest innovation hub in North America, was created by Canadian civic leaders who donated CAD 14 million and gathered additional support from private firms, governments, and the University of Toronto. For Ansell and Gash (2018), platforms "facilitate the interaction of different skills, resources, knowledge or needs" by soliciting the contribution of independent stakeholders. They intermediate between local-, regional- or national-level initiatives to orchestrate "many-to-many" interactions (Ansell & Gash, 2018). They may possess the general or health sector-specific expertise and follow a more traditional market approach to innovation or a socially oriented one, such as Yunus Social Business, cofounded decades ago by Nobel Peace Prize Laureate Prof. Muhammad Yunus.

Platforms in top-ranking universities seek to create vibrant spaces for researchers, trainees, and non-academic partners from a variety of fields to come together in more dynamic ways (Galbraith et al., 2019). Reputed examples include the Stanford Byers Centre for Biodesign in the US or the Innovation & Entrepreneurship Lab (ieLab) of the Swiss Federal Institute of Technology, ETH Zürich. These platforms enable universities to attract impactful industrial partners, enroll brilliant students, and recruit high-caliber researchers. University provosts thus keep an eye on what other institutions do to innovate and, as Chap. 1 underscored, responsible innovation is a core component of a well-thought-out twenty-first-century innovation agenda. The health and social care sector is particularly cherished by these intermediating platforms because of its alignment with the "knowledge for society" mission of universities (Page et al., 2018).

Intermediating platforms are ideally positioned to orchestrate the work of multiple health innovation stakeholders along the RIH pathway. Nonetheless, innovation in health and social care raises distinct responsibility issues and calls for business expertise adapted to RIH-oriented entrepreneurs. These entrepreneurs make great strides to address persistent health inequalities, deliver safe, affordable, easy to use, high-quality products, and reduce the environmental footprint of their solution. To do so, they can operate on a for-profit or a not-for-profit basis or combine both logics to sustain their operations (Saebi et al., 2019). As seen in Chap. 4, responsible business models strive to bring more value not only to users and purchasers but also to society (e.g., holding a B Corp Certification, having a pricing scheme based on ability to pay, employing individuals with particular needs). Thus, the values and long-term purposes of responsible entrepreneurs may not align with all intermediating platforms.

A growing number of platforms describe themselves as socially oriented because they explicitly choose to provide support to entrepreneurs addressing social and environmental challenges (Sansone et al., 2020). These platforms welcome entrepreneurs who set in place inclusive innovation development processes as well as collaborative business approaches. Such transparency and openness may not be valued by intermediating platforms with a traditional market approach that prioritizes intellectual property and profitability. Collaborative design strategies do, however, fit perfectly with platforms that aim to develop twenty-first-century solutions to twenty-first-century problems (see Box 9.1).

Box 9.1 Examples of Intermediating Platforms for Twenty-First-Century Solutions

The Center for Technosocial Innovation, Université de Montréal, Canada:

- Inven_T's mission is to provide creative solutions to social problems. Solutions are codesigned, right from the start, with local partners and a broad community of end users.
- Inven_T grants start-up funding and offers personalized support services, from ideation to the implementation of a novel product, organization, or service.

Box 9.1   (**continued**)

Project Raphael, Bar-Ilan University, Israel:

- Initiated by the Azrieli Faculty of Medicine, this social incubator's mission is to improve health in disadvantaged regions by creating academic-community partnerships.
- It enables the local community and health and social care organizations to define what they see as the most pressing problems and to develop creative solutions.

Accelerate2030, Switzerland:

- Initiated and led by Impact Hub in Geneva, this scaling program connects entrepreneurship to the United Nations' Sustainable Development Goals (SDGs) while promoting a sustainable business approach.
- It helps entrepreneurs to develop their partnerships and measure their impact in more than 20 locations in Africa, Asia, Eastern Europe, and Latin America.

Intermediating platforms typically possess the innovation management expertise required to orchestrate the resources responsible entrepreneurs need from innovation system stakeholders. These include tangible and intangible resources that can help responsible innovators establish and grow a business. Tangible resources refer to concrete support such as temporary workspace, access to health and social care settings, equipment, or legal and administrative services. Intangible resources refer to support that is mostly obtained through social exchanges such as mentoring, coaching, or networking (Hausberg & Korreck, 2020). In practice, responsible innovators often need both kinds of resources, and the latter must be adapted to their entrepreneurial journey (Silva et al., 2022).

SUPPORTING RESPONSIBLE INNOVATORS ALONG THEIR ENTREPRENEURIAL JOURNEY

Despite the growing literature on intermediating platforms, what benefits innovators derive in practice from their support remains poorly documented and this is especially true for those in the health sector (Page et al., 2018). A number of studies suggest that intermediating platforms improve

the innovation and business performance of start-ups (Sedita et al., 2018), but others indicate that their support does not influence the growth and survival of these emerging enterprises (Lukeš et al., 2019). Such diverging results are partly due to the different ways in which researchers measure their impact and performance (Hausberg & Korreck, 2020).

In our own research, we observed that the support obtained by 14 small and medium-sized enterprises (SMEs) engaged in the production of RIH in Quebec, Ontario, and Sao Paulo varied according to their legal structure (Silva et al., 2022). Within our sample, eight for-profit organizations more frequently obtained support from platforms with a traditional orientation (75%) than from socially oriented platforms (25%). The reverse holds for six not-for-profits that more frequently obtained support from socially oriented platforms (65%) than from traditional ones (35%). We also observed that not-for-profits did not obtain support before reaching a late-stage venture maturity (i.e., when having reached a stable growth rate). In contrast, for-profits were supported at earlier stages and often for successive stages in their journey.

These findings have practical implications because of the "domino effect" at play: entrepreneurs who obtain early support are more likely to get visibility, build confidence, develop their network, and consolidate their business plan (Sedita et al., 2018). They are then in a better position to obtain further support from other sources.

Our study also examined entrepreneurs' views on the support obtained from intermediating platforms. Several appreciated their business expertise, especially those who were "trained scientists" and had "to learn how to structure a business model" (anonymized respondent from Sao Paulo: N-SP) (Silva et al., 2022). For another entrepreneur, it had "been extremely helpful from day one and continues to be" because there is a lot to learn when "you're such a small company" and "you're doing many things for the first time" (E-ON).

Criticisms were also shared. Several intermediating platforms were perceived as not interested in supporting not-for-profits or as having a poor understanding of non-traditional innovation. For instance, an entrepreneur sought help from many platforms but "most of them declined" because they only support profit-oriented start-ups (J-SP). Another one "got squeezed out pretty quickly" of a platform because its innovation managers "didn't see the economic potential" of her innovation (H-QC). Likewise, another platform was "very focused on selling the product" and "didn't want" to support entrepreneurs who were rather "selling the

action" of co-building eco-responsible lighting systems for communities without electricity access (Q-SP).

After such mismatches, a number of entrepreneurs received support from socially oriented platforms, which had positive impacts on their journey. For instance, they learned about "social impact modelling" (C-QC), became part of a lively "B Corp community" (E-ON), or discovered a platform that was "the place to be" because it "put the social change above the business model":

> Through the program, you learn that you need each of them to make it work […] they focus on making you drive your social mission first and foremost. That's really important because other incubators are more like 'what's your business plan? what's your revenue model?' That's a turnoff (F-ON).

In fact, responsible entrepreneurs need business support adapted to their mission and organizational structure. For instance, a socially oriented intermediating platform taught one organization to analyze and improve its not-for-profit business model by using a SDGs-oriented framework:

> Many things from our financial and legal model are right, which gives us more confidence because we went from a non-governmental organization (NGO) that had BRL 30,000 a year to an organization that now has a budget of BRL 1 million a year. And doing all this with volunteers is scary, right? Thus, we got it, 'wow, our financial report is fine, our compliance is right.' That was really nice to see. We also picked up some other inputs about how we can improve our marketing and sales (Q-SP).

Our study suggests that responsible health entrepreneurs who lack managerial expertise should look for support from platforms at an early stage in their entrepreneurial journey (e.g., before creating their organization). Because there are key differences between traditional and socially oriented platforms, it is also important to identify several potential platforms and compare their mission and the partners with whom they work more closely (Sansone et al., 2020). As we clarify in the next section, the goal should be to increase the "harmony" between one's core entrepreneurial aspirations and the "instruments" a given platform can orchestrate within the health innovation system.

By remaining attuned to what responsible health innovators aim to achieve and the specific challenges they face as entrepreneurs, we believe

that several intermediating platforms can create the right conditions to nurture and grow RIH. For instance, intermediating platforms can adopt a cohort approach, which involves selecting a group of innovators and providing them with training activities that cover the whole innovation pathway. Being part of a hand-picked cohort of entrepreneurs stimulates emulation, that is, learning by being exposed to exemplary entrepreneurial teams who share similar aspirations and challenges. Because intermediating platforms often compete to attract the best start-ups, strategies that prompt creative encounters that would not easily happen otherwise (e.g., hackathons, investor's pitch, crowdsourcing events) are certainly well-aligned with the spirit of RIH.

How Leaders of Intermediating Platforms Can Use This Book to Forge the RIH Pathway

Health innovation development is a longsighted process that requires the artful combination of different bodies of knowledge and disciplinary skills. Intermediating platforms must deploy various strategies to foster productive collaboration between different groups. Each group brings its own "instruments," but the capacity to create RIH as a collective depends upon the "partitions" everyone will play, and the time spent "rehearsing" together. Though practice is essential, first-rate governance is what brings mastery to the process. This is why managers of intermediating platforms must develop an RIH-oriented leadership, one that purposefully orchestrates the skills, know-how, and resources of the multiple individuals called to contribute to RIH.

As Fig. 9.1 suggests, to responsibly tackle an important health problem, physicians, health and social care providers, biomedical engineers, and industrial designers need to listen to, and adjust their "scores" to those of patients and diverse social groups who will be affected by the innovation. Because health innovations increasingly include digital tools and artificial intelligence-based solutions, finding ways to "harmonize" the contributions of digital tool developers, data scientists, clinicians, healthcare managers, patients, and their informal caregivers is increasingly important. Yet, to lead a proficient "RIH orchestra," one must turn to innovation managers.

In their role as orchestrators of RIH, the task of innovation managers is two-pronged:
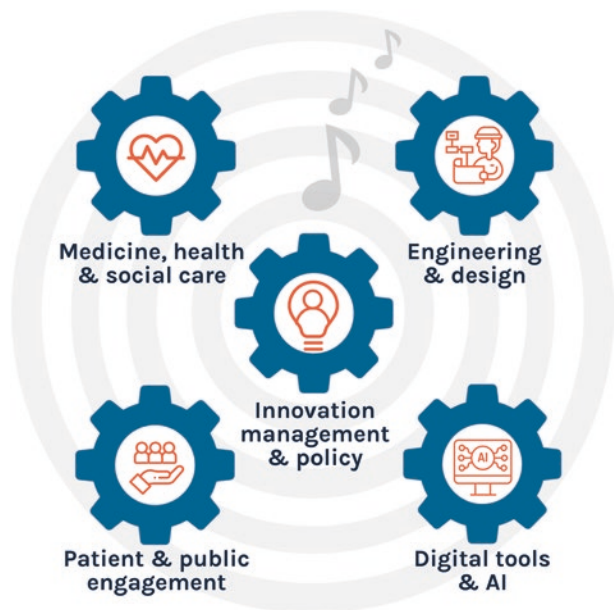
Fig. 9.1 Orchestrating the contributions of different disciplines and bodies of knowledge

- To set a new health innovation "partition" that fosters health equity and consolidates the sustainability of health systems
- To harmonize the specific contributions of multiple stakeholders

Following a stepwise process that allows for periodic evaluation, feedback, and improvement, Tables 9.1, 9.2, 9.3, and 9.4 summarize how the leaders of intermediating platforms can use the concepts and tools found in each chapter of this book to progressively embark on, and carve an RIH pathway that is adapted to their own context and means. The left column in each table offers a summary of the key concepts and tools. The right column describes corresponding activities that can be organized by innovation managers. It concisely indicates who should interact with whom, what tasks should be accomplished, how, and to what ends.

There is a progression from Tables 9.1, 9.2, 9.3, and 9.4 that will bring the innovation management team to better appraise the nature and scope of the efforts required and determine at what pace they wish to carry them

Table 9.1 How to introduce the intermediating platform to RIH concepts and tools

Chapter 1. Introduction The origins of RIH and the new path it opens for: • Taking care of our health • Strengthening health systems • Providing more value to users, purchasers, and society • Using fewer resources • Reducing environmental impacts	With the support of high-level executives, create space to fully discuss with managers and staff the opportunity to make way for RIH. In line with the SDGs and other twenty-first-century challenges, choose to engage your organization off the beaten path. Identify intersectoral collaborators who will help your organization support the development of high quality and safe health and social care innovations. Adequately convey the message that such innovations can concurrently strengthen health system, increase equity, provide more value to society, use fewer resources, be eco-responsible, and economically viable.
Chapter 2. Getting Started What is RIH • An overview of the five value domains and nine attributes of RIH • A design-thinking tool to tease out health innovators' design assumptions	Develop and set in place a variety of training activities (e.g., seminars, master classes, workshops) to introduce the key components of the RIH conceptual framework. Use concrete examples of innovations that will enable your team and attendees to clearly define the value they bring to population health and health systems, and their economic, organizational, and environmental value. Showcase health innovators who considered responsibility throughout the lifecycle of their innovation and in different geographic contexts. Use the Responsible Design Compass to help innovation teams tease out their design assumptions and better grasp RIH.

out. The overall rationale is to establish and maintain strong linkages with the RIH concepts and tools and identify the skills and competencies the innovation management team may have to secure to gradually develop a convincing portfolio of RIH projects.

As a first step, we suggest leaders of intermediating platforms adequately brief the high-level executives about the strategic role of RIH and organize activities to introduce the RIH concepts and tools to their team, collaborators, and target audiences (Table 9.1). The goal is for everyone to better grasp what RIH entails and identify who can contribute relevant expertise.

Table 9.2 How to prepare the intermediating platform to support RIH projects

Chapter 3. Generating a Responsible Health Innovation Idea	
Four RIH attributes that guide the ideation process to: • Address a relevant health problem • Provide a dynamic solution to a health system need • Reduce health inequalities • Support health system sustainability	Using projects previously supported by your organization or exemplary cases, develop material that concisely illustrates solutions that improve population health and strengthen health systems. For each example, ask participants to debate: • Why this health problem matters • What health system need is being tackled • What health inequalities are at stake • How it contributes to the sustainability of the health system
Chapter 4. Fleshing Out a Venture That Can Responsibly Tackle the Problem	
Two RIH attributes that guide the development of a responsible organization by: • Engaging relevant stakeholders • Providing more value to users, purchasers, and society	Reexamine the range of innovation stakeholders with whom your organization interacts, reach out to groups who have firsthand knowledge of health and social care issues, and devise strong collaborative processes. Make sure your team holds business expertise that is diversified and up to date on how different organizations (not-for-profits, for-profits, hybrids) deliver value to users, purchasers, and society.

Table 9.3 How to build the intermediating platform's organizational capacity for RIH

Chapter 5. Designing a Responsible Solution	
Three RIH attributes to design a responsible product, service, or digital tool that: • Delivers greater value to more people using fewer resources • Reduces its environmental footprint throughout its lifecycle • Mitigates potential negative impacts on users	To competently support entrepreneurs who will deliver twenty-first-century solutions, your organization should develop a strong command of three subject areas: • Frugal innovation and manufacturing • Sustainable product design, including for AI and digital tools • Health and social care issues from an applied social science perspective

(*continued*)

Table 9.3 (continued)

Chapter 6. Making RIH	
A multidisciplinary approach to health innovation calls for a multidisciplinary design toolbox: • Several existing tools and approaches can be leveraged to make RIH	By drawing on the RIH toolbox, your organization can establish its own list of preferred tools. While identifying tools adapted to your region, make sure to cover the following competencies: • Tools to engage with relevant stakeholders • Tools to provide more value to users, purchasers, and society • Tools to deliver greater value to more people using fewer resources • Tools to reduce the environmental footprint throughout the lifecycle • Tools to mitigate negative impacts on users

Table 9.4   How to take stock of the RIH projects supported by the intermediating platform

Chapter 7. Bringing It All Together	
Innovation teams can improve their design decisions by identifying: • Creative synergies between RIH attributes • Tensions that require further design thinking • The most compelling trade-offs in view of the overall aim of RIH	Using projects previously supported by your organization, conduct a series of redesign exercises in which your team identifies how synergies between RIH attributes can be realized and the tensions that remain hard to resolve. By contextualizing each redesign exercise, determine on what basis design decisions and trade-offs can be justified.
Chapter 8. Assessing the Degree of Responsibility of a Health Innovation	
Decisions made at an early or later stage can be rigorously informed by knowing how to: • Apply the RIH Assessment Tool • Use its results to establish priorities and steer innovative projects along an RIH pathway	Set in place a multidisciplinary committee comprising external stakeholders and apply the RIH Assessment Tool to the projects you are supporting. Synthesize the arguments through which the committee reaches consensus over discrepant scores and draw lessons to consolidate how your organization can better support RIH projects. Decide how your organization can embed the RIH Assessment Tool within its activities in a transparent and productive manner.

The second set of activities prepares the intermediating platform to embark on a more clearly defined RIH path (Table 9.2). By reconsidering previously supported innovation projects in light of the six RIH attributes described in Chaps. 3 and 4, the management team can spot missed opportunities to improve the value these projects bring to population health and health system as well as ways to better connect the core idea to the venture's structure. If such expertise is not already part of the platform's close collaborators, we suggest reaching out to individuals who have firsthand knowledge of health and social care issues and to individuals who are knowledgeable about non-traditional business models.

The third set of activities further develops the platform's organizational capacity to provide skilled guidance to responsible entrepreneurs (Table 9.3). There are three bodies of knowledge to be mastered: frugal innovation, sustainable design, and health and social care issues from an applied social science perspective. Working with the RIH toolbox (Chap. 6), the management team can search for a series of tools adapted to the region in which it operates and that can help innovators fulfill the nine RIH attributes.

As part of the final set of activities, the management team should identify in advance when it will take stock of the RIH projects it will have supported over time. Before this can be achieved, it would be wise to consolidate the team's understanding of the potential synergies and tensions between the RIH attributes (Table 9.4). We therefore suggest conducting redesign exercises with a sample of previously supported projects to clarify how the team intends to guide entrepreneurs' decisions and trade-offs. Lastly, following the three-step evaluation process described in Chapter 8, it will be possible to apply the RIH Assessment Tool to the projects supported by the platform. Both the evaluation process and its results should prove highly informative.

The overall premise of the stepwise approach described from Tables 9.1, 9.2, 9.3, and 9.4 is that intermediating platforms can competently set in place activities to nurture and grow a portfolio of RIH projects, draw lessons in due course, and realign strategies when appropriate. Hence, gathering the feedback of responsible innovators is essential and should shed light on the shifting challenges they face along their entrepreneurial journey and how intermediating platforms can help them overcome these challenges.

Addressing the challenges responsible entrepreneurs face and building a strong portfolio of RIH projects require a long-term vision that is shared

by other innovation system stakeholders as well. In the next chapter, we thus clarify why both health and social care managers and innovation policymakers must innovate to enable RIH entrepreneurs to find and work with multiple allies.

Summary Points

> **Box 9.2   Chapter 9 Summary Points**
> - RIH can be envisioned as a new "partition" for the health innovation community.
> - Intermediating platforms can grow and nurture RIH by orchestrating the knowledge, skills, and resources it requires.
> - Their leaders can carve a sustainable RIH path by translating this book's concepts and tools into a stepwise approach with frequent feedback loops, and by building RIH-oriented organizational capacity.
> - As they anticipate and address the challenges faced by responsible entrepreneurs along their journey, intermediating platforms can develop a compelling portfolio of RIH projects.

References

Ansell, C., & Gash, A. (2018). Collaborative platforms as a governance strategy. *Journal of Public Administration Research and Theory, 28*(1), 16–32.

Galbraith, B., McAdam, R., & Cross, S. E. (2019). The evolution of the incubator: Past, present, and future. *IEEE Transactions on Engineering Management*, 1–7. https://doi.org/10.1109/TEM.2019.2905297

Hausberg, J. P., & Korreck, S. (2020). Business incubators and accelerators: A co-citation analysis-based, systematic literature review. *The Journal of Technology Transfer, 45*(1), 151–176. https://doi.org/10.1007/s10961-018-9651-y

Lukeš, M., Longo, M. C., & Zouhar, J. (2019). Do business incubators really enhance entrepreneurial growth? Evidence from a large sample of innovative Italian start-ups. *Technovation, 82–83*, 25–34. https://doi.org/10.1016/j.technovation.2018.07.008

Page, W., Garbuio, M., & Wilden, R. (2018). The role of incubators and accelerators in healthcare innovation. In R. Wilden, M. Garbuio, F. Angeli, & D. Mascia (Eds.), *Healthcare Entrepreneurship* (pp. 87–106). Routledge.

Saebi, T., Foss, N. J., & Linder, S. (2019). Social entrepreneurship research: Past achievements and future promises. *Journal of Management, 45*(1), 70–95.

Sansone, G., Andreotti, P., Colombelli, A., & Landoni, P. (2020). Are social incubators different from other incubators? Evidence from Italy. *Technological Forecasting and Social Change, 158*, 120132. https://doi.org/10.1016/j.techfore.2020.120132

Sedita, S. R., Apa, R., Bassetti, T., & Grandinetti, R. (2018). Incubation matters: Measuring the effect of business incubators on the innovation performance of start-ups. *R&D Management, 49*(4), 439–454.

Silva, H. P., Lehoux, P., & Sabio, R. P. (2022). Is there a fit between incubators and ventures producing responsible innovations in health? *Health Policy and Technology*, 100624.

CHAPTER 10

Clearing Obstacles, Harnessing Drivers

Abstract This chapter explains why increasing responsibility in the health innovation industry cannot rely solely on individual innovators' shoulders. For Responsible Innovation in Health (RIH) to flourish, responsible innovators must be able to find and work with multiple allies. We thus review the drivers and obstacles that are found in the health and social care sector as well as those found in the innovation policy sector. By emphasizing, on the one hand, how academic health centers can develop an RIH-oriented role, and, on the other hand, the way social finance and impact investors can leverage RIH entrepreneurial projects, it underscores the importance of "doing" responsibility collectively.

Pressing Forward the Twofold Change of RIH

In Chap. 1, we explained how RIH is rooted in Responsible Research and Innovation (RRI), a field of research that largely transformed European innovation policies. For three of its key founders, RRI is "avowedly ambitious" in its move from *risk governance* to *innovation governance* (Owen et al., 2021). Such transformation implies both reimagining and reconfiguring "the norms, institutions and socio-political systems that direct and

govern innovation" (Owen et al., 2021). Likewise, RIH calls for a profound transformation of the current shareholder- and market-driven innovation system that is found in many countries around the globe (Mazzucato, 2018).

This chapter argues that RIH can grow and scale if we transform the "rules of the game" that characterize established health innovation systems. Emphasizing that RIH calls for a twofold change—in health and social care systems as well as in innovation systems—we clarify how systemic change can unfold in these two sectors. Such change entails revisiting what we *know* about health innovation, what we consider *valuable*, and what provides *power* to whom.

Obstacles and Drivers in Health and Social Care Systems

In the 1990s, policymakers across multiple countries began emphasizing the need to control the growth in healthcare spending. This resulted in pressure not only on workforce recruitment and service provision but also on new drugs, medical devices, and information systems (Roncarolo et al., 2017). For several observers, innovators face multiple barriers when

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Box 10.1   Obstacles to Health Innovation

- The disconnect between innovators, health and social care providers, and third-party payers translates into different opinions on the value of health innovation.
- Innovators may overestimate the value of their solution, form unwarranted assumptions about clinicians' or patients' needs, and make costly and/or avoidable mistakes.
- The feedback of health and social care organizations are rarely made public, even though they often deal with solutions that poorly meet the needs of patients and clinicians or neglect the context in which care is delivered (e.g., clinical workflows, patient pathways).
- Innovators struggle to scientifically validate the effectiveness of a new product and then to scale it across a "circumvoluted" health system.
- Innovation policymakers are isolated from practical health and social care delivery issues, resulting in innovation policies that poorly align with health system needs.

Source: Adapted from (MacNeil et al., 2019)

seeking to deploy their solutions in health systems (see Box 10.1). To overcome these obstacles, the key question we should ask is: "what kinds of innovations do health and social care systems need and how can systems of innovation deliver them?" Today, rather than complex, costly, and hard to scale innovations, health systems need responsive, affordable, and highly usable solutions.

As critical thinkers and problem-solvers, health innovators are uniquely positioned to find creative and sustainable solutions to the multifaceted health and social care problems we face today. However, innovators who do not interact closely with a broad range of health and social care providers may "narrowly focus on empowering physicians" and fail to deliver the most impactful solution (MacNeil et al., 2019). Innovators should thus approach and work with organizations where they can acquire firsthand knowledge about health and social care problems and from multiple viewpoints.

Academic health centers play a key role in health innovation because of their expertise and active involvement in clinical research (Lega et al., 2017). While all health and social care managers could foster more responsible health innovation development processes, leading academic health centers are actively developing capacity to this end. For instance, Box 10.2 summarizes how the Hospital Center of the Université de Montréal (CHUM) in Quebec deliberately supports responsible innovation initiatives in the field of artificial intelligence (AI).

Box 10.2   Responsible Innovation in AI at the CHUM
A lifecycle approach to responsible AI-based innovation at the CHUM
To steer quality partnerships around AI projects, the CHUM formalized a process that covers the whole innovation lifecycle: codesign, experimentation in a real-life context, implementation, impact measurement, and scaling (if positive impacts are demonstrated).

To validate the innovation's relevance at an early stage, the CHUM identifies internal champions who have expertise in the domain targeted by the innovation and explicitly includes patients and their relatives.

It also asks potential partners to explain their commitment to the CHUM's core principles for responsible innovation in AI, which are as follows:

Box 10.2 (continued)

- **Innovative**: "By capitalizing on the common and creative strength of patients, teams, and partners through an open and inclusive approach, our choices are daring, our actions are forward-thinking, our approach promotes learning, teaching, and communicating while being based on data and knowledge."
- **Responsible**: "Guided by benevolence and humanism, our actions promote rigor, inclusion, equity, respect for human rights, autonomy, privacy, and sustainable development. The CHUM is a signatory of the Montréal Declaration for a Responsible Development of Artificial Intelligence."
- **Relevant**: "Inspired by the real needs of the population and stakeholders, our choices are judicious and aim to generate tangible and lasting benefits for society" (CHUM, 2021).

Despite the growing importance attached to inclusion and codesign in health services, research shows that "lower level employees are often left out" of innovation processes (Busch-Casler et al., 2020). This bears important implications for RIH because the practical needs and problems that can be brought to innovators' attention depend upon *who* contributes to the design process, which, in turn, influences *where* in the health and social care system the solution will be used and *by whom*.

For instance, if an innovator wishes to help children who have cystic fibrosis and must perform tedious daily exercises to remove mucus from their lungs, asking questions to a medical specialist or to a parent will shed light on different aspects of the problem and will thus open different design avenues. For instance, an open-source community called Breathing Games adopted a codesign approach with multiple participants to develop several video games and hardware components that make such therapy both more playful and effective for children. By supporting the capacity for self-care (e.g., visual feedback indicates the volume of air expelled), their solutions help parents focus on key aspects of their parental role.

In contrast to such a bottom-up approach, we found in one of our studies that top-down power relations often determine the managers and clinicians with whom innovators are able to interact (Lehoux et al., 2021b). In particular, a physician-centered governance limited innovators' capacity to engage a more diversified set of stakeholders, and this was observed in Ontario, Quebec, and Sao Paulo. Several of these innovators

were nevertheless conscious of the challenges patients living in rural, remote, or resource-constrained neighborhoods and communities faced. They turned such obstacles into opportunities to innovate, confirming that increased collaboration with local practitioners can support better care for patients living outside well-serviced areas (Alrabie, 2020).

As Box 10.3 summarizes, there are important drivers in health systems to further develop an RIH-oriented managerial role around:

- Facilitating inclusive innovation processes
- Articulating key systemic challenges
- Defining the level and intensity of care required by different types of solutions

Box 10.3   Health System Drivers to Harness Innovation Toward RIH
Facilitating inclusive design processes

- Foster onsite interactions between innovators, clinicians, researchers, all categories of health and social care managers, patients, caregivers, and citizens, which may spur more innovative solutions.
- Provide all user groups with the time, space, and means to articulate the problems to be addressed by a given innovation.
- Mitigate the power relations that impede inclusive design processes.
- Develop appropriate strategies to meaningfully engage vulnerable patients and/or caregivers in design processes.

Increasing responsiveness by articulating health system challenges

- Rely on data to clarify the importance of systemic challenges regarding: demography, epidemiology, human resources, service delivery, knowledge, and governance.
- Create a unique point of entry for innovators where they can be referred to relevant interfacing teams and obtain support.
- Assemble interdisciplinary teams (clinicians and all categories of managers) who can clarify and explore with innovators "what the demand is" without "killing" novel ideas too quickly.
- Be prepared to revisit how services are organized.

> **Box 10.3   (continued)**
>
> **Adjusting the level and intensity of care required by an innovation**
>
> - Identify what currently impedes the capacity of general practitioners and community care providers to attend to their local patients' needs.
> - Identify how innovations may easily integrate patient pathways and clinical workflows.
> - Anticipate how the practices of health and social care practitioners at all levels within the system are likely to be affected by a novel solution.
> - Set in place inter-organizational teams reflecting the composition of the health system to interface with innovators.
>
> Source: Adapted from (Lehoux et al., 2021a)

For instance, if health and social care managers wish to support patients' and caregivers' autonomy and consolidate primary care through innovation, they should counter-balance specialized care-centered dynamics. To this end, we suggest creating a unique point of entry for innovators so they can be swiftly referred to an interdisciplinary team mandated and equipped to contribute to the innovation process (e.g., hosting onsite visits, organizing ideation activities, engaging vulnerable patients and caregivers). Such teams should reflect the health and social care system as a whole, foster intersectoral collaboration, and create a shared commitment toward RIH. This implies bringing to the table front-line workers, home care experts, and community-based organizations who know a great deal about the needs of social groups who must cope with economic and health problems daily.

Obstacles and Drivers in Innovation Systems

For McGahan et al. (2020), knowing how private firms respond to societal challenges and generate positive societal impact looms "as the most important management problems of this century." Indeed, entrepreneurs are increasingly called upon for solving social, economic, and environmental problems that cross national boundaries. How can innovation systems

support such entrepreneurial activities? This is a key issue for both innovation policymakers and investors because innovation is a source of economic development, but it also requires a lot of capital. In 2021, health innovation start-ups globally raised USD 44 billion from angel investors, accelerators, corporate ventures, and private equity funding (StartUp Health, 2022). This level of funding is twice as much as the preceding year, and more than a 20 times increase was registered in the past ten years.

Despite their capacity to drive innovation, start-ups face many challenges and a large proportion of them do not survive. For instance, the five-year survival rate of new firms in Canada varies between 51% and 63% (Industry Canada, 2018). Though a venture may not survive because it is acquired by a larger firm, Cantamessa et al. (2018) found that failures within a sample of 214 start-ups mainly had to do with their business model and the way they were managed. Other factors included their innovation, customers, and ecosystem (investments, public policies, regulations, or competition).

Responsible entrepreneurs strive to generate social and environmental value on top of economic value, something that entrepreneurs *tout court* do not have to achieve (Ranabahu, 2020). Our work with 16 small and medium-sized enterprises (SMEs) in Canada and Brazil indeed showed that producing RIH comes with key business challenges at the individual, organizational, and system level (Lehoux et al., 2021a).

Table 10.1 indicates that the novelty of these organizations' entrepreneurial path raises the difficulty of defining as clearly as possible what a *responsible entrepreneurial identity* entails. Other challenges may appear, at first glance, as challenges that affect any kind of venture such as scaling one's production processes to catch up with a steep growing demand. However, many of these challenges pushed entrepreneurs to adapt their business model in ways that put at risk the responsible innovation at the core of their mission while lacking the support of the broader ecosystem. Entrepreneurs in our study were indeed pressured to become financially sustainable by investors and/or shareholders who did not fully recognize that these entrepreneurs were generating value for society rather than mainly "shareholder value" (Geissdoerfer et al., 2018). For instance, five organizations within our sample developed pricing strategies based on ability to pay or on a redistributive logic and five made their innovations freely available to beneficiaries. To be economically viable, 10 were managing two revenue models or more and 11 were catering to two or three market segments altogether.

Table 10.1 Business challenges faced by RIH-oriented entrepreneurs

Individual-level challenges	
• Defining a responsible entrepreneurial identity	Establishing a clear responsible entrepreneurial identity is difficult while the innovation is still being vetted.
• Upholding a responsible mission	It falls on entrepreneurs' shoulders to protect and position their nascent responsible value creation activities within a network that is not yet established or sufficiently supportive.
Organizational-level challenges	
• Building nimble organizational capacity	Entrepreneurs must secure the right multidisciplinary team and consolidate their skills for everyone to become quickly proficient in a variety of tasks.
• Scaling responsive production processes	To respond to a growing demand, entrepreneurs must consolidate their production process while developing organizational capacity to improve the innovation and solve any emergent technical problems.
• Struggling toward financial sustainability	In their struggle to attain financial sustainability, entrepreneurs keep redefining their revenue models and market segments, which affect the degree of responsibility of the innovation.
System-level challenges	
• Juggling with misaligned funding sources	While having to fulfill the varying requirements of multiple sponsors, entrepreneurs keep searching for ways to generate revenues and obtain more stable and larger sources of funding.
• Fulfilling ethical, legal, and regulatory responsibilities	The capacity to understand and fulfill complex ethical, legal, and regulatory requirements is in tension with the development of partnerships that matter to responsible value creation activities.
• Accounting for value in use	Value in use refers to the economic, social, and/or environmental value ultimately created by the innovation. Properly accounting for such value requires resources, capacities, and data that small organizations typically lack, but are key to their competitive strategy.

Adapted from (Lehoux et al., 2021a)

Hence, like we described in Chap. 4, the way responsible entrepreneurs can create social, environmental, and economic value should be clarified at the point of inception of their venture, when different types of investors and sources of revenues can be fully explored (Santos et al., 2015). These entrepreneurs require financial and policy support adapted to their core ambition and to the challenges they face. While every organization in our

study struggled to secure financial support aligned with their mission, some chose to move toward more affluent markets to attract private investors or venture capitalists. However, this type of financing will put them on a trajectory where creating value for shareholders overrides all other considerations (Lehoux et al., 2016).

Other economic drivers such as impact investing or social finance are better suited to RIH, which requires financing that is directly aligned with social and environmental value creation (Han et al., 2020). This type of financing can be a more effective lever for launching and growing responsible organizations (Voegtlin et al., 2018). Investors in these areas use performance measures that fully account for the social and environmental benefits entrepreneurs generate, that is, the value they create for society. For RIH to grow and scale, investors should be proactive and not wait for the "right" entrepreneurs to knock on their door. They must work in close collaboration with the intermediating platforms we described in Chap. 9 and leverage existing and emerging innovation policy drivers.

When synthesizing the lessons learned from responsible innovation projects in different fields, we found that public policies can support their emergence, production, and diffusion by actively shaping public and private markets that are responsive to them (Lehoux et al., 2019). For example, by creating large public procurement markets, Germany deliberately stimulated the development of a renewable energy sector and a large cluster of companies specialized in energy efficiency. Our synthesis highlighted how creating temporary "protective niches" for responsible innovations is key. Several policy levers (e.g., strategic priorities, public procurement, regulation, tax credits) can be used to this end and the goal is to enable responsible innovators to break away from the beaten path. Such drivers play three roles that evolve over time (Verhees et al., 2015):

1. *Shielding* emerging responsible innovations by temporarily holding off pressures from mainstream selection environments
2. *Nurturing* emerging responsible innovations to improve their technical and economic performance
3. *Empowering* responsible entrepreneurs by changing selection criteria in favor of the scaling of responsible solutions

At this point, readers may wonder why protection is required? Can't a responsible innovation prove its value on its own? The answer is "probably not" because responsible innovators compete on an unequal basis against

traditional businesses. It is unequal because the costs of the social and environmental damages caused by traditional firms are currently ignored. A new generation of innovators and entrepreneurs is increasingly willing and able to eliminate such "externalities" (Geissdoerfer et al., 2018). For these pathbreakers to enter and transform the current ecosystem, public policies must redress the playing field where an unequal distribution of power reinforces an unequal distribution of responsibility (Wiarda et al., 2021).

This is something mission-oriented innovation policies can help accomplish. For Mazzucato (2018), such policies can drive more responsible innovations by providing *directionality* to innovation efforts. The aim should be to create economic value that goes hand in hand with social and environmental value. For instance, recognizing that servers consume a lot of electricity, the B Corp Ecosia created a search engine that fights climate change (described in Chap. 4, Box 4.2). In 2019, it was the first company from the digital sector to become carbon *negative*, producing twice as much renewable energy as it consumes. It also refuses advertising contracts from companies producing social and environmental damages.

"Doing" Responsibility Collectively

As aptly put by Stahl (2019), it is important to ask "who is responsible for responsible innovation?" There are indeed many stakeholders in innovation systems and not a single institution responsible for reconciling their diverging interests. Nevertheless, the time has come to address the largely untapped potential for innovation in health and social care and remove the "silos" between health policies and innovation policies (MacNeil et al., 2019). RIH not only establishes productive linkages between these two policymaking domains but also provides them with rigorous means to steer innovation toward equitable and sustainable health systems (Abrishami & Repping, 2019).

As a collective, the health innovation community should recognize the networked nature of RIH as well as its transformative potential (Lehoux et al., 2021a). Responsible entrepreneurs need to rely on responsible suppliers, distributors, retailers, and so on, and thus typically deploy a collaborative strategy (Hlady-Rispal & Servantie, 2018). For instance, an organization helps another one to develop a novel component that is either more fugal or eco-responsible in exchange of a stable supply. This

increases the development of RIH-oriented capacities and solutions across organizations as multiple entrepreneurs engage in shared responsible value creation. This is a process where reciprocity between entrepreneurs sharing similar skills and values brings responsible entrepreneurial activities at scale (Defourny & Nyssens, 2010).

Given the challenges we all face today, RIH should thus be viewed as the responsibility of an extensive trailblazing network of innovators who can move things forward by harnessing key drivers and boldly forge a rewarding twenty-first-century health innovation pathway.

Summary Points

> **Box 10.4   Chapter 10 Summary Points**
>
> - RIH calls for a twofold change: in health and social care systems and in innovation systems.
> - RIH can grow and scale if we transform what we know about health innovation, the values upon which we make decisions, and the rules that currently favor the status quo.
> - Health and social care managers should counter-balance power relations and facilitate innovators' access to practitioners who have firsthand knowledge of health and social care problems.
> - RIH requires individual entrepreneurial skills, organizational capacities, and the support of other actors in the innovation system.
> - For a collective way of "doing" responsibility to thrive, trailblazing health and social care managers and investors can boldly forge a rewarding twenty-first-century health innovation pathway.

References

Abrishami, P., & Repping, S. (2019). Nurturing societal values in and through health innovations: Comment on 'What health system challenges should responsible innovation in health address?'. *International Journal of Health Policy and Management, 8*(10), 613.

Alrabie, N. (2020). Integrating professionals in French multi-professional health homes: Fostering collaboration beyond the walls. *Health Services Management Research, 33*(2), 86–95.

Busch-Casler, J., Haubner, S., & Pinkwart, A. (2020). Employee involvement in innovation activities in hospitals: How perception matters. *Health Services Management Research*. https://doi.org/10.1177/0951484820943600

Cantamessa, M., Gatteschi, V., Perboli, G., & Rosano, M. (2018). Startups' Roads to Failure. *Sustainability, 10*(7). https://doi.org/10.3390/su10072346

CHUM. (2021). Interest validation form—Partnership request with CHUM. https://app.smartsheet.com/b/form/d6984f326ccc459590f8f030c9c0f85c

Defourny, J., & Nyssens, M. (2010). Social enterprise in Europe: At the crossroads of market, public policies and third sector. *Policy and Society, 29*(3), 231–242.

Geissdoerfer, M., Vladimirova, D., & Evans, S. (2018). Sustainable business model innovation: A review. *Journal of Cleaner Production, 198*, 401–416.

Han, J., Chen, W., & Toepler, S. (2020). Social finance for nonprofits: Impact investing, social impact bonds, and crowdfunding. In *The Routledge companion to nonprofit management* (pp. 482–493). Routledge.

Hlady-Rispal, M., & Servantie, V. (2018). Deconstructing the way in which walue is created in the context of social entrepreneurship. *International Journal of Management Reviews, 20*(1), 62–80. https://doi.org/10.1111/ijmr.12113

Industry Canada. (2018). *Canadian new firms: Birth and survival rates over the period 2002–2014.* Ottawa, Canada: https://www.ic.gc.ca/eic/site/061.nsf/eng/h_03075.html

Lega, F., Prenestini, A., & Rosso, M. (2017). Leadership research in healthcare: A realist review. *Health Services Management Research, 30*(2), 94–104. https://doi.org/10.1177/0951484817708915

Lehoux, P., Daudelin, G., Denis, J.-L., Gauthier, P., & Hagemeister, N. (2019). *Pourquoi et comment sont conçues les innovations responsables? Résultats d'une méta-ethnographie., Innovations*(2), 15–42.

Lehoux, P., Miller, F. A., & Daudelin, G. (2016). How does venture capital operate in medical innovation? *BMJ Innovations, 2*(3), 111–117.

Lehoux, P., Silva, H. P., Denis, J.-L., Miller, F. A., Pozelli Sabio, R., & Mendell, M. (2021a). Moving towards responsible value creation: Business model challenges faced by organizations producing responsible health innovations. *Journal of Product Innovation Management, 38*(5), 548–573.

Lehoux, P., Silva, H. P., Oliveira, R. R., Sabio Pozelli, R., & Malas, K. (2021b). Responsible innovation in health and health system sustainability: Insights from health innovators' views and practices. *Health Services Management Research*. https://doi.org/10.1177/09514848211048606

MacNeil, M., Koch, M., Kuspinar, A., Juzwishin, D., Lehoux, P., & Stolee, P. (2019). Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory processes. *Health Policy, 123*(2), 203–214.

Mazzucato, M. (2018). Mission-oriented innovation policies: Challenges and opportunities. *Industrial and Corporate Change, 27*(5), 803–815.

McGahan, A. M., Bogers, M. L., Chesbrough, H., & Holgersson, M. (2020). Tackling societal challenges with open innovation. *California Management Review*. https://doi.org/10.1177/0008125620973713

Owen, R., von Schomberg, R., & Macnaghten, P. (2021). An unfinished journey? Reflections on a decade of responsible research and innovation. *Journal of Responsible Innovation*. https://doi.org/10.1080/23299460.2021.1948789

Ranabahu, N. (2020). 'Wicked' solutions for 'wicked' problems: Responsible innovations in social enterprises for sustainable development. *Journal of Management & Organization*, 1–19.

Roncarolo, F., Boivin, A., Denis, J.-L., Hébert, R., & Lehoux, P. (2017). What do we know about the needs and challenges of health systems? A scoping review of the international literature. *BMC Health Services Research, 17*(1), 636. https://doi.org/10.1186/s12913-017-2585-5

Santos, F. M., Pache, A.-C., & Birkholz, C. (2015). Making hybrids work: Aligning business models and organizational design for social entreprises. *California Management Review, 57*(3), 36–58. https://doi.org/10.1525/cmr.2015.57.3.36

Stahl, B. C. (2019). Who is responsible for responsible innovation? Lessons from an investigation into responsible hnnovation in Health: Comment on 'What health system challenges should responsible innovation in health address? Insights From an International Scoping Review'. *International Journal of Health Policy and Management, 8*(7), 447.

StartUp Health. (2022). *2021 Year-End Insights Report: $44B raised globally in health innovation, doubling year over year.* New York, USA: https://www.startuphealth.com/insights-reports

Verhees, B. R., Kern, F., & Smith, A. (2015). The role of policy in shielding, nurturing and enabling offshore wind in The Netherlands (1973–2013). *Renewable & Sustainable Energy Reviews, 47*, 816–829. https://doi.org/10.1016/j.rser.2015.02.036

Voegtlin, C., Scherer, A. G., McWilliams, A., Rupp, D., Siegel, D., Stahl, G., & Waldman, D. (2018). New roles for business: Responsible innovators for a sustainable future. In *The Oxford handbook of corporate social responsibility: Psychological and organizational perspectives.* Oxford University Press.

Wiarda, M., van de Kaa, G., Yaghmaei, E., & Doorn, N. (2021). A comprehensive appraisal of responsible research and innovation: From roots to leaves. *Technological Forecasting and Social Change, 172*, 121053.

Conclusion

Abstract Wrapping up with the way the COVID-19 pandemic exemplifies why health innovators' creativity and problem-solving skills are pivotal to making health and social care more equitable and sustainable, we summarize in this last chapter our aims of writing this book. We also invite health innovators to fully embrace their role as influential "care-makers." By leveraging the multiple yet currently scattered Responsible Innovation in Health (RIH) drivers described in Chap. 10, health innovators and their allies can deliver meaningful as well as impactful twenty-first-century solutions. RIH is, after all, a practice as well as a vector of transformational change.

Keywords Responsible Health Innovation • Ethic of Care • Responsible Research and Innovation • Health Innovation Stakeholders

The Context in Which We Wrote This Book

Inspired by the idea that responsible innovation means "taking care of the future" (Stilgoe et al., 2013), it is on 5 June 2020 that our team gave a "go" to this book project. We had been working remotely due to SARS-CoV-2 for a while, and the usually comforting Quebec summer season was approaching despite the sorrows and uncertainties caused by the

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pandemic. The zoonotic nature of COVID-19, that is, a disease that emerges from the changing relationships between humans, animals, and the environment, made RIH even more timely (Watts et al., 2021). Because of our understanding of what makes people healthy and others not (Evans et al., 1994), we agreed with *The Lancet*'s editor-in-chief when he emphasized the way biological, social, and economic factors act synergistically to exacerbate the consequences of COVID-19 among vulnerable groups (Horton, 2020). The fact that the latter included health and social care workers in lower-paid jobs who are themselves at risk because of their gender, skin color, or immigration status revealed how inconsistent and fragile health systems are, that is, not built for the twenty-first century.

The same critique also applies to innovation systems. The pandemic revealed the highly globalized nature of the supply chains of medical drugs, equipment and supplies, and the intricate political interdependencies they create between countries around the globe (Silva et al., 2020). The massively unequal distribution of the COVID-19 vaccines showed that the World Trade Organization's (WTO) agreements as well as shareholders' greed are, after all, the most enduring obstacles to health innovation (Lehoux et al., 2021). As such, they should be cleared right away if we are serious about handling any of the Sustainable Development Goals (SDGs). We need innovation systems that foster mutually beneficial relationships between health, the economy, and the environment. As aptly put by Mazzucato (2020):

> Now is the time to do things differently—not only because Covid-19 poses a major threat to our health and economy, but because greater challenges lie ahead as our planet continues to heat up. Unless we use this crisis to change our ways, we'll diminish our chances of overcoming the next one.

An economy better fit for climate change not only may reduce the likelihood of other zoonoses but also has profound consequences for health. According to an extensive report on health and climate change, "if the response to COVID-19 is not fully and directly aligned with national climate change strategies," rich countries will fail to meet their targets, and this will damage health systems around the world, today and in the future (Watts et al., 2021).

Though we are sending this book to print in a context that augurs tensions, risks, and uncertainties, we place our confidence in the health

innovation community. Our first objective while writing the book was to introduce RIH to this ever-growing community and clarify concepts that are key to the design and production of responsible devices, services, digital tools, or solutions based on artificial intelligence (AI). We explained why RIH adopts a global perspective on population health and health systems. We adopted a practical approach and took care to illustrate with real-world examples the nine attributes of RIH. Though the examples that we have summarized in boxes are not inherently 'perfect', they can inspire innovators, prompt them to identify and tackle possible shortcomings, and move their own innovation project in the right direction. Through these concepts and real-world examples, innovation stakeholders can support health equity and health system sustainability by envisioning what types of innovations are needed and how they should be developed and brought to end users.

The pursuit of the second objective of the book is now largely in readers' hand in so far as it aims to bring a lasting impact on the way innovation stakeholders think about and develop solutions to twenty-first-century challenges, including the SDGs. Because health and social care provision is firmly rooted in an evidence-based culture, the book was designed to equip readers with a stepwise approach and an initial toolbox they can adapt in order to engage their own teams and organizations in a scientifically informed RIH pathway. Readers are thus now prepared to "take care of the future" and further consolidate the skills needed to address pressing health and social care problems.

Health Innovators of the Twenty-First Century Are "Care-Makers"

Though rarely recognized as such, health innovators play a key intermediary role between those who *give* care (e.g., nurses, physicians, occupational therapists) and those who *receive* care, that is, patients, vulnerable groups, and communities. For Tronto (1993), care is a practice that includes "everything that we do to maintain, continue, and repair our 'world' so that we can live in it as well as possible. That world includes our bodies, ourselves, and our environment."

When examining how health innovators with training and experience in biomedical engineering, industrial design, clinical sciences, or business

approach the concept of care in their practice, we came to see health innovators as "care-makers," that is, action-oriented professionals whose daily work is to envision, design, and materialize care-dispensing tools (Rivard et al., 2021). We believe that a fuller appreciation of the role of "care-makers" in health and social care services would enable consolidating the practical "hard" and "soft" skills such a practice requires (Lloyd, 2019). For instance, in their work as problem-solvers, health innovators *care* about unmet needs and ways to improve care. They mobilize their resources and skill set to *assume responsibility* to solve problems. They "*make care*" by striving to design impactful, usable, and ingenuous products and services that can outperform current solutions. By being proficient user-centered design practitioners, they are *responsive* to end users' feedback from the ideation to the evaluation stages.

The tension between what individual innovators can do and what enterprises prioritize (Chan, 2018) partly explains the skepticism of Responsible Research and Innovation (RRI) scholars for whom it remains unclear whether and how businesses can embark on a responsible innovation path (Wiarda et al., 2021). For André and Pache (2016), the will and ability to take care of others should be prerequisites for doing business responsibly and this is something RIH emphasizes through its Business model attribute. Although health innovators' practices are not solely driven by care or responsibility principles, they can certainly push businesses to develop responsible innovations *with* care. This is why we emphasized throughout the book the importance of the hard, yet creative collective "care-making" work multiple innovation stakeholders must accomplish together.

We thus believe that Owen et al. (2021) are right when they point out the need to address and change the "norms, logics and institutions which compete and resist RRI as a process of transformative change." We wrote this book to contribute to such transformation, seeking to provide health and social care innovation stakeholders with the compass and gears needed to embark on their own RIH journey. For them to successfully tackle pressing health and social care problems that cross sectors and national boundaries, key "care-making" skills can be nurtured and fully consolidated. Afterall, RIH is a practice as well as a vector of transformational change.

Summary Points

Box 11.1 Chapter 11 Summary Points

- The COVID-19 crisis highlighted the extent to which health systems and innovation systems are not built for the twenty-first century.
- Structured around the nine attributes of RIH, this book offers a practical stepwise guide that is informed by solid and extensive research.
- Readers are now prepared to identify, from an RIH perspective, what types of innovations are needed, how they should be developed and brought to end users.
- As their RIH journey begins, may the next generation of health innovators fully embrace their role as "care-makers."

References

André, K., & Pache, A.-C. (2016). From caring entrepreneur to caring enterprise: Addressing the ethical challenges of scaling up social enterprises. *Journal of Business Ethics, 133*(4), 659–675.

Chan, J. K. (2018). Design ethics: Reflecting on the ethical dimensions of technology, sustainability, and responsibility in the Anthropocene. *Design Studies, 54*, 184–200.

Evans, R. G., Barer, M. L., & Marmor, T. R. (1994). *Why are some people healthy and others not?: The determinants of the health of populations.* Transaction Publishers.

Horton, R. (2020). Offline: COVID-19 is not a pandemic. *The Lancet, 396*(10255), 874.

Lehoux, P., Pozelli Sabio, R., Alami, H., Rivard, L., & Silva, H. P. (2021). Rewriting the story of how the world developed COVID-19 vaccines. A work of fiction on responsible health innovation path creation. In J.-L. Denis, C. Régis, & D. Weinstock (Eds.), *Pandemic societies.* McGill-Queen's University Press.

Lloyd, P. (2019). You make it and you try it out: Seeds of design discipline futures. *Design Studies, 65*, 167–181.

Mazzucato, M. (2020). Capitalism Is broken. The fix begins with a free Covid-19 vaccine. *The New York Times.* https://www.nytimes.com/2020/10/08/opinion/international-world/capitalism-covid-19-vaccine.html?smid=em-share

Owen, R., von Schomberg, R., & Macnaghten, P. (2021). An unfinished journey? Reflections on a decade of responsible research and innovation. *Journal of Responsible Innovation*. https://doi.org/10.1080/23299460.2021.1948789

Rivard, L., Lehoux, P., & Hagemeister, N. (2021). Articulating care and responsibility in design: A study on the reasoning processes guiding health innovators' 'care-making' practices. *Design Studies, 72*, 100986.

Silva, H. P., Oliveira, R. R., Pozelli Sabio, R., & Lehoux, P. (2020). Favorecendo o bem comum em tempos de COVID-19: A perspectiva da inovação responsável em saúde [Fostering the common good in times of COVID-19: The Responsible Innovation in Health perspective]. *Cadernos de Saúde Pública, 36*(7), e00157720.

Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy, 42*(9), 1568–1580. https://doi.org/10.1016/j.respol.2013.05.008

Tronto, J. C. (1993). *Moral boundaries: A political argument for an ethic of care.* Routledge.

Watts, N., Amann, M., Arnell, N., Ayeb-karlsson, S., Beagley, J., Belesova, K., Boykoff, M., Byass, P., Cai, W., & Campbell-lendrum, D. (2021). The 2020 report of The Lancet Countdown on health and climate change: Responding to converging crises. *The Lancet, 397*(10269), 129–170.

Wiarda, M., van de Kaa, G., Yaghmaei, E., & Doorn, N. (2021). A comprehensive appraisal of responsible research and innovation: From roots to leaves. *Technological Forecasting and Social Change, 172*, 121053.