Responsible Assessments

Frameworks for a Value-Based Governance of Assistive Technologies

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Acknowledgements

Summary

This thesis investigates Responsible Research and Innovation (RRI) and its possible application for assessing assistive technologies. Such assessments aim to produce ethically acceptable solutions as well as enhanced value for the user groups. RRI connects science, innovation, society and citizens in the creation of social goods or the realisation of social values through research and development processes.

Although RRI has been an ideal for the governance of science for almost a decade, it remains little studied, in particular in the field of health and assistive technologies. The notion has received support from several European research funding agencies, but is still only in its infancy when it comes to concrete application with and for citizens and society. The goal of this thesis is to investigate how the governance of assistive technologies can become more responsible through assessments. The research process underlying this investigation was itself inspired by RRI.

Through extensive literature searches and several engagement activities with potential users, important stakeholders and their representatives, this thesis investigates the performance of socio-ethical assessments of assistive technologies in light of RRI. It draws on earlier research on Technology Assessment (TA) and applied ethics – and the interconnections between these two traditions – to investigate how these traditions might deliver assessment frameworks in line with the normative demands of RRI; and how to relate these traditions to Health Technology Assessments (HTA), the main approach to making policy decisions on new health interventions. By using of a combination of two such frameworks, the Ethical Matrix and the Socratic approach, this thesis suggests that an exploratory approach to RRI can inform assessment strategies and has the potential to enhance responsibility through both process and product selection. In particular, the thesis illustrates that there are lacunas in the municipal innovation process, where value decisions are made, and that structured assessment methodologies could improve the quality of such decisions.

The thesis contributes to an understanding of what RRI could entail in practical research through using its methodological and normative positions as points of departure for investigations into the values in assistive technologies. It also introduces a new approach to innovation chains for assistive technologies in municipalities and it explores how to enhance methods in applied ethics through a combination of the Ethical Matrix and the Socratic approach.

Sammendrag

Avhandlingen undersøker hvordan ansvarlig forskning og innovasjon (Responsible Research and Innovation – RRI) kan anvendes som grunnlag for normative vurderinger av velferdsteknologier. Slike normative vurderinger har som mål å skape løsninger og produkter som etisk sett er mer akseptable og som gir økt verdi for mulige brukergrupper. RRI er en tilnærming til å forstå og påvirke hvordan vitenskap, innovasjon, samfunn og medborgere kan skape samfunnsgoder eller virkeliggjøre samfunnsverdier gjennom forsknings- og utviklingsprosesser.

Til tross for at RRI nå har eksistert som et ideal for planlegging og styring av forskning for nærmere et tiår så er tilnærmingen lite utforsket innen helse eller velferdsteknologier. Tilnærmingen har fått oppslutningen fra flere europeiske forskningsråd og finansieringskilder, men er kun i oppstarten hva gjelder faktiske anvendelser sammen med og for borgere innen forskning og utvikling. Gitt at denne avhandlingen springer ut av tenkningen om RRI så er dens overordnede mål å undersøke hvordan styringen og utviklingen av velferdsteknologier kan gjøres mer ansvarlig. Selve forskningsprosessen er også fundert i RRI. Gjennom litteraturstudier og en rekke ulike møter med mulige brukere og andre berørte parter undersøker avhandlingen hva det vil si å gjennomføre sosio-etiske vurderinger i lys av RRI. Ut fra tidligere forskning på Technology Assessment (TA) og anvendt etikk – så vel som skjæringspunktene mellom disse – undersøker avhandlingen hvordan etablerte normative rammeverk fra disse tradisjonene kan bidra til vurderingsformer og –metoder som svarer til de normative kravene i RRI samtidig som de er mulige å kombinere med medisinsk metodevurdering (HTA) som er den sentrale tilnærmingen til å fatte politiske beslutninger om innføringen av nye intervensjoner på helseområdet. Ved å bruke en kombinasjon av to slike rammeverk, etiske matriske og den sokratiske tilnærmingen, viser avhandlingen hvordan en utforskende tilnærming til RRI kan utvikle vurderingsstrategier som har mulighet for å styrke ansvarlighet både i vurderingsprosessene og i valget av teknologiske løsninger. Avhandlingen påpeker at det finnes rom i kommunale innovasjonsprosesser der verdibaserte beslutninger fattes og der mer strukturerte vurderingsprosesser kan øke kvaliteten på utviklingen og valget av teknologiske løsninger.

Avhandlingen bidrar til en økt forståelse for hva RRI kan medføre i praktisk forskning og innovasjon ved at den bruker metodiske og normative innsikter fra RRI som utgangspunkt for å undersøke hva verdiene som står på spill ved innføring av velferdsteknologier. Videre åpner avhandlingen opp for nye måter å nærme seg innovasjonskjedene for velferdsteknologier i

kommunene, og den utforsker hvordan etisk matrise og den sokratiske tilnærmingen, som er etablerte metoder i anvendt etikk, gjensidig kan berike hverandre

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Attachments

Forsberg, E.-M., & Thorstensen, E. (2018). A Report from the Field: Doing RRI from Scratch in an Assisted Living Technology Research and Development Project. In F. Ferri, N. Dwyer, S. Raicevich, P. Grifoni, H. Altiok, H. T. Andersen, Y. Laouris and C. Silvestri (Eds.), *Governance and Sustainability of Responsible Research and Innovation Processes* (pp. 19–26). DOI: https://doi.org/10.1007/978-3-319-73105-6_3

Thorstensen, E. (2017). Responsible Help at Home: Establishing Indicators for a Product Assessment Methodology. In D. M. Bowman, A. M. Dijkstra, C. Fautz, J. Guivant, K. Konrad, C. Shelley-Egan, and S. Woll (Eds.), *The Politics and Situatedness of Emerging Technologies* (pp. 167–182). Berlin: IOS Press. Reprinted with permission. Web-address: https://www.iospress.nl/book/the-politics-and-situatedness-of-emerging-technologies/

Thorstensen, E. (2019a). Responsibility for Assistive Technologies: Product Assessment Frameworks and Responsible Research and Innovation. *Etikk i Praksis - Nordic Journal of Applied Ethics*, *13*(1), 55–80. DOI: https://doi.org/10.5324/eip.v13i1.2525

Thorstensen, E. (2019b). Stakeholders' Views on Responsible Assessments of Assistive Technologies through an Ethical HTA Matrix. *Societies*, *9*(3), 51. https://doi.org/10.3390/soc9030051

1 Introduction

Most people on the planet foresee and will experience old age and, at some stage, a large proportion will need some assistance. At the same time, our daily lives are increasingly interwoven with technological products, infrastructures and processes, so using technological solutions to address frailties, illnesses and disabilities is not a new idea. Current introductions of assistive technologies aim to curb, stabilise or even reduce the growth in the number of health personnel and health professionals. These technologies have the twin goals of increasing quality of life by making people more autonomous, more independent and more capable, while economising on an unsustainable growth in health costs.

Responsible Research and Innovation (RRI) is an approach to the study, policy development and governance of new and emerging technologies. This approach aims to understand and steer innovation toward societally beneficial objectives through a democratisation of research and innovation processes. Even though the notion and different practices of RRI have had a large influence in a limited circle for a decade, there have been few direct explorations of what it could mean to apply the policy and governance approach to actual research and innovation. One contribution of this thesis is to explore how RRI can be understood and converted to a basis for research and innovation in practice. The thesis investigates what it might involve to draw on the normative and epistemic resources from RRI in the field of assistive technologies with a focus on assessment processes for novel products and services. Consequently, the assessment methodologies that are in line with RRI's normative programme are referred to as *responsible assessments*.[1]

There are two different motivations for combining a study of RRI and of assistive technologies. The first is that assistive technologies might have large consequences for individuals and groups, and for society as a whole. Consequently, these technologies should be researched, developed and implemented as responsibly as possible. This practical and normative perspective on assistive technologies – based on the resources in RRI – is a second contribution from this thesis.

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[1] The terms "Responsible Research and Innovation" and "Responsible Innovation" share an unfortunate rhetorical property with the term "responsible assessments", with the connotation that whatever falls outside of their application is *irresponsible*. This connotation is not intended.

Since assistive technologies aim to improve individual lives and to economise on health costs while RRI aims to democratise technology, research and innovation, the second motivation is how to combine these two fields of knowledge and values. While RRI has been developed for health policy and has been systematically investigated as a foundation for research and innovation policy (Pacifico Silva et al. 2018), the practical and real-world research and innovation dimension seems underexplored. A third contribution of this thesis is of methodical nature through discussing how assessments might contribute to the responsible use of assistive technologies in society, health services, homes and lives.

The main question underlying this thesis is "How can assistive technologies be governed in a responsible manner?", which is mainly a question for the policy domain. This thesis investigates how assessments of new and emerging technologies can inform policy. The research question then is "How can the resources in RRI contribute to responsible assessments of assistive technologies?". This theme will be revisited in the conclusion, and constitutes a reflection on the second contribution of how to bring RRI into assistive technologies.

Chapter 2 explains RRI and how it relates to assessment and, more specifically, what separates assessment from research and innovation, which are the main foci in RRI. To provide context it discusses assistive technologies and the status of their assessment and presents the overarching project for this thesis, the Assisted Living project.

The methodology is discussed in Chapter 3, which looks at the challenge of how to perform relevant research that provides an answer. This chapter also outlines a frame for discussing the quality of an assessment. It provides a systematic presentation of the criteria that ought to be used for an assessment to qualify as responsible. The underlying idea is that good quality is a prerequisite for responsibility, with respect to both knowledge and action, that is, a responsible assessment needs to provide relevant factual knowledge concerning the situation as well as a space for intervention while safeguarding the democratic ambitions in RRI. This theoretical chapter provides the context for the discussion of the research presented in the four articles in Chapter 4.

Each of the four articles presented in Chapter 4 pursues the research question in a distinctly different manner. It is primarily in these articles RRI is translated and operationalised into a basis for research and innovation in practice through the development of the assessment approach, called the Ethical HTA Matrix. The first article highlights challenges related to

transdisciplinarity, communication, project planning and control, and quality.[2] It is not based on a traditional research question, but it explores how to adapt RRI thinking to a research project aimed at research, innovation and development. The article provides a rationale for why assessments of outcomes are vital to RRI since the suggestions in RRI largely refer to processes and procedures. It presents the Assisted Living project and creates a background for the later stages of this thesis.

The second article addresses the main values that assessments of assistive technologies should take into account from multiple perspectives.[3] A central perspective is the literature that is explicitly linked to RRI or that is core to the disciplines, programmes and thoughts underlying what is currently referred to as RRI. As all forms of RRI underline the importance of public engagement and stakeholder inclusion, a second perspective considers the values of potential users – from two categories, older adults and health professionals – and central stakeholders – consisting of technology providers, service providers, service designers and their interest groups.

The third article builds upon the findings in the second and investigates existing assessment frameworks that might be used for assessing assistive technologies in line with the conclusions from the second article.[4] It introduces that such an assessment framework should be compatible with Health Technology Assessment (HTA) as a prerequisite since HTA is a central methodology among decision-makers in health policy and health services. A conclusion from the investigated literature is that there are four candidates that meet the criteria from RRI as developed in the second article. However, they could all benefit from some modification to be even more adapted to RRI.

The fourth and last article applies a combination of two of the frameworks and investigates whether this combination provides a useful approach to assessing an example of assistive

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[2] Forsberg, E.-M., & Thorstensen, E. (2018). A Report from the Field: Doing RRI from Scratch in an Assisted Living Technology Research and Development Project. In F. Ferri, N. Dwyer, S. Raicevich, P. Grifoni, H. Altiok, H. T. Andersen, Y. Laouris, C. Silvestri (Eds.), *Governance and Sustainability of Responsible Research and Innovation Processes* (pp. 19–26). https://doi.org/10.1007/978-3-319-73105-6_3

[3] Thorstensen, E. (2017). Responsible Help at Home: Establishing Indicators for a Product Assessment Methodology. In D. M. Bowman, A. M. Dijkstra, C. Fautz, J. Guivant, K. Konrad, C. Shelley-Egan, & S. Woll (Eds.), *The Politics and Situatedness of Emerging Technologies* (pp. 167–182). Berlin: IOS Press

[4] Thorstensen, E. (2019). Responsibility for Assistive Technologies: Product Assessment Frameworks and Responsible Research and Innovation. *Etikk i Praksis - Nordic Journal of Applied Ethics*, *13*(1), 55–80. https://doi.org/10.5324/eip.v13i1.2525

technology, a GPS localisation system.[5] It also explores how and where such an approach might be of assistance in municipal innovation systems. The material for this article comes from interviews with central decision-makers and stakeholders in the development and acquisition of assistive technologies.

In the discussion in Chapter 5, the overarching question is "How has this research contributed to the responsible assessments of assistive technologies?", which is addressed with reference to the theoretical framework. The focus is on the final assessment approach, as presented in the fourth article, configured by the specific analyses and choices made in the three earlier articles. These analyses and choices are discussed critically since they played a role in contextualising the final assessment approach. The discussion ends with a reflection on the relations and possible conflicts between ethical frameworks and RRI. This discussion is the foundation for the third contribution of this thesis by addressing how assessments might contribute to the responsible use of assistive technologies.

Where relevant, earlier contributions from work outside of the Assisted Living project and assistive technologies are drawn on – following a long-term interest in the theme and the phenomenon of proper methodological grounding for assessments of new and emerging technologies. In particular, research conducted in the Ethical Bio-TA Tools (2003–2005) (Beekman et al. 2006), the EST-Frame project (2012–2014) (Forsberg et al. 2013) and the Naturalness in Human Cognitive Enhancement project (2013–2017) (Forsberg et al. 2017).

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[5] Thorstensen, E. (2019). Stakeholders' Views on Responsible Assessments of Assistive Technologies through an Ethical HTA Matrix. *Societies*, *9*(3), 51. https://doi.org/10.3390/soc9030051

2 Background

2.1 Responsible Research and Innovation

This chapter looks at the motivations behind RRI as discussed in the literature. It starts with a brief historical background before discussing some of the main positions and contributions more systematically. Some of these contributions serve as points of departure for a preliminary presentation of the concept of responsible assessments.

I understand RRI as a normative programme that attempts to reconfigure the relationships between research and innovation on the one hand and society on the other, for a more democratic, sustainable and inclusive future through the research and innovation system.[6] The success of this ambition rests primarily upon a proper understanding of the two sides and their relations, moreover the suggestions for novel relationships and configurations need to work in practice if RRI is to stand out as legitimate.[7]

Several scholars have attempted to define RRI.[8] What they share is a prescriptive approach to governing science and a commitment to reflecting on or understanding the purpose of research and innovation (Pellizzoni 2018). Most RRI scholars underline that research and innovation should produce outcomes that are not only positive in an economic or industrial sense but also socially beneficial. In addition, one of the central ideas in RRI is that research and innovation, in their present configuration, contribute to the creation of novel natural and social risks (see e.g. Beck (1992)), which requires a governance response. However, there are differences in the level of governance scholars aim for. For RRI to be accepted these presuppositions must be acknowledged, shared and accepted by those with power in the fields where science and society meet.

2.1.1 A background to RRI

de Saille (2015) has accounted for developments in the political strategising and changing goals of European research and innovation policy. She places the introduction of RRI in the transitions from creating research infrastructures and common European research areas in the

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[6] Doing research in and on an area in constant development such as RRI has specific challenges. The proposal for the Assisted Living project was based on the thinking and practices of RRI as conceptualised up to 2015 but our understanding of what RRI is or entails has changed.

[7] One such suggestion being to close or break down the assumed distance between science and society.

[8] See Owen et al. (2012); Owen et al. (2013); von Schomberg (2013); Wickson and Forsberg (2015).

late 2000s to a focus on research as the basis for European competiveness in new and emerging technologies. In the same period, de Saille saw an awareness in European research policy of avoiding public antipathy towards genetically modified organisms (GMO) since the legitimacy of EU policies depend to a large degree on delivering good outcomes for a majority of European constituencies. A priority in European research policy then became measures to avoid a repetition of the GMO controversies prior to what was perceived as a future transformative technology, nanotechnology (de Saille 2015). From the outset, nanotechnologies were framed as a driving force for economic competiveness, and RRI has been connected to the field and its potential applications from its earliest conceptual articulations (Shelley-Egan et al. 2018). In the early 2010s, different parts of the European Commission and other EU policymakers produced concepts of "embedding innovation into society", and explored how one could combine the creation of new innovation pathways or methods with ways of securing economic growth and social benefits. Such an approach to innovation might then become a marketable product in its own right (de Saille 2015). This approach gained momentum and Timmermans (2017b) found that the number of persons involved in RRI activities doubled each year from 2009 to 2014.

From a different perspective, Zwart et al. (2014) emphasise that the newness of RRI – as compared to earlier ELSA (ethical, social and legal aspects) programmes – is precisely the orientation towards the socio-economic dimensions of research and innovation rather than in the novelty of the methodologies employed in RRI. They connect the ELSA programmes to the societal and political concerns over the new advances in gene technology.[9] Some problems identified with the ELSA studies have been: a lack of investigating assumptions and world-views underlying disagreements between technical and humanistic approaches; a missed opportunity to study and understand the power dynamics common to technical and humanistic approaches; a history of mutual distrust between technical and humanistic approaches; an unquestioning acceptance of academic knowledge hierarchies; and a lack of attention to the materiality and systems of objects, in both nature and culture (Wickson et al. 2015). Furthermore, the ELSA phenomenon was not unified and had its share of internal disagreements and power struggles –mainly between ethicists and Science, Technology and Society (STS) scholars (Zwart et al. 2014). However, the central ideal, and sometimes also the

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[9] This section is not intended as an exhaustive presentation of the ELSA/ELSI (ethical, social and legal aspects/implications) history or development and its relation to RRI. For more in-depth discussions see, for example, Forsberg (2014); Myskja et al. (2014); Oftedal (2014); Rip (2014); Nydal et al. (2015).

real situation, was a mutual collaboration between the natural or technical sciences and the human or social sciences (Zwart et al. 2014). Whereas ELSA was limited to research, RRI has a wider ambition of influencing overall research policy.

Furthermore, RRI has been heavily influenced by traditions in Technology Assessment (TA) and STS. A majority of RRI papers connect to STS literature (Ribeiro et al. 2016), but TA thinking is visible in the extensive emphasis placed on participation (Participatory TA) and on co-production thinking (Constructive TA). The notion of ethical tools was developed under the ELSA programmes to connect the socio-constructivist thinking in TA with the normative ambitions in applied ethics (Lucivero 2015).

In the European Commission and through Horizon 2020, RRI has been connected to six policy areas, colloquially referred to as the RRI keys: public engagement, open access, gender, ethics, science education and, early on, to governance (European Commission 2012). The challenge-driven approach to research under Horizon 2020, where RRI is included as an element in addressing important policy areas, is novel since the challenges are far more complex than earlier ones (like placing a man on the moon) and they concern the whole socio-economic system of interconnected states and policy areas (Robinson and Mazzucato 2019). Underlying the European Commission's approach to RRI is also the process-based view similar to the AIRR approach, as articulated by Owen et al., when it comes to the dimensions, but without a specific commitment to care, responsiveness and stewardship.

RRI has been implemented through research funding, such as the European Horizon 2020, the Research Council of Norway, the Dutch Research Council (NWO) and the UK's Engineering and Physical Sciences Research Council (EPSRC). As mentioned, the European approach in Horizon 2020 connected RRI to the specific policy areas of gender (equality), ethics, public engagement, open access and science education, but highlights that RRI "is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation" (European Commission 2014). The other funding agencies operate in a similar fashion, but no common articulation across funders has yet been presented.[10]

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[10] Refer to Owen (2014); Gulbrandsen and Rynning (2016); Norges Forskningsråd (n.d.); The Dutch Research Council (n.d.) for precise articulations of their different approaches.

2.1.2 Conceptualisations of RRI

This thesis and its constituent articles have tried to remain open in their understanding of RRI, but has maintained a view of RRI as a process with expectation to the normative outcomes and with a corresponding lighter emphasis on RRI as policy goals. Several different understandings have been included to avoid taking sides in the different normative articulations of RRI. This inclusiveness was especially important in Thorstensen (2017c) and Thorstensen (2019a), which explored what values and norms were to be included in assessing assistive technologies.

RRI is normative to the effect that it combines perspectives on: 1) how to do science and innovation differently through a range of mechanisms or through attention to specific policy areas; and 2) how to connect policymaking or politics and science through engagement with stakeholders and/or citizens. In sum, it is normative by demanding of science and innovation that it is conducted in a responsible way, leading to socially beneficial outcomes.

Pellizzoni (2004) provides an understanding of a concept of responsibility through the relation of the state vis-à-vis its subjects or citizens. Pellizzoni describes an evolution from responsibility as governmental maternalistic/paternalistic care for citizens' well-being, via a focus on responsibility as liability in the first legalisation initiatives for the environment, up to the current predominant understanding of responsibility as accountability, that is, to provide a detailed account of and a justification for choices and actions. As Pellizzoni (2004) points out, current regimes of governance as accountability are vulnerable to problems such as: greenwashing; freeriding; participation limited to a select set of actors; verification according to indicators rather than real outcomes; and cherry-picking of accounting standards. In addition, there is the overarching problem of uncertainty; one cannot know what future problems and challenges there might be or what their distribution will look like (see Beck (1992)). Pellizzoni highlights that there is an additional approach to responsible governance, which he labels as responsiveness. Responsiveness consists of a mode where openness, listening and inclusion between governor and governed constitute the approach to discussing uncertainties or risks. Pellizzoni shows a strong contrast between accountability and responsiveness in an attention to indicators in the former and on process and results (real outcomes) in the latter. Pellizzoni's account of responsiveness constitutes the frame for the notion of responsibility in this thesis. As I will return to in Chapter 3.2 and Chapter 5, it is the ability of the Ethical HTA Matrix, as discussed in Thorstensen (2019b), to fulfil the criteria

for responsible assessments and its relation to the wider discussions in RRI that forms the basis for how it can be reconfigured in order to enhance its potential for responsibility.

The two most influential academic contributions to the development of RRI have been given by René von Schomberg and a group centred around Richard Owen, Phil Macnaghten and Jack Stilgoe in the UK. These two approaches have different focal points for how to achieve responsible research and innovation, and their approaches are not exclusive, but rather complimentary. von Schomberg places an emphasis both on the produced outcome and the processes leading to these outcomes whereas the UK group mainly looks at the processes for making policy decisions regarding research and innovation. Where these two approaches differ to some extent is consequently in the attention to products. von Schomberg (2012; 2013) connects RRI to products through the products ability to contribute to the realisation of values – or having the right impacts, in von Schomberg's terminology. These values, von Schomberg suggests, could be extracted from basic political documents such as the Treaty on the European Union. Furthermore, these values should consequently give research and innovation a direction towards addressing what is called societal Grand Challenges. von Schomberg sees these Grand Challenges as being defined based on the Treaty on the European Union and that it is a collective effort to identify these challenges. von Schomberg defines RRI as "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)" (2013: 63). He separates between three different aims in RRI: (ethical) acceptability, sustainability and societal desirability. It seems that one outcome can fulfil all three criteria, but the relations between the aims are not presented in detail.

It is in the working processes towards meeting societal challenges that von Schomberg and the Owen group are the most similar – except that Owen et al. (2012; 2013) do not explicitly discuss Grand Challenges and they tend to use the phrase Responsible Innovation rather than RRI.[11] The similarity consists in recommending a series of epistemic and normative structuring tools to identify good processes (in both the normative and epistemic sense) in

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[11] There is a tension between the notions of "Responsible Research and Innovation" and "responsible innovation", as recently thematised by Owen and Pansera (2019) and since there is a lack of agreement on the differences (see the recent review by Frodeman (2019)), this thesis treats the two notions as synonymous, and uses the abbreviation RRI to cover them both.

order to ensure societally beneficial outcomes. Owen et al. have created a division known as AIRR (anticipation, inclusion, reflexivity and responsiveness) of these different structuring tools. As examples of each of these aspects of the tools one can find foresights, user-centred design, codes of conduct etc. The research and innovation processes including adequate use of such structuring tools will qualify as responsible.

At the core of Owen et al.'s understanding of RRI is an orientation towards the future based on what they describe as care and enacted through responsiveness. They define RRI as "a collective commitment of care for the future through responsive stewardship of science and innovation in the present" (Owen et al. 2013: 36). There are similarities between Owen et al. and von Schomberg when it comes to the collective dimension and a reliance on responsiveness, but a notable difference between the positive tenor of scientific advances in von Schomberg and the neutral stewardship in Owen et al. This responsive stewardship is to be realised through processes as suggested in the AIRR dimensions. As a summary, one could say that where von Schomberg proposes substantive goals and values as well as processes, Owen et al. propose procedural ideals.

Chapter 5 returns to debates on RRI from a position close to that of von Schomberg (2012) since the main topic is assessments. However, since the use of RRI/RI varies between different scholars and policy contexts, it is fruitful to mention some of the central positions already at this point. With regard to the systematic differences in approaches to RRI, Timmermans (2017a) searched and accounted for the main ones. He found that a common rationale was the view that research and innovation systems should change to achieve goals that match social and ethical objectives. Both the state to be achieved and the process towards this novel reconfiguration of the research and innovation system are denominated by the term "responsible".

According to Timmermans (2017a) studying RRI as a research object reveals significant differences between accounts of what RRI consists of. One central difference is how contributors perceive the place of responsibility in the research and innovation policy landscape. The concrete relation between RRI and research and innovation processes vary between these different accounts. Timmermans finds that von Schomberg (2013), Owen et al. (2013) and Stahl et al. (2013) conceptualise RRI as "a process aimed at R&I" rather than as part of the research and innovation processes themselves. The remaining sources also see RRI as related to the research and innovation process (Grunwald 2011a; Sutcliffe 2011; European Commission 2012) , but differ in that the RRI Expert Group (European Commission 2013)

and van den Hoven (2013) see RRI as integral to such processes, whereas others see RRI as the condition for responsible research and innovation processes. The majority perceive RRI to be a prerequisite for, or a process aimed at, research and innovation to address societal challenges, and only a minority consider RRI as part of actual research processes. In other words, the ambition of using RRI as a resource for practical assessments in this thesis extends beyond how the majority have conceptualised RRI.

The rationales among these different contributions for doing RRI seem more harmonious, according to Timmermans (2017a). The emphasis is on how to create social benefits or to realise social values through or simultaneously with the abolition of current irresponsible practices. And how to establish novel forms of assessment and regulations in a way that takes into account the complexities in and the time for transition from idea to consequences.

The main approaches to implementing RRI consist in collective processes that target different levels in the governance or performance of research and innovation. van den Hoven (2013) and the Value Sensitive Design methodology is among the few approaches that suggest how to include values in producing actual outcomes of research and innovation. The RRI Expert Group also understands RRI as connected to actual and tangible products and the assessments of these products. The Expert Group sees RRI as a vehicle for realising "societal needs" and "ethical aspects". Societal needs are understood as,

> contributing to achieving objectives of sustainable development (consisting of economic, social as well as environmental aspects) and contributing to achieving normative objectives such as 'equality of men and women' or an improvement of the 'quality of life' which are also core European objectives expressed in the Treaty on European Union" (European Commission 2013, 56).

While ethical acceptability is defined as "compliance with both the EU charter on fundamental rights as well as the safety of products regarding the acceptable risk of products" (European Commission 2013, 56).

Rommetveit et al. (2019) frame RRI and the different actors and perspectives as an epistemic network (see Haas (1992)). Through these lenses, they see RRI discourse and practice as aiming at "novel associations across previous science–society interfaces: articulating academic, disciplinary and relevant experience-based specialist knowledge in order to respond to a societal or institutional problem (or question)" (Rommetveit et al. 2019: 5). In their analysis of the differences between two diverging strands within the RRI network, they identify one as system-based – by using words and phrases such as shaping, designing,

anticipation and feedback – encouraging practices of anticipating the future with respect to policy responses. The other different strand is more occupied with making diagnoses, distancing itself from promising and future-making, and as fundamentally suspicious of close associations between researchers and policymakers. Such fundamental differences do not seem to be an obstacle to using the same *infra-concepts*, as they call them, of responsibility, framing, engagement and so on. These underlying epistemic and normative differences should not be feared or ignored but recognised as logical and legitimate consequences of a disciplinary plurality.

2.1.3 Criticism of RRI

There have been several different forms of criticism of RRI and this section addresses those that are relevant to this study.[12]

In 2010 Grunwald (2011b) was already asking whether and how ELSA or STS had influenced the field of nanotechnology. He concluded that they had impacted societal debate and research funders, but had little influence on shaping or steering innovation and research in nanotechnologies. In this context, Shelley-Egan et al. (2018) question the actual effects of RRI engagements and activities on the actors in research and in innovation since RRI largely functions outside research institutions' core context and since RRI activities are developed by academics outside research and innovation systems. This latter point and the lack of connection between RRI and existing tools in innovation systems and industry is also developed by Dreyer et al. (2017). van Hove and Wickson (2017) argue that researchers tend to see RRI as an obstacle to performing good science, and Dreyer et al. (2017) find that there is little dialogue between RRI and other methods aiming at creating social benefits in the industry sector.

A different criticism of RRI's foundations is raised by Blok and Lemmens (2015) and developed by von Schomberg and Blok (2018) in that RRI seems to presuppose technological rather than system- or service-based innovations. This criticism resonates in the health sector especially given that service delivery and human resources are challenges and that the cost of technological innovations and their implementation exacerbate these challenges (Lehoux et al. 2019). Another point relevant to the health sector is that RRI seems to presuppose a power

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[12] For more comprehensive accounts, refer to Zwart et al. (2014), Ribeiro et al. (2016) and Timmermans (2017a). More specific criticism can be found in Bensaude Vincent (2014), Van Oudheusden (2014) and Rip (2016).

symmetry between all the actors in the innovation chain (Blok and Lemmens 2015). Pellizzoni further reflects on the power imbalance, writing that the "'mutual responsiveness' of innovators and stakeholders is likely to result in a major disclaimer – we shared the choice, we share the blame" (2018: 209). In professional ethics, a major theme is differences in knowledge and power between nurse and patient or between medical doctor and patient. Consequently, the position Pellizzoni characterises would be highly problematic in the health field, and his criticism is returned to in Chapter 5.[13]

2.1.4 Responsible assessments

The concept of responsible assessment will be given more space later in this thesis. For now, it is central to link the concept to RRI and to what distinguishes research and innovation from assessment.

In the scholarly discussion on RRI, von Schomberg (2012) has contributed conceptually to the discussion of how to integrate expertise with what he refers to as the right impacts of science and technology. For von Schomberg, such right impacts are those that are founded on or are in agreement with high-level societal values, such as those from the Treaty on the European Union. Of course, the processes of realising these values should themselves be carriers of normative ideals, such as democracy. To realise the right impacts, von Schomberg proposes what he refers to as *normative filters*, methods for systematising issues connected to ethical acceptability, sustainability and social desirability. These normative filters are, in practice, a range of assessment methods to systemise the current state of scientific and social knowledge in order to avoid pick-and-choose approaches. What von Schomberg (2012) sees as missing are knowledge assessment mechanisms to assert the quality of available knowledge for policy processes. Recently, von Schomberg (2019) has connected the practice of assessment to RRI since there is a need for assessments that ensure socially desirable goals, that might point to market failures, that can discuss how innovation relates to values, that can focus on the innovation outcomes rather than the potentials, that makes stakeholders responsive to each other and that include anticipation in order to give directions to innovations. The proper scope of assessments should, according to von Schomberg, not be limited to the technological

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[13] There are suggestions on how to mediate between the ideals of total symmetry and total paternalism (see Emanuel and Emanuel (2002)), which also relate to different conceptualisations of informed consent (see Thorstensen (2018)).

option as such, but include the changes that the technology system makes on the public's values and expectations.

Central to the conceptualisation of assessments in this thesis is what Kaiser et al. (2010) discuss as "the assessment regime" which "as a whole is concerned with those evaluation aspects that are regarded as crucial for the social acceptability of novel technologies." (Kaiser et al. 2010: xii). They see this regime as constituted of two spheres, knowledge and values. Ethicists or social scientists target the latter, which often play out as deliberations, dialogues or participation in pursuit of a technology's acceptability, while natural scientists are in charge of the knowledge dimension.[14] Furthermore, as Parson (1995) notes, assessments should be useful or relevant for a competent but non-expert decision-maker.

Kaiser et al. (2010) discuss assessments that are explicitly orientated towards a normative standard, which are mainly different forms of TA or ethical assessments. That which separates these assessments from research and innovation activities could be said that the latter seek other values. Research is typically orientated towards truth-seeking, which is an epistemic value (Gundersen 2018). Innovations typically seek acceptance through customer satisfaction, whereas assessments investigate normative acceptability through values that are predefined or found through a deliberative process.

The overall orientation in this thesis to assessments as part and parcel of RRI follows von Schomberg (2012) in relating RRI to products through assessments of different sorts that should secure ethical acceptability and societal desirability and contribute to sustainable development. However, this perspective does not exclude other approaches to RRI such as AIRR (anticipation, inclusion, reflexivity, and responsiveness) approach, as outlined by Stilgoe et al. (2013), or the European Commission's view. However, von Schomberg aligns RRI related to product assessment directly to the TA tradition and other types of assessment, whereas Stilgoe et al. (2013) seem to subsume the different forms of assessment as tools for achieving anticipation, inclusion, reflexivity and responsiveness.

The combination of responsible assessment as concept and as practice is discussed in Chapter 3.2, which provides a frame for addressing the responsibility in an assessment practice. Central overarching elements from the above discussion on RRI are responsibility as responsiveness and an orientation towards the purpose of assessments.

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[14] This "division of moral labour" and how it should be configured is in itself a debate and a field of study in RRI (see Shelley-Egan (2011)).

2.2 Assistive technologies

As Thygesen (2009) points out, the institutionalised thinking behind independent housing with access to technological health assistance emerged in the 1990s. To better understand current use of the term "assistive technologies" and inherent problems with the terminology, there is a need for a brief investigation into the meaning of the words and their references.

Brey (2012) suggests that there are three levels relevant to an ethical analysis of technology: 1) the technology level; 2) the artefact level; and 3) the application level. Technology is "a collection of techniques that are related to each other because of a common purpose, domain, or formal or functional features" (Brey 2012: 310). The relations between these levels are not fixed; one technology might be implemented in different artefacts and "the same underlying artefact can emerge into different technologies in terms of usage and application" (Stahl et al. 2010: 23). More often than not, the actual level under discussion is tacitly assumed by the authors. The level used in this thesis to analyse and assess assistive technologies is what Brey refers to as the artefact level; as demonstrated by the following examples of different uses of the terms related to, or seen as synonymous with, assistive technologies.

As an example of how engineering presents this divide, one might look at an analysis of papers in engineering sciences on Ambient Assisted Living by Calvaresi et al. (2017). They included 236 papers and identified 37 different kinds of technology, ranging from environmental sensors to Wii over microphones, Braille and laser – which in Brey's system would qualify as artefacts. In addition, they present what they call "techniques adopted to design AAL [ambient assisted living] supports", listed as "Data computing, Activity recognition, Artificial Intelligence, Networking, Custom Algorithms, Position tracking, Probabilistic theory" (Calvaresi et al. 2017: 249). The techniques seem to be the underlying the creation of the technologies and would qualify as technology in Brey's system.

If one looks at the most recent Norwegian *Realisations of Gains* report, which uses the term "welfare technology", they recommend Norwegian municipalities to install: electronic medication support; GPS tracking and warning; electronic door locks; digital remote surveillance; passive warning system (bed sensors, flooding sensors, some detectors); logistical solutions for health personnel; and telehealth and telemonitoring (Melting 2017). These are all assistive artefacts and the underlying technologies might be different.

Hofmann (2013b) uses a different classification for welfare technology, based on its purpose:

- Communication support

- Compensatory technology, assistive technology
- Help for everyday practical tasks
- Disease monitoring
- Remote treatment
- Rehabilitation technology
- Entertainment
- Social and emotional support and stimulation.

Underlying each purpose is a range of features, and one might use the same kind of technology or artefact to achieve different purposes. It is helpful to take the purpose of the technology as a point of departure, then one can assess more easily whether or not a specified function has been met. Hofmann seems to classify the *application* of assistive technologies (welfare technologies) according to what they are expected to achieve.

Furthermore, most of Hofmann's purposes and all of Calvaresi et al.'s technologies and techniques could be used for medical technologies. Medical technologies are regulated by law, whereas practice seems to indicate that assistive technologies are not tested as strictly, as discussed later. To complicate matters, health technologies tend to target one condition (such as a pacemaker), whereas assistive technologies target general daily living. Elaborating on this difference, Novitzky (2016) places health technologies in hospitals or other institutional settings, whereas assistive technologies are often located in homes. Thus, the question of the distinctiveness of assistive technology from its close cousin health technology seems difficult to solve without asking the relevant ministry, as there are legal consequences in classifying a product as a health technology.

Even though there are differences at the definiens level, there are also a range of definienda that are used as though they are synonymous. One example can be found in Haux et al. who present assistive technology – and its Nordic cousin welfare technology – as referring to the same phenomenon as "ambient assisted living for health care, ambient assistive technologies for health care, ambient intelligence for health care, health-enabling technologies, pervasive computing technologies for health care, pervasive health, pervasive health care, smart home technologies for health care, and ubiquitous health care" (2016: 577). This synthetic alignment of terms might be useful for pragmatic purposes, but these words also point to very different phenomena that have highly different governance regimes, such as legal regulation, remuneration (cost) and institutional support. A pressing question then is whether one can speak about RRI in assistive technologies and assume that one can transfer the insights to fields covered by the other terms. Even more radical is whether assistive technologies is a category in which every member shares a large enough number of features (in the technology,

the use situations or their governance) that one can transfer research and development insights from one form of technology to another. These questions further problematize an effort, as suggested by von Schomberg (2019), to address the full system rather than the single technology, artefact or application. As I will return to in the discussion, there are some functions or purposes that might be assessed in general, but as the artefact themselves might differ between suppliers and product generations, a general artefact assessment seem improbable.

The conclusion of these reflections is that assistive technologies is a term used to denote a range of items and compositions of items that are used for a wide range of purposes, both publicly and privately. They rarely have a direct health effect, but should facilitate for health effects.

2.2.1 How are assistive technologies assessed?

As the articles summarized in Chapter 4 discuss intensively how to perform assessments of assistive technologies in line with RRI and how to create a clear link to current practice in Health Technology Assessments (HTA), they will not be discussed here. HTA is a systematic assessment of the safety, security, effect and costs of new medical procedures. What is presented here is earlier research on the assessment of assistive technologies and what might be learnt from these earlier assessments and their uses.

The UK assessment called the Whole System Demonstrator (WSD) seems to be the most comprehensive assessment of assistive technologies to date. The WSD was aimed at answering a simple and straightforward question, formulated by Gornall (2012) in the aftermath as "does the use of technology as a remote intervention make a difference?" More than 6,000 patients were involved from 2008 in cluster randomised trials in three different socio-economic locations. There were also extensive qualitative studies with all stakeholders (Newman et al. 2015), studies related to quality of life and well-being (Hirani et al. 2014), cost-effectiveness (Henderson et al. 2013; Henderson et al. 2014), use of health services (Steventon et al. 2013), experiences of health professionals (MacNeill et al. 2014), withdrawals (Rixon et al. 2013), mortality and secondary care (Steventon et al. 2012); and changes in the condition (Steventon et al. 2014).

The WSD might more aptly be called a research project than an assessment since it covered a range of studies. However, the overarching and guiding question is value-based and it qualifies as an assessment according to Kaiser et al. (2010). What the WSD illustrates is the

need for a range of systematic and rigorous studies to perform assessments. According to Hofmann (2013b) and Boucher (2018), the WSD thus constitutes the exception to the rule of assessing assistive technologies, where assessments tend to depend on studies that lack high quality. However, the WSD budget was very high and few research and development processes can invest such large sums under the current institutionalisation of assistive technologies. Furthermore, as Barlow, Bayer and Curry write concerning research on assistive technologies, "controlled trials are often unfeasible" (2006: 396) due to the organisational complexity of assistive technologies. This situation is problematic, as Novitzky et al. (2015) assert, since assistive technologies aim at a level of finesse and functioning that should abolish the need for humans as a safety net. This means that they should be required to have a higher level of safety than other technological devices.

Research on the assessment practices and the knowledge foundation for assistive technologies paints a rather bleak picture, despite the thoroughness of the WSD. Topo (2008) finds a bias towards caregiver needs and suggests that this is because caregivers are the main source of information when it comes to assessments. Nickelsen (2013) shows that different stakeholders seek to realise disparate values and, just as important, that their means of fulfilling those values and balancing conflicting values differ from one stakeholder category to another. Brandser (2015) likewise finds that there are many actors fighting for their interests in the implementation of novel technologies. There is a battle in the health professions as to whether to implement technologies – and what their eventual role should be. Political power issues and economic issues are also at play. Beedholm et al. (2016) found that a bathing robot saved the formal caregivers from strenuous tasks, so they had an ulterior motive for supporting the introduction of this assistive technology that went beyond the well-being of the patient. Pols and Willems (2011) document how user relationships are important in connection with the assessment of technologies. They state that it is difficult to find a unit that ought to be evaluated before one has observed how the intended goals have been put into practice by using the technology.

As seen with the WSD, it is possible to conduct large-scale trials with assistive technologies, and to include a range of suggested methodologies from the literature, such as investigation into relationships, organisational issues, views of the professionals, conflicting values and technological quality or stability. According to Novitzky et al. (2015) there is a moral need for

firm quality control through assessments in this field because one aim behind assistive technologies is to replace human labour with devices.[15]

A general picture that emerges is that assessments are conducted to provide decision-makers with an unequivocal message about the proposed technology. If one employs TA terminology the purpose of these assessments is to give an overview of the actual functioning of a device and its consequences or to inform a decision on new policies (Hennen et al. 2004). However, this seems to be a rather narrow scope – as seen from the TA tradition – and there is a range of other purposes for making assessments, discussed further in the theoretical framework in Chapter 3.2 and in Chapter 5.

2.2.2 RRI in assistive technologies

In 2016, Weinberger et al. (2016) called for an increased implementation and use of RRI in assistive technologies for persons with dementia. There have been some progress in this field, but the main use of RRI in the health field has been the contributions from a network around Pascale Lehoux. These contributions have focused on the health and technology field in general. As discussed, the difference between health technologies and assistive technologies is not very clear, but health technologies aim at a direct health effect whereas assistive technologies aim at care and might have an indirect health effect.

As discussed in the literature review for the Assisted Living project (Thorstensen 2017b), there are several contributions to the study of research and innovation related to assistive technologies that could be called de facto RRI.[16] The main contributions are included in the analyses in Thorstensen (2017c) and Thorstensen (2019a).

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[15] The assessment of assistive technologies is very different from the situation in research and development in pharmaceuticals, where the price of one new drug was estimated at US$ 1 billion in 2000 (Jones and Wilsdon 2018). While it extends beyond the scope of this thesis to explain the differences, one could look at how assistive technologies are institutionalised differently to pharmaceuticals. Furthermore, a sociological focus on assistive technologies versus pharmaceuticals or medical technologies, shows how assistive technologies are typically used by different professional and semi-professional groups. They are often prescribed by an occupational therapist, and put in use and maintained by home carers who do not have a tertiary education, while pharmaceuticals and medical technologies are in the domain of medical doctors or registered nurses with a tertiary education. Finally, medical technologies are typically connected to hospitals, a more prestigious workplace than the home services (Fevang 2009).

[16] Randles et al. use the notion of de facto RRI to denote "how actors themselves de facto frame, and embed understandings of responsibility into the full scope of research and innovation contexts, situations, organisational settings and professional practice" (2016: 32).

Some contributions to the study of assistive technologies and RRI have been made. Kickul and Iakovleva (2017) have analysed the existing assistive technologies innovation pathways according to the AIRR dimensions and find that inclusion is the dominant aspect, and Oftedal et al. (2017) have looked at the drivers for firms to engage in RRI. Furthermore, Oftedal et al. (submitted) suggest that start-ups in e-health are motivated by responsibility and propose that RRI departs from this motivation rather than engage in a top-down approach to imposing RRI. Thapa and Iakovleva (2019) have made descriptive historical case study in medical technologies of how business organization can create social impact, and find that mission statements, early stage inclusion and a focus on learning activities are central elements.[17]

Pacifico Silva et al. (2018) launched what they call an "integrative framework for responsible innovation in health". Their article describes the elements that could be used to support robust and responsible innovation in the health sector I account briefly for their position in the third article (Thorstensen 2019a). Even though a large number of researchers in RRI are also involved in different aspects of health studies, there was very little attention on RRI in health prior to Pacifico Silva et al. (Timmermans 2017b). Their articulation is condensed in Table 2.2.

Table 2.2 The value domains and dimensions of responsible innovation in health (Pacifico Silva et al. 2018: 6)

Value domain	Dimension
Population health	Health relevance: Does the innovation address a relevant health problem?
	Ethical, legal and social issues: Was the innovation developed by seeking to mitigate its ethical, legal or social issues?
	Health equity: In what ways does innovation promote health equity?
Health system	Inclusiveness: Were the innovation development processes inclusive?
	Responsiveness: Does the innovation provide a dynamic solution to a health system need or challenge?
	Level of care: Is the level of care required by the innovation compatible with health system sustainability?
Economic	Frugality: Does the innovation deliver greater value to more people using fewer resources?
Organisational	Business model: Does the organization that produces the innovation seek to provide more value to users, purchasers or society?

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[17] See also Kickul et al. (2019), Konrad et al. (2019) and Wåge and Stangeland (2019) for similar case studies in digital health.

Environmental	Eco-responsibility: Does the innovation limit its negative impacts throughout its lifecycle as much as possible?

This is an excellent example of overcoming the problem, as pointed out by Shelley-Egan et al. (2018), of connecting an ongoing discussion about how to understand and assess health policy and innovations in health to the discourse about general ideas in RRI and actual practice in domain specific innovation policy practices and challenges. Of particular interest is that Pacifico Silva et al. place the established RRI dimensions of inclusiveness and responsiveness as elements in the health system. Consequently, it is the health system (and delivery systems) that should be characterised by inclusive processes and seeking to develop flexible solutions that can be used beyond the specific local conditions.[18] In a discussion with experts in the health technology sector, Rivard and Lehoux (2019) found that they are supportive of the framework, but that the experts underline the practical difficulties in for example involving a wide range of stakeholders while aiming for speedy arrival of products to the market. As Auer and Jarmai (2018) point out in their study of the Austrian medical device sector, there is a basic moral drive among producers to develop products that improve life quality through improved health.

Oftedal et al. (2019) orientate their discussion of innovation in healthcare towards issues of power and the need for a different view of patients as that of being limited to recipients of healthcare. There are additional studies of the how RRI might be applied in the governance or policy of health technologies developed by Demers-Payette et al. (2016) and Lehoux et al. (2019). These address differences between the health and technology systems, and how to operationalize RRI in health in order to address the most pressing challenges.

2.2.3 Summary

When discussing assistive technologies, it can be difficult to know what term to use and what different terms refer to. Assistive technologies, as all technologies, can be assessed according to their internal technological units, on a combined level as artefact or as a concrete application. Furthermore, there is a range of related terms that tend to be used interchangeably with assistive technologies. The term assistive technology in this thesis is used to describe a technological artefact that has potential for indirect health effects and that could have a direct

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[18] As addressed in Thorstensen (2019b), the values mentioned by Pacifico Silva et al. had a mixed reception in the interviews conducted. This reluctance should not be understood as *irresponsibility*, but that the interviewees lacked either *knowledge* of all the criteria or *capacity* to influence the acquisition of assistive technologies.

effect on other spheres of life, such as welfare, safety or sociability. This combination of direct and indirect connections between the product and the postulated effects makes assistive technologies difficult to assess.

Assistive technologies quite often suffer from narrowly conceived assessments. Sometimes this narrowness is due to organisational factors, but frequently these assessments lack both quality and a critical apparatus. Due to their direct as well as potential effects, assistive technologies should be assessed based on high quality research and with a reflective and critical approach to how the assessor conceptualises values.

2.3 The Assisted Living project

Given that the context of this research is the Assisted Living project, it is time to give a short presentation of the project, its composition, aims and developments, which will shed light on the connections between the articles in this thesis. The following description is based on Forsberg and Thorstensen (2018), which is also the first article in this thesis.

The Assisted Living project was a response to a call from the Research Council of Norway to develop RRI in the field of information and communication technologies (ICT). However, the project was not put in place for the sole purpose of developing RRI since the collaboration between the partners stemmed from 2013 and had its basis in a common interest for responsible use of technologies in the health sector. The Assisted Living project's original target group was persons with Mild Cognitive Impairment / Dementia (hereafter MCI/D) whom the project would engage with the intention of creating technological solutions for them to live in their homes for as long as possible. However, due to the fact that those recruited through the generous collaboration of an assisted living facility in Norway did not have the MCI/D diagnosis and because the Assisted Living's advisory group saw the limitation to MCI/D as unnecessary and the project's aim as relevant for all residents, a wider range of participants was included.[19] Colleagues from health science evaluated the cognitive functions of the participants included in the technology trials;[20] and every resident was invited to open events called Dialogue Cafés.[21]

A primary step in the project was to adapt an RRI process to include this intended user group. Kennedy and Ter Meulen (2016) provided the project with a view on the state of the art for including persons with MCI/D, which served as an important guide since the project should be able to welcome persons with reduced cognitive functions. The Dialogue Café is a concept similar to the World Café, which is a participatory approach to building upon the ideas of others on a pre-defined theme in a relaxed atmosphere while enjoying a snack (Anderson

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[19] The Assisted Living project (2017).

[20] See Casagrande et al. (2018); Casagrande and Zouganeli (2018); Holthe et al. (2018a); Casagrande et al. (2019); Casagrande and Zouganeli (2019) for descriptions of the technology research and the nature of the interventions.

[21] The Assisted Living project obtained permission for all personal data collection, storage and research from the Norwegian Centre for Research Data, all participants had the capacity to consent and signed a consent form for each event. The project was considered by the regional committees for research ethics not to be engaged in health research.

2011). We had to adjust the original concept due to the mobility demands of the World Café and to be inclusive of people with reduced cognitive capacities.

The Assisted Living project understood from the outset that an RRI process is a research and innovation process that includes:

1. A specific focus on addressing significant societal needs and challenges
2. A research and development process that actively engages and responds to a range of stakeholders
3. A concerted effort to anticipate potential problems, identify alternatives, and reflect on underlying values, and
4. A willingness from relevant actors to act and adapt according to 1–3 (Wickson and Forsberg 2015: 1153).

The operationalisation of these four points is presented in Forsberg and Thorstensen (2018).

The proposal to the Research Council of Norway for the Assisted Living project contained the following description of its ambitions:

> By adapting an RRI framework, the project aims to: a) map how stakeholders and experts perceive the state-of-the-art of responsible welfare technologies, focusing on assisted living technologies (ALT), in Norway and internationally; b) develop ALT solutions for users with mild cognitive impairment and dementia (MCI/D), through an RRI approach; c) judge by an integrated HTA approach whether technologies introduced through an RRI process score better than currently implemented technologies; and d) create a wider dialogue on responsible welfare technologies for the future, reflecting on alternatives and options (see also Forsberg and Thorstensen (2018: 21))

All the different aims of the Assisted Living project were approached through three avenues – health sciences, ICT and engineering, and RRI – each with a PhD student. For a) Casagrande (2017) focused on ICT and sensor-based aids; Holthe et al. (2018b) conducted a literature review on degrees of involvement with possible technologies by persons with MCI/D and their caregivers; and Thorstensen (2017b) looked into what responsible welfare technologies might mean through a literature review.

For b) the Assisted Living project established cooperation with a group of committed older adults at a Norwegian assisted living facility (see Zouganeli et al. (2017), for a description). They provided the Assisted Living project with insights into daily challenges as well as views on possible solutions. The project's understanding and discussions of these views formed a central core for selecting which solutions to develop and test. In the planning of the project,

the consortium decided to pursue holistic home systems that could adapt themselves to an individual user through machine learning, a so-called self-learning system.[22]

Point c) is the background to this thesis as it sought to find a method by which HTA could be enriched with perspectives from RRI and thereby serve as a basis for assessing the envisaged assistive technology developed through the project. The investigation into the possible compatibility with HTA in Thorstensen (2019a) should be read against this background. However, as this solution did not materialise, a full-scale integrated HTA could not be conducted.[23] Consequently, the developed methodology needed to be applied to an existing solution as presented in the final article (Thorstensen 2019b).

Point d) is covered by a multi-stakeholder foresight, an international study into the development processes of assistive technologies in the UK, Germany and Norway with a continuous dialogue with stakeholders through the project's reference group based on the TranSTEP methodology as developed by Forsberg et al. (2016).

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[22] See Russell et al. (2010) and Tørresen (2013) for in-depth explanations of machine learning and its relation to artificial intelligence.

[23] The project's ambition of comparing two different solutions and assessing them to ascertain the differences between a product developed through an RRI process and a product not developed through an RRI process is methodologically very challenging.

3 Method and Theory

3.1 Methods

The articles constituting this thesis are based on different methods, but of central importance has been to develop an assessment approach based on how different actors value and understand assistive technologies.

Forsberg and Thorstensen (2018) is mainly a descriptive account of how the Assisted Living project understands and has operationalised RRI and of experiences and practices. It is consequently a conceptual approach with reflections based on experience. The sources for these experiences are notes taken during the Dialogue Cafés by the facilitators, as well as transcripts from the advisory group meetings and my own notes and recordings from reflective exercises. In brief, the article describes what had been done thus far, and the reasons for doing so.

Thorstensen (2017c) is based on a literature review and on encounters with older adults residing at a Norwegian assisted living facility and with health care professionals from Oslo interviewed in five focus groups. The purpose of the article was to ascertain what values are involved in experiences with assistive technologies. It is important to understand these values to know how to assess assistive technologies with respect to the users' and other stakeholders' values. The literature review was structured with kind assistance from a university librarian with respect to the databases to search.[24] The EBSCO, Web of Science and Science Direct databases were searched on 2 February 2016. After trials and tests on different sets of search strings, to cover both overall RRI studies on ICT and more specific studies of RRI and assistive technologies one search string was targeted towards RRI and ICT and another was targeted at RRI and assistive technologies.[25] The abstracts of the results showed if they had direct relevance for the literature review by reporting on the state of the art of RRI and assistive technologies. The RRI and ICT search provided 413 articles, of which 368 had none

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[24] I hereby express my gratitude to University Librarian Bettina Grødem Knutsen at OsloMet for guiding me through the maze of databases (and all other assistance), and all eventual mistakes are my responsibility alone. A richer description of the searches is in Thorstensen (2017b).

[25] The strings were: 1) ("Responsible research and innovation" OR "Responsible Innovation" OR "Social studies of science" OR "Science and technology studies") AND ("ICT" OR "Sensor*"); and 2) ("Responsible research and innovation" OR "Responsible Innovation" OR "Social studies of science" OR "Science and technology studies") AND ("Ambient living" OR "Ambient assisted living" OR "Welfare technology" OR "Welfare technologies").

or very little relevance. The search did reveal two special issues on very relevant themes.[26] After checking for duplicates this left a total of 50 articles. The RRI and assistive technologies search only provided six papers, but after checking for overlap with the previous search, one article was left. This was then followed on 21 April by a search of the Directory of Open Access Journals (DOAJ) and of Google Scholar, since many RRI-related studies are published first as deliverables to research projects or as reports. After correcting for overlaps with the previous search, this added 28 new studies plus previous knowledge of two ethical reviews on the theme (Hofmann 2013b; Novitzky et al. 2015). Based on this new research, the "snowball method" was applied, that is, using the references in the works to identify other studies of interest, which yielded 13 new studies. Having read the complete material, the methods, findings and conclusions were structured based on the operationalisation of RRI by Wickson and Forsberg (2015), and the policy areas covered by RRI according to the European Commission (2012). The input from this review can be seen in the second article, "Key concerns from the literature", about how assistive technologies affect the lives and well-being of older adults.

The second part of the material for this study came from five focus groups and the two first engagements with residents at the assisted living facility in a format called Dialogue Café. There was a total of 24 participants in the five focus groups; all participants worked in some aspect of the home health services, but had different professional backgrounds. The topic was technologies in home health care, moderated by one experienced researcher and a co-moderator to benefit from the strongest feature of focus groups, which is bringing out views and ideas through interactive discussion between participants with a similar background (Hennink 2014). All the focus groups were recorded and transcribed verbatim, and the transcripts were shared among the interviewers.[27]

The transcripts were used to look into how the participants valued assistive technologies, based on a model promoted by van de Poel (2013), which distinguishes between values and norms. Norms are prescribing actions that are justified by values. Norms point towards

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[26] *Technological Forecasting and Social Change*, Volume 93, Pages 1–146 (April 2015); Science, Technology and the "Grand Challenge" of Ageing; *ALTER - European Journal of Disability Research/Revue Européenne de Recherche sur le Handicap*, Volume 3, Issue 2, Pages 85–184 (April–June 2009); Ageing, Technology and the Home: Researching new care configurations/Vieillissement et technologies : recherches sur les nouvelles configurations du soin à domicile.

[27] See Appendix A for the interview guide.

actions; either towards prescriptions or restrictions of actions. Actions can be "cooking", "falling", "shopping". Values are then what norms aim to realise, or what the norms are "for the sake of", that is, "one should avoid falling for the sake of well-being". Here the action is "falling" and the value is "well-being". The starting point was to look for such norms as the basic themes for coding in Nvivo (Ryan and Bernard 2003), before reading the whole transcribed manuscript and coding the cases where the value behind this norm was stated, or implied by context. These values were then coded accordingly. The same analytical method was applied to the material from the Dialogue Cafés. However, these were not transcripts but summaries of the group discussions and a final résumé by an appointed co-ordinator. The second article used material from the two Dialogue Cafés; the first discussed challenges in daily living and the second discussed possible technological solutions. The analyses of the focus groups and the Dialogue Cafés were used to ascertain what the participants valued (regardless of technology) both overall and with a sensitivity for individual viewpoints.

In Thorstensen (2019a) the selection of socio-ethical candidates was based not only on the frameworks that appeared in the literature review, but also on the frameworks discussed in the studies on integration of HTA and socio-ethical issues. The method for comparison is adequately described in the article and will not be repeated here, but the choices are discussed in Chapter 5.

There were also some methodological choices for Thorstensen (2019b). There is an account in the paper, but the main choice was which decision-makers to approach for assistive technologies, and how to approach them. The goal was to gain knowledge of whether, and how, the Ethical HTA Matrix could be used in the governance of assistive technologies. Expert interviews should be open and flexible, with a list of themes to be covered but without a strict structure (Meuser and Nagel 2009). GPS localisation systems were chosen as the object to discuss with the interviewees, as realistic a case of an assistive technology where the Ethical HTA Matrix had been applied. The questions were structured on a Socratic approach under the different stakeholder categories and under *well-being, dignity* and *fairness*. The questions had guided the study of the reports, papers and documents. The literature was collected based on several reports from SINTEF that had performed tests with GPS localisation devices and systems, on their lists of references and Google Scholar notices on who had referred to these studies. The findings were placed in a matrix structure.

In a process for an Ethical Matrix, the values affected need to be assigned a weight by the stakeholders themselves (Mepham et al. 2006; Forsberg 2007a). This was achieved by

establishing contact with a Norwegian municipality using the GPS localisation system. Through negotiations it was agreed that they should assist in finding persons who could assign importance to the different values, based on the scale proposed by Forsberg (2007a) of *important*, *very important* and *not important*. The municipality distributed the forms to health professionals and next of kin and to representatives who made procurement decisions. As the object of study was not these stakeholders' opinions, no demands were set concerning representativeness or other statistical measures. The inputs were only meant provide content for the Ethical HTA Matrix truthfulness, and not to be a study in their own right.

One-to-one interviews that lasted approximately 20 minutes were conducted with the persons with dementia, who all had capacity to consent according to their nurse. Following Kennedy and Ter Meulen (2016), as little stress as possible was placed on them and the interview was more of a conversation about experiences with using a GPS localisation tool. The questionnaires were filled in afterwards, with the assigned importance as understood from the conversation.

The input from the stakeholders, the final Ethical HTA Matrix was developed, which then formed the basis for the interviews. The interviews were recorded, but not transcribed. Notes were made of key points on further listening.

3.2 Theoretical framework

The overall objective of this thesis is to contribute to the responsible governance of assistive technologies through a methodological development of responsible assessments. The ambition is that the outcome will influence the policy-making process of assistive technologies. To investigate the quality of the findings and conclusions, it is necessary to have a frame for the investigation. The approach in this thesis is to develop a suitable assessment method, starting with a study of the literature and followed by empirical investigations. Its aptness for informing a policy- or decision-making process should determine what kind of theoretical framework should frame the discussion.

The results and the methodology presented in the fourth article (Thorstensen 2019b) depends on the research in the two prior articles (Thorstensen 2017c; Thorstensen 2019a) and on the conceptualisations in the first article (Forsberg and Thorstensen 2018). Accordingly, feedback on the results as presented in fourth article should set the stage for the reflections on the previous work. To structure these reflections, it is appropriate to draw on the research and theoretical conceptualisations for social and ethical assessment of new technologies.

3.2.1 Responsible assessments

In an early paper von Schomberg (2012) had connected RRI explicitly to assessments of new and emerging technologies, especially Technology Assessment (TA). It is worth emphasising that this thesis connects to the established fields of TA, which aim to understand (and influence) the possible trajectories of technologies in society. However, this thesis has a narrower scope than most TA projects since it uses the value potential in RRI to adapt existing assessment tools in assistive technologies to investigate their usefulness for what I refer to as *responsible assessment*. A further ambition is to extend the assessment of social and ethical dimensions of specific assistive technologies so that influential stakeholders can perform their own small-scale TAs based on RRI.

As Forsberg et al. (2015) write, the concept of *responsible assessment* has two dimensions. The first is how assessments of science and technology might increase – or just affect – the overall responsibility of research and innovation processes (including their policy aspects). The second dimension concerns how the assessment practices themselves practice responsibility. In Forsberg et al.'s parlance, the first dimension is orientated towards advising *for* responsibility, while the second seeks to advise *with* responsibility. Pacifico Silva et al. (2018) introduction of RRI in health is an example of advising for responsibility, since they

point to specific substantive themes that ought to be addressed in the health domain for innovations or innovation policies to be *responsible*. While advising *with* responsibility would depend on the conceptualisation of responsibility.

Pellizzoni (2004) remarks how the concept of *responsibility* is constituted by two different traditions. One emphasises imputability, or the capacity to trace one action back to an agent, and the other emphasises justification, or the search for the reasons why the agent performed the action. As mentioned, a main aim in RRI is to anticipate the potential outcomes of research and innovation. Likewise, a responsible technology assessment should anticipate the creation of ties between agents and their actions and the reasons for performing those actions. Under conditions of responsiveness, or being receptive before committing to an action, a responsible assessment would imply an understanding of what people wish for and value and how those values and preferences are affected by a decision to implement, for example, an assistive technology. People's values and preferences depend on background, class, work, personality, nationality, religion, and interests – just to mention some factors. There are several suggestions on how to perform anticipatory analyses that take into account such differences while providing decision- or policy-makers with the knowledge to enable them to modify their decisions. Another important feature of responsible assessment practices is their quality criteria. What remains a challenge is finding a measure that can compare the quality of these suggested approaches according to specific criteria, that is, how responsible the assessment approach can be said to be.

One approach that has investigated the quality of normative frameworks that aim to inform policy- or decision-making can be found in Kaiser et al. (2007). In the context of so-called ethical tools, they discuss what they refer to as the soundness of ethical frameworks, which is the quality of a procedure that includes the relevant factual knowledge through a competent ethical analysis. Even though Kaiser et al. focus explicitly on ethical frameworks, their criteria for ascertaining soundness are relevant to wider normative assessments. Their understanding of soundness and some recent modifications are discussed below, followed by proposed improvements to their analysis of the quality of normative frameworks, ending with a return to the relationship between ethical frameworks and wider RRI frameworks.

3.2.2 Framework qualities

There are two main approaches to the integration of explicit normative content into the tradition and practices of TA. As Lucivero (2015) points out, one of the rationales behind the

Ethical Bio-TA Tools project was the lack of explicit normative approaches in TA and a deficit of social information in the tradition of bioethics, medical ethics and applied ethics in general. The Ethical Bio-TA Tools project originated in applied ethics, in the participatory processes in TA and, as a third dimension, in Corporate Social Responsibility. Others have taken more constructivist approaches based on the normativities of the technologies and how one might align such normativities to enhance societal value (cf. Swierstra et al. (2009); Coeckelbergh (2012)). I will return to this approach in the discussion of the relation between the Ethical HTA Matrix and RRI (see Chapter 5.2.2). The theoretical framework in this thesis relies on the tradition from applied ethics.

As a member of the Ethical Bio-TA Tools project (2002–2005), I participated in one early effort to provide a general formulation on the soundness of ethical frameworks based on the following indicators,

1. Inclusion of values at stake
2. Transparency
3. Multiplicity of viewpoints
4. Exposition of case-relevant ethically-relevant aspects
5. Inclusion of ethical arguments (Kaiser et al. 2007)

These indicators stem from a discussion in the applied ethics and TA community on how to decide on the suitability of one normative approach over another. In an earlier book, we followed the suggestion put forward by Moula and Sandin (2015) of reducing Kaiser et al.'s indicators to two, *transparency* and *comprehensiveness*, while adding *user-friendliness* (Forsberg et al. 2017). Moula and Sandin follow Kaiser et al.'s understanding of transparency, but subsume inclusion of values at stake, multiplicity of viewpoints, case-relevant ethically relevant aspects and ethical arguments under *comprehensiveness*, since these all point to one and the same quality. Unlike Kaiser et al., they add the category *purposiveness* – "how well tools achieve their designated purposes" (Moula and Sandin 2015: 272). Purposiveness, they argue, is not a property of the tool itself, but rather a property of the tool in its context. Consequently, they separate the qualities of the tool from how well it works in a given case. They add the criterion of procedural fairness, a tool's capacity to reduce power imbalances. Furthermore, they provide an additional sub-category of ethical tools, decision-making tools that should contain "the *ability to guide users to a decision according to ambition*, and *theoretical justification of decision supporting mechanism*" (Moula and Sandin 2017: 123 - italics in original). They point to a weakness of ethical tools in general, namely, the use of the term "tool". Of course a tool should give you an outcome, otherwise why would one use it?

The criticism of the whole ethical tools project inherent in Moula and Sandin's criteria, which is echoed by others, [28] was anticipated by Beekman and Brom (2007) and the Ethical Bio-TA Tools project:

> While one cannot expect – and should not wish – that the use of ethical tools would lead to a unique and completely satisfactory answer, one should expect that they are capable of simplifying and facilitating decision-making processes by capturing those considerations that are needed for an ethically well-considered judgment. Ethical tools require skillful use and should not be confused with calculating machines or algorithms. They are practical methods designed to assist those who want to improve ethical deliberations by capturing a broad range of ethically relevant aspects of an issue (Beekman and Brom 2007: 8).

Their view differs from Moula and Sandin's expectations of guiding and they have a different ambition, namely, to simplify and facilitate the decision-making process. Forsberg (2007b) argues that even though tools such as the Ethical Matrix in themselves do not lead to conclusions, they provide a critical apparatus for justifying moral judgements. Ethical tools as a concept might even include methods for showing the divergence of opinions on an issue rather than pointing to a unified answer, as is the case with the Ethical Delphi (Millar et al. 2007). It might be easier to think of ethical tools as tools for doing ethics rather than tools for reaching decisions. Accordingly, the understanding of why one conducts an assessment becomes a central issue, and one cannot assume that the sole purpose of an assessment is to reach a conclusion. I return to this point in the discussion of *purposiveness*, but signal here that tools ought to give a wider or deeper understanding of the normative and factual issues and their interconnection.

While the reduction from four elements in Kaiser et al. (2007) to comprehensiveness in Moula and Sandin (2015) and Forsberg et al. (2017) might be considered a form of economising, I remain unconvinced that merging four indicators into one creates a more refined approach to an analysis of the tools and therefore avoid further use of the terms soundness and comprehensiveness and limit myself to using the indicators for discussion concerning responsible assessments.

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[28] The lack of a process for achieving a conclusion is a criticism of ethical tools raised by Cotton (2014) in his review of the Ethical Matrix, and echoed by Reijers et al. (2017), who consider that the lack of a structure for separating different sociotechnical alternatives is a drawback with ex post assessment methods.

In the literature after Kaiser et al.'s formulation, several possible criteria for the evaluation of assessment methods have been suggested. The following distinguishes between criteria that relate to the tool or framework itself and contextual criteria as proposed by Moula and Sandin. It can be difficult to separate these clearly, but such problems are a theme of the discussion. There are two types of contextual criteria: one involves who the users are and why the tool is applied at all (*user-friendliness* and *purposiveness*); the other regards the quality of the performance of the assessment (*interactive quality*).

The following is an account of my understanding of these criteria, which concludes with a proposal on analysing the quality of an assessment approach.

3.2.2.1 Inclusion of values at stake

As RRI is orientated towards creating social benefits and realising ethical values through research and innovation, a framework would need to include the goods and values that might be affected by a decision. The absence of a relevant value might bias a decision and have consequences at a later stage in the societal reception of the technology, as witnessed in the European discussion on GMOs in the 1990s (which is a central part of the background for ethical tools) (Wynne 2001; Beekman and Brom 2007).

While this criterion is easy to state, it demands more in terms of analysis, since the completeness of relevant values can be approached from above, in terms of the scholarly qualities of the framework, and from below, when it comes to stakeholder validation.

3.2.2.2 Multiplicity of viewpoints

Participatory methods for stakeholders should understand their different interests, values and preferences with respect to the issue. Consequently, any outcome will be based on some of these interests, values and preferences. It is preferable to be explicit about this particularity of the method because it makes clear that when discussing the social world (as opposed to the physical world), there is no privileged "view from nowhere" (Nagel 1986). Since democratic societies are pluralist, as a rule no one point of view or moral doctrine should as a rule be given priority (Ross 2002) and the range of existing concepts of what is right and good should be included.

Based on the argument put forward by Kamm (2007) on the intricacy of ethical viewpoints, Moula and Sandin (2015) state that a multitude of viewpoints might conflict with the ideal of transparency, or even be contrary to transparency.

In their discussion on the inclusion of stakeholders in policymaking processes, Coenen and Grunwald (2017) promote the idea that engagements and dialogues should be *modest* in scope, which they understand as focusing on concrete applications, so that only relevant civil society organisations and policymakers are invited, rather than a wide plethora of ecological, political or age-specific groups. Furthermore, this view suggests that one should emphasise the futures that might take place in the policy processes regarding new technologies, and be wary of a tendency to oversell the transformative powers of one technology.

The criteria for framework quality could contain some conflicting elements, and it could be an empirical question whether transparency conflicts with multiple viewpoints, and I return to this question in the discussion. However, based on the lessons from the sometimes-biased assessments of assistive technologies as discussed above, this criterion is relevant and its hypothetical detrimental effects should be explored.

3.2.2.3 Transparency

One motivation for introducing ethical tools was to move beyond the closed world of committee-based decision making, possibly influenced by invisible power and prestige. To avoid these suspicions, there seems to be a consensus that transparency is the most effective and the proper attitude and practice to document the steps in the different phases of an assessment to show how the conclusion follows from the different arguments.

To analyse transparency in a more refined manner, I have made a tripartite division of transparency to test in this thesis. This division is inspired by the study of legitimacy and Schmidt's (2013) tripartite division, who distinguishes between input, throughput and output legitimacy. Legitimacy rests upon a relevant public approval of the goodness or rightness of an issue: input legitimacy is the inclusion of the right people or themes in making a decision; throughput legitimacy is that the decision is made according to a fair, good or, in other aspects, correct manner; while output legitimacy is that the right goods are given to the right people or distributed in a good manner.

As studies in governance indicate, the quality of a process – or its throughput legitimacy – cannot be the object for a trade-off where more or less of the one might compensate for the other (Schmidt 2013). This difference separates throughput legitimacy from the output and input dimensions where a deficit in one might be compensated for by the other being perceived as legitimate. In addition, a lack of throughput legitimacy may lessen both input and output legitimacies. Consequently, throughput is a crucial factor in that it might only have

a negative effect on the other modes of legitimacy. Following from this division for legitimacy, I introduce, what I believe to be a novel division for transparency and distinguish between input transparency, throughput transparency and output transparency.[29]

Based on Schmidt's (2013) division *input transparency* is an openness about all the elements that are provided, collected or used in order to provide substantive impact on the process. This not only encompasses the different stakeholders and their relevance, but also other sources of knowledge and the choice of secretariat or facilitator. *Throughput transparency*, refers to the documentation and communication on how one step leads to the next and the procedure includes evaluations of facts, values and arguments. *Output transparency* then refers to the degree of openness of the direct goods produced (or the absence of such goods) by process and by distribution.[30]

My novel concept of input, throughput and output transparency are, in a sense, prerequisites for the different types of legitimacy. Without insight into what or who is included in a decision, it seems unlikely that input legitimacy will be high. The same point is valid for the throughput dimension and this situation will normally be the case for output. Where it will be different with regard to output is specifically when the output is intangible, as in the form of providing advice based on a process that is intended for further use. It seems reasonable to look at epistemic output as a form of collective good that everyone might share without harming another's access to the same good. Consequently, these goods should be cared for. In the context of providing advice through assessments, the outcome is epistemic in all cases. They produce knowledge through the valuation of a given situation. One important factor in responsible assessments is consequently that they provide useful, good or right knowledge.

One central question that has been not addressed this far is *transparency towards whom*? Bodies tasked with, for instance, a mandate to provide options on assistive technologies are often expert- or stakeholder-based. The ideal of transparency is often thought of as being towards the public (Sunstein 2018). However, there are enormous public costs associated with

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[29] See also Reynaers and Grimmelikhuijsen (2015) who refer to *process transparency* rather than throughput transparency. I prefer to use throughput transparency for systematic reasons. Likewise for the notion of output transparency, which is called *communicative quality* by Bütschi et al. (2004), who refer to this notion as the assessment process' communication to the outside world.

[30] The notion of output might refer to a range of effects of an action. It is beyond the scope of this thesis to explore the differences between such effects, but see McLaughlin and Jordan (1999) and Taylor-Powell and Henert (2008) for further discussion and conceptual clarification.

obtaining information on such decision making. A complementary view on safeguarding transparency suggests that openness should also be directed towards a body appointed by the public or relevant stakeholders, such as quality assurance boards or ombudsmen. These differ from the public in that they have a mandate to intervene. If transparency is understood as transparency of the process towards proper public regulators, then a more substantive and systemic approach to transparency might be strengthened (Kostadinova 2015).

From a foundational discussion of RRI, Zwart et al. ask, "Which interpretation of responsibility are we to pursue? Relying on 'process' and 'dialogue' runs the risks of missing the mark and delivering responsible innovations that fail to address the grand challenges on a macro-scale" (2014: 17). This can be seen as a hidden criticism of approaches that rely solely on procedural criteria for what should count as responsible. In this respect, a proposal by Coenen and Grunwald (2017) to separate between a *weak* and a *strong* form of RRI seems salient. Based on readings of quantum technology policies, they argue for what I refer to as *output transparency*, that is, that the results of engagement activities and dialogues connect to policy deliberations or decision-making processes and are not only contained within the sphere of a project or technology field.

The notion of transparency and its use as a criterion for tools should not be limited to the tool and its users, and should provide a wealth of information. In plans for Ethical Impact Assessments, transparency comes from involving stakeholders as controllers at distinct stages (Wright 2015; European Committee for Standardization 2017). This approach meets a demand for structured transparency and is aligned to the ideals in RRI.

In the context of establishing quality criteria for tools, this idea of output transparency points to a need to apply a tool that yields the form and content a process initiator would benefit from in the next stage. In other words, achieving output transparency rests upon the purpose of the assessment.

3.2.2.4 Relevance, reliability and scientific quality

Forsberg (2007a) argues that ethical tools should be evaluated by their reliability. She divides reliability into two categories:

> intramethodological stability (i.e., that the same assessor(s) in relevantly similar situations should reach the same conclusion) and intermethodological stability (i.e., that different (groups of) assessors in relevantly similar situations should reach the same conclusion) (Forsberg 2007a: 31)

She concludes by stating that 100% reliability seems unrealistic, and queries what the tolerance should be for divergence between two applications in two different contexts on the same issue. Forsberg also proposes validity as a possible criterion for the evaluation of tools, but avoids this measure as it is problematic to assert what constitutes a valid moral judgement. In their discussion of methods for public engagement, Rowe and Frewer (2004) see validity as challenging because of problems with finding the proper scope and range of the instrument for measuring it. They state that the same concerns are applicable to a discussion on reliability. Moula and Sandin (2015) question Forsberg's assumption that intermethodological stability should be a criterion since if the users of a tool in two different settings have divergent views on the prioritisation of the same value, then the tool should give different outcomes in the two situations. Otherwise, Moula and Sandin write, the tool would seem to be biased towards one specific view. Perhaps Moula and Sandin are not being charitable with this criticism as Forsberg specifies that one should only expect such outcome similarity in "relevantly similar situations".[31] I will follow Forsberg in refraining to assess validity, but also refrain from a reliability assessment, as the assessment approach explored here to a lesser extent is orientated towards drawing conclusions, but rather on facilitating structured dialogue. As both reliability and validity are problematic measures in this context, I will rely on the other parameters in the analysis of the quality of the Ethical HTA Matrix.

In the discussion of the TAMI-project, Bütschi et al. (2004) separate between scientific, interactive and communication quality criteria as the higher order criteria for the qualities in TA. For scientific quality, they aim for scientific robustness understood as a combination of scientific perspectives through interdisciplinarity and scientific reliability.[32] Reliability is

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[31] The hypothetical situation that two similar groups will conduct identical assessments seems unrealistic. There are two different aspects that make the notion of intramethodological stability a hypothetical issue. The first is the observation from so-called NEST-ethics (New & Emerging Science and Technology) of a tendency to emphasise different ethical aspects of technologies at different stages of their development (Swierstra and Rip 2007). The second is that our views on novel technologies are not based solely on our internal values, but are fundamentally dependent on external events (such as Fukushima) or issues related to perceived distributive injustices and also vary within societies depending on other social parameters, such as trust in government (Biotechnology and the European Public Concerted Action group 1997; Correljé et al. 2015; Hochschild 2016; Kitada 2016). In addition, it is uncertain whether it is a capacity of the tool, its application, or simply the matter at hand that yields the different or similar outcome.

[32] Interdisciplinarity needs further elaboration as a theoretical term, which is understood differently depending on different views on the reality claims of scientific theories (Schmidt 2011). I will not problematise these issues further.

sought since experts might mix their personal preferences with scientific advice. Tools for establishing reliability can be meetings between experts or between experts and citizens or extended peer review, that is, a process where non-experts are in to express their opinion on scientific facts and conclusions (Funtowicz and Ravetz 1993).

If one holds the position that scientific quality cannot be established outside a relation to politics, such as Jasanoff (2011), this view might entail that either the political should be given priority or that the pluridisciplinary (either trans- or interdisciplinary) should be given priority when it comes to the assessment of scientific quality. With their notion of "case-relevant ethically relevant aspects", Kaiser et al. (2007) seem to open up a more dialectical understanding for a discussion of the proper relation between science, scientific advice and policy and the connection between these relations and the division between facts and values. In the current setting, which is not orientated to ethics, it is possible to relabel this criterion as "case-relevant policy-relevant aspects". This means that the discussion over reliability becomes a question of how well a tool is able to present and represent the relevant positions of different stakeholder categories with respect to the issue. Hence, the term relevance seems to be notion that can cover both "case-relevant policy-relevant aspects" and reliability. Pragmatically, "relevance" counters the objection concerning the lack of conclusions, since a policy relevant assessment could provide the material for a conclusion or maybe the policy purpose is not to reach a conclusion. It covers reliability in the sense that, through meeting policy, conclusions become validated and controlled against common morality and common sense.

3.2.2.5 Inclusion of ethical arguments

Kaiser et al. (2007) argue that the relevant factual information and its connection to ethical viewpoints contributes to the strength of a framework. If one accepts that an ethical position is reached through a process similar to that of a reflective equilibrium (Rawls 1971), then a central feature of an ethical framework would be not only to present principles and facts, but also the relevant ethical arguments.

This criterion displays or communicates the relation between a situation and its valuation . The valuations might well differ from stakeholder to stakeholder as well as between stakeholders and between ethical principles.

3.2.2.6 Purposiveness

Regarding the criterion of *purposiveness,* the most systematic attempt at characterising and systematising different purposes of assessment seems still to be the European TAMI project (**T**echnology **A**ssessment (TA) in Europe; between **M**ethod and **I**mpact) (Hennen et al. 2004). They distinguish between types of impact and types of issue. The different impacts are *raising knowledge*, *forming attitudes*, and *initialising actions*; while the different issues relate to *technological aspects*, *societal aspects* and *policy aspects*. As shown in the EST-Frame project, different forms of assessment, such as risk or economic assessments, can be categorised according to the TAMI impacts and issues. Even though there are some patterns as to what purpose the different forms of assessment aim to serve, it is difficult to state that there are clear regularities (Forsberg et al. 2013). A useful point of departure is the TAMI distinction in types of impact and types of issues, which is presented in Table 3.2.

Focus of the assessments		Role of assessment in policy making process		
		Cognitive – raising knowledge	**Normative – forming attitudes**	**Pragmatic – initialising action**
Object	**Scientific/ technological aspects**	Scientific Assessment a) Technical options assessed and made visible b) Comprehensive overview on consequences given	Agenda Setting f) Setting the agenda in the political debate g) Stimulating public debate h) Introducing visions or scenarios	Deframing of Debate o) New action plan or initiative to further scrutinise the problem at stake p) New orientation in policies established
	Societal aspects	Social Mapping c) Structure of conflicts made transparent	Mediation i) Self-reflection among actors j) Blockade-running k) Bridge building	New Decision-making q) New ways of governance introduced r) Initiative to intensify public debate taken
	Policy aspects	Policy Analysis d) Existing policies assessed e) Setting the agenda in the political debate	Re-Structuring the Policy Debate l) Comprehensiveness in policies increased m) Policies evaluated through debate n) Democratic legitimisation perceived	Decision Taken s) Policy alternatives filtered t) Innovations implemented u) New legislation passed

Table 3.2 TAMI Typology of impacts (Hennen et al. 2004: 63)

Building upon the TAMI approach and thinking, Forsberg et al. (2016) suggest that reflections on the purposes are internal to the assessment process but exterior to the actual assessment, as part of what they call the TranSTEP model. This choice relates to the

reflectivity aspect of RRI as articulated by Owen et al. (2013) since it is based on the argument that declaring the purpose of an assessment is in itself a normative act (see also Hofmann (2005a)).

Forsberg et al. have a different scope to Moula and Sandin in that they investigate the integration of assessment approaches through enhanced reflection on what sort of knowledge is actually needed. Rather than purposeful methods, Forsberg et al. use the notion of "targeted methods" and refer to the TAMI project.

Since the overarching theme for this thesis is exploratory with respect to how assessments might improve governance, it also uses the criterion of purposiveness in an exploratory manner. It investigates for what purposes the Ethical HTA Matrix might be useful in the research and innovation of assistive technologies as a means to enhance responsibility.

3.2.2.7 User-friendliness and frugality

Kaiser et al. (2007) report that there was a conflict between the Ethical Matrix' ability to structure ethical concerns and its *user-friendliness*. Moula and Sandin (2015) suggested including user-friendliness as a criterion for measuring the quality of ethical tools as it is external to the quality of a tool for performing ethical deliberation, but relates to "how demanding a tool is with regard to economic resources and time" (Moula and Sandin 2015: 275).[33] They take a different approach to Rowe and Frewer (2000) concerning the evaluation of public participation exercises. Rowe and Frewer suggest that a significant criterion of success is whether adequate resources are assigned to the suggested method, which is a different, or even opposite, perspective from the one underlying Moula and Sandin's suggestion. We all have an intuition concerning the meaning of user-friendliness and limiting it to economic resources and time seems counterintuitive. Moula and Sandin's criterion could more adequately be described in terms of resources and be labelled as an efficiency criterion, that is, when two tools are comparable on all other criteria, the more efficient one should be chosen. One might want to include an efficiency criterion, but one needs to keep in mind that assessments require resources, as Rowe and Frewer point out. Inspired by Pacifico Silva et al. (2018), a criterion that could encompass points from both Moula and Sandin and Rowe and Frewer is that of *frugality* since they include resource requirements, and that they should be

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[33] Moula and Sandin describe user-friendliness as something not very demanding for the users, but this formulation is difficult to argue either for or against since what is demanding might also be rewarding – see Rothenberg (1993).

spent adequately but not unreasonably on the task – although both efficiency and frugality should be kept distinct from user-friendliness.

The issue of user-friendliness also opens up the question of who the intended user is supposed to be. Some degree of professional competence is required in each assessment domain: economic assessments need a knowledge of different approaches to the study of costs and benefits; risk assessments require a knowledge of both the assessed unit and its impact in different environments, which is rarely held by one individual; for an EU impact assessment, many different competences are needed to understand the impacts a suggested change might have on industry, land use, traffic and so on (Forsberg et al. 2013). While non-ethicists should be able to apply ethical tools (see Forsberg et al. (2017); Kaiser et al. (2007), Beekman and Brom (2007) underline that the competent use of such tools is a prerequisite for obtaining sound results and, more specifically, for including multiple viewpoints. Kaiser et al. seem to imply that competence is connected to ethics, which creates a tension between some of the ambitions behind the tools.

Understanding the user-friendliness of other assessment approaches can be inspired by other fields of activity. It is measured in software development by the system usability scale (Brooke 1996), which is also a part of the assessment protocol that creates the basis for *The Matrix*. In the field of assistive technologies, the Technology Assessment Model (TAM) is frequently applied to understand the use or non-use of devices (Venkatesh and Davis 2000). This model connects user-friendliness not only to the device, but also to its perceived usefulness – which is affected by relevance, quality of output and results and the perceived ease of use. In design, there is talk of a conceptual model as a fit between user, designer and product (Norman 2013). In the study of literature, there is the notion of the implied or postulated reader, which designates the ideal reader the author had in mind (Booth 1983).

These considerations lead to the conclusion that *user-friendliness* is a theme to be explored in the discussion more than being assessed as part of the quality of the framework. There are two central dimensions to be explored: first, who is the implied user of the tool; and, second, what sorts of adaptation – of either user or tool – are necessary to use the Ethical HTA Matrix and can similar tools be adapted for a better fit to the desired users.

3.2.2.8 Interactive quality

Both Moula and Sandin (2015) and Bütschi et al. (2004) discuss the importance of the *procedural fairness* or *interactive quality*, as they respectively call the same phenomenon. A

central idea behind Ethical Bio-TA Tools came from experiences with ethics committees where procedures were limited to round table discussions without any consideration of power imbalances or strategic behaviours. Procedural fairness describes methodological throughput elements that can affect results or outcomes and their legitimacy. These elements can be separated into different phases: agenda setting, dialogue standards and decision procedures (Bütschi et al. 2004). A framework should then allow participants to understand and discuss the agenda and the underlying priorities; the process should have inbuilt methods for securing equal access to the discussion; and the eventual decision should be made according to a procedure of which participants have a reasonable degree of mutual understanding and that qualifies as legitimate.

This criterion is different from throughput transparency since the interactive quality pertains to the action taking place and transparency refers to the relevant public having proper access to the information concerning these actions. However, as discussed under transparency, throughput transparency is a prerequisite for the relevant public or competent body to have knowledge concerning the interactive quality.

3.2.3 Concluding remarks

A good assessment is a responsible assessment. This section argues that there is a need to evaluate the quality of assessments, which can be performed by looking at the quality of evaluations from the earlier discussion on ethical tools or frameworks. Chapter 5.1 discuss how the Ethical HTA Matrix relates to the criteria discussed above.

Pellizzoni's (2004) conceptualisation of responsibility as responsiveness is expressed in the theoretical framework on how well an approach is able to take into account a rich understanding of the matter at hand, how this affects different stakeholders, and how these stakeholders value these effects.

As argued above, the evaluative framework proposed by Kaiser et al. (2007) conceptualises and operationalises how well an assessment approach manages to include values from different stakeholder perspectives in a transparent manner with regard to input, throughput and output, while delivering relevant information on the underlying arguments. Furthermore, there are central contextual elements that influence the responsiveness. I have argued that the main elements are the purpose of an assessment, its user-friendliness and its frugality, but in addition there is the quality of the interaction between stakeholders and the facilitator and among the stakeholders.

The subsequent discussion emphasises the following elements: how and why are these values included, which discusses my choice of combining the Ethical Matrix with the Socratic approach; how the Ethical HTA Matrix and my testing of it relates to input transparency; a case for why the Ethical HTA Matrix seems a better fit with the ideals of transparency due to its simple structure; a debate on the traceability of the conclusions; a suggested need for increased output transparency in HTA in light of RRI; the potential of the Ethical HTA Matrix to contribute to increased transparency in both RRI and HTA.

Given the multiplicity of viewpoints it seems relevant to discuss whether the underlying research for developing the Ethical HTA Matrix also took into account a range of viewpoints and challenges related to obtaining values through public engagements, ending with reflections on how the Ethical HTA Matrix represents the relevant stakeholders as well as diversity. When analysing relevance, the discussion concentrates on how the Ethical HTA Matrix and its results were received by the informants, before discussing how it expands the field of the political through its focus on health professionals. A final point in the discussion on relevance is whether the format of the tools is still relevant for informing policy as they were developed for a specific sociological context. Give that these are ethical tools there is a brief discussion of the ethical arguments.

An exploration of purposiveness, user-friendliness and frugality, and interactive qualities aims to enlighten why, where and how an Ethical HTA Matrix might be applied to expand responsibility.

Finally, it should be noted that the motivations behind RRI are connected to solving social and political challenges, rather than to purely technological challenges, through research and innovation. A focus on responsibility as responsiveness provides a normative procedural demand for learning about those affected by novel technologies as well as in-depth studies of the technologies themselves. In the health system, responsiveness implies that solutions should take into account local knowledge and values, but without limiting itself to this horizon. The notion of a responsible assessment is based on a responsive attitude to values for a select technology that addresses a social or political challenge.

4 Articles

Forsberg, E.-M., & Thorstensen, E. (2018). A Report from the Field: Doing RRI from Scratch in an Assisted Living Technology Research and Development Project. In F. Ferri, N. Dwyer, S. Raicevich, P. Grifoni, H. Altiok, H. T. Andersen, Y. Laouris and C. Silvestri (Eds.), *Governance and Sustainability of Responsible Research and Innovation Processes* (pp. 19–26). https://doi.org/10.1007/978-3-319-73105-6_3

Thorstensen, E. (2017). Responsible Help at Home: Establishing Indicators for a Product Assessment Methodology. In D. M. Bowman, A. M. Dijkstra, C. Fautz, J. Guivant, K. Konrad, C. Shelley-Egan, and S. Woll (Eds.), *The Politics and Situatedness of Emerging Technologies* (pp. 167–182). Berlin: IOS Press.

Thorstensen, E. (2019a). Responsibility for Assistive Technologies: Product Assessment Frameworks and Responsible Research and Innovation. *Etikk i Praksis - Nordic Journal of Applied Ethics*, *13*(1), 55–80. https://doi.org/10.5324/eip.v13i1.2525

Thorstensen, E. (2019b). Stakeholders' Views on Responsible Assessments of Assistive Technologies through an Ethical HTA Matrix. *Societies*, *9*(3), 51. https://doi.org/10.3390/soc9030051

This section summarises the four papers included in this thesis. It looks at the respective research questions, the main findings and how they contribute to increasing knowledge. It concludes by highlighting how these articles fit into the overall thesis.

4.1 From Scratch

Forsberg, E.-M., & Thorstensen, E. (2018). A Report from the Field: Doing RRI from Scratch in an Assisted Living Technology Research and Development Project. In F. Ferri, N. Dwyer, S. Raicevich, P. Grifoni, H. Altiok, H. T. Andersen, Y. Laouris and C. Silvestri (Eds.), *Governance and Sustainability of Responsible Research and Innovation Processes* (pp. 19–26). Cham: Springer International Publishing. DOI: https://doi.org/10.1007/978-3-319-73105-6_3

We wrote this article with the intention of sharing our experiences in working with RRI with the larger RRI milieu in Europe. *From Scratch* provides an overview of the challenges of implementing the rather abstract notion of RRI in practice, and the responses to those challenges based on RRI thinking and discussions. The definition of RRI used in the project was:

1. A specific focus on addressing significant societal needs and challenges

2. A research and development process that actively engages and responds to a range of stakeholders

3. A concerted effort to anticipate potential problems, identify alternatives, and reflect on underlying values, and

4. A willingness from relevant actors to act and adapt according to 1–3 (Wickson and Forsberg 2015: 1153).

The Assisted Living project approached the societal challenge of an ageing society through an investigation of individual needs. We highlighted a point of general interest, namely the conflict that arose in engagements with the elderly between what they saw and expressed as challenges in daily life and the reality. We approached them in small groups and discussed challenges and solutions in detail. Between 12 and 18 people took part in the engagement activities. However, among the participants who volunteered to test the solutions recommended through the engagement activities, few expressed a real need since they had found their own bricolaged solutions in their homes.

Outside of the end user engagements, a central part of the stakeholder involvement in the project was the TranSTEP model developed in the EST-Frame project (Forsberg et al. 2014;

Forsberg et al. 2016). The idea was to include a combination of area experts, civil society organisations and central policymakers on the project's advisory board. The working method of this group was to increase reflection on how the Assisted Living project understood the underlying choices.

The internal learning processes of the Assisted Living project team was developed with a view of collaboration as the ability to formulate and reflect on questions, as developed in hermeneutic schools of didactics of history (see (Körber 2011; Körber and Meyer-Hamme 2015). In a very literal manner, questions are necessary for responses – and responsiveness demands that one poses a question to oneself. Through working on questions to each other, one's own background becomes a theme and a subject matter. To develop this approach the first session queried the issue of transdisciplinary research through a selection of key words and topics that characterised transdisciplinarity. The second session explored this further through people identifying which fields, disciplines or domains inside of the project they felt they needed to know more about. In the third meeting, the topics were the similarities and differences among the researchers in terms of their causal assumptions, that is, what would happen when the Assisted Living project installed its solution for the elderly. These questions were taken up again after the project had gained experience with the proposed solutions.

The responsiveness part of RRI has three different aspects: the first is based on interactions with end users and the Assisted Living project's capacities to adapt the register of possible technical solutions from the technical partner to the expressed wishes; the second is how the Assisted Living project takes into account and publicly responds to the suggestions from the advisory board; the third aspect is how project members can inform assumptions and discuss value questions internally through reflective work.

4.2 Help at Home

Thorstensen, E. (2017). Responsible Help at Home: Establishing Indicators for a Product Assessment Methodology. In D. M. Bowman, A. M. Dijkstra, C. Fautz, J. Guivant, K. Konrad, C. Shelley-Egan and S. Woll (Eds.), *The Politics and Situatedness of Emerging Technologies* (pp. 167–182). Berlin: IOS Press. Reprinted with permission. Web-address: https://www.iospress.nl/book/the-politics-and-situatedness-of-emerging-technologies/

This paper asks and answers the question, what are the main values that assessments of assistive technologies should take into account? The paper begins by reflecting on ageing as a social challenge before presenting its rationales, which were closely related to the Assisted Living project aim of looking at how the innovation process influences the outcome. The Assisted Living project was a novelty in RRI studies since it posed the fundamental question: Does an RRI-based process actually improve the product? The paper states that it is necessary to assess whether a product derived from an RRI process is deemed better (or not) by its users as compared to a non-RRI baseline study. It does not claim that such a comparison is sufficient to establish the superiority of an RRI-based process since factors other than the internal processes inside a project might be influencing research and innovation.

This article's empirical basis is four different sources. The first is a literature review, discussed later in this thesis, which inquires into the knowledge status when it comes to RRI in assistive technologies. There is a brief account of the most prominent concerns in the literature, such as: a lack of knowledge on how people actually live with assistive technologies; that users themselves could and should set the success criteria; the framing effects of research and policy on older adults and the research process; the perils of a technology push that implies the need to reflect on alternatives to technology and how they might be stigmatising and increase isolation or in other ways alter lives and create novel risks. A reoccurring issue with assistive technologies is privacy and data security.

The second source comes from experiences in the Dialogue Cafés in the Assisted Living project. An analysis of a discussion with older adults in an assisted living facility in Norway, showed how they talked about central situations in their lives and how technologies related to these situations. Central concerns were socialising, empowerment, amplification of positive situations and reduction of negative situations, safety and security. Their relation to privacy seemed ambiguous since they had clear preferences about not bothering relatives and using social media solutions, but seemed relaxed about video monitoring.

Other themes emerged from the third source, the project advisory board, such as fun and stimulation. They saw the future of assistive technologies as transcending the public/private division and that solutions should be developed that are flexible enough to achieve this aim.

Since health professionals and care workers are an important stakeholder category for assistive technologies, the fourth source was focus groups where I acted as a facilitator. Their views regarding assistive technologies for users related mainly to safety, efficiency and reliability. Our informants further stressed the issue of training, in which next of kin should be involved.

Based on these sources, and in particular on the considerations of what an RRI product assessment should aim for as articulated by Stilgoe et al. (2013), I argue that the Assisted Living project would benefit greatly from an assessment methodology that can differentiate between a range of topics and open up to a deliberation around them. The topics are:

- The good life

- Risks and benefits before use

- Risks and benefits in use

- Distribution of risks and benefits

- Distribution of responsibilities

- Training.

When it comes to more structural concerns for the assessments, I argue that they should include perspectives from different stakeholders and be able to take contextual issues into account.

4.3 Responsibility for

Thorstensen, E. (2019a). Responsibility for Assistive Technologies: Product Assessment Frameworks and Responsible Research and Innovation. *Etikk i Praksis - Nordic Journal of Applied Ethics*, *13*(1), 55–80. DOI: https://doi.org/10.5324/eip.v13i1.2525

Responsibility for builds directly upon *Help at Home* through its use of the values and criteria for an assessment approach in discussing several existing ethical frameworks and approaches. The purpose of the article is to investigate what existing assessment frameworks could be used to assess assistive technologies in line with the conclusions from the second article as well as substantive values from RRI. It is a prerequisite that an assessment framework should be compatible with Health Technology Assessment (HTA) since HTA is a central methodology among decision-makers in health policy and health services.

Analysis and discussion was based on both the ability to function in coordination and interaction with HTA and on a compatibility with RRI. A very open notion of RRI is understood in light of the European Commission's key indicators of RRI, the criteria from stakeholder engagement in *Help at Home*, and scholarly discussions on RRI – with a particular emphasis on Responsible Innovation in Health (RiH) (Pacifico Silva et al. 2018) – in addition to other central contributors such as Owen et al. (2013), von Schomberg (2013) and Strand et al. (2015).

Traditionally, HTA has focused on safety, security and efficiency, understood as the cost-effectiveness of a given health intervention. I address some of the vocal criticism against HTA as a narrow methodology not open to logics other than efficiency, with a perspective that downplays solutions which enhance individual agency and promotes medicalisation. To the extent that social and ethical dimensions are included, they have suffered from being analysed independently of other epistemological dimensions in HTA. Suggestions to remedy this dissociation mainly add complexity to the procedure while subsuming social and ethical issues under general effectiveness research. According to Hofmann et al. (2015) one remedy is to include socio-ethical tools that require HTAs to interact or coordinate with other disciplines. Their overview of such approaches lists, among others, axiological methods (Socratic, EUnetHTA) and the Ethical Matrix. I discuss and analyse these methods in particular, and add the Ethical Impact Assessment, which emerged through the literature review.

I conclude that what seems to differentiate these socio-ethical assessment frameworks from RRI is the lack of reflection on purposes – with the exception of the Socratic approach. They differ from RiH on frugality and social entrepreneurship. With respect to the RRI keys the four frameworks are rather similar, except for the lack of inclusion of sustainability in the Socratic approach and the HTA Core model. For ETIA, the Ethical Matrix and the HTA core model to be fully developed into RRI tools, they need to include uncertainties and ignorance, which they could achieve by modifying their output structure to highlight these elements. The structure of HTA outcomes might well inform RRI, whereas RRI might inform HTA in highlighting that one cannot assume that the medical epistemic or the risk epistemic should have superior value compared to other epistemic domains. RiH contributions regarding the business model, frugality and, especially, health relevance are welcome specifications from RRI to HTA. They share a commitment to reflection on alternatives, but this has a more solid foundation in HTA due to the inherent demands for evidence of the novel technology's superior effect. Consequently, these two processes might be mutually beneficial.

4.4 The Matrix

The place of this article in the thesis is to test the results from *The Matrix* by applying a combination of the Ethical Matrix and the Socratic approaches, called the Ethical HTA Matrix, in order to investigate how decision-makers in assistive technologies perceive an assessment approach in line with RRI. The overarching questions are whether it is helpful or not, and in what contexts it could be helpful.

A proper case test was performed on a GPS system for locating persons carrying a tracking device, where next of kin are first responders through a smartphone-based application. This and similar systems are among the recommendations from the Norwegian Directorate for Health when it comes to assistive technologies that municipalities ought to consider implementing.

Questions from the Socratic approach were structured into the Ethical Matrix for the relevant stakeholder categories. Content was added from Responsible Innovation in Health (RiH) such as climate as a stakeholder, frugality and added social value. These themes formed the basis for a structured literature search for articles, reports and other publications containing tests or assessments of GPS localisation systems. This structuring and the substantive content of the values associated with a GPS system is central to the article as it displays and justifies the content of the final matrix. This content was validated through a web-based questionnaire for all stakeholders, except for persons with dementia who were interviewed in person. These stakeholder engagements formed the basis for weighing – or assigning importance to – the different values affected by the introduction of a GPS localisation system.

The second part of the article is based on interviews with 13 decision-makers in the field of assistive technologies. Key personnel with a long experience in implementing assistive technologies or policies for assistive technologies were visited and a list of themes was discussed on the basis of the completed Ethical HTA Matrix with the GPS localisation system as a case.

As a tool for making a decision regarding whether or not to develop, procure or implement an assistive technology, the Ethical HTA Matrix was seen by all interviewees as containing an abundance of information. I critically discuss my choice of not structuring the values and the consequences according to their importance in addition to other formatting choices, such as colours, weight on the values and the novel category of critical factors, which refers to contextual elements needed for an assistive technology to produce the proposed values.

What emerges through the interviews is that there are spaces in municipal innovation systems where values could and should be discussed in a more structured way. Some informants saw value in using a tool such as the Ethical HTA Matrix at the early stages of thinking about what possible values an assistive technology should aim at and using these values as guiding principles in the political and administrative assessment of a technology. Others found that there is a need for structured discussion around health professional and caregiver experiences at early stages or in pilot phases. They suggested that a tool such as the Ethical HTA Matrix could structure such reflections by concentrating on one topic without losing an overview of the situation.

4.5 Summary

The first article, *From Scratch* (Forsberg and Thorstensen 2018), presented the overall ambitions of the Assisted Living project as an RRI project. While the second, *Help at Home* (Thorstensen 2017b), provided an overview of the central concerns that an RRI-based assessment should address for assistive technologies. The third article, *Responsibility for* (Thorstensen 2019a), builds upon *Help at Home* and discusses how those central concerns place limits on and requirements for what kind of assessment tool or framework a researcher or practitioner might select to ensure that an assessment is in line with RRI and relevant for assistive technologies. The fourth and last article, *The Matrix* (Thorstensen 2019b), applied a combination of two tools from *Responsibility for* and sought out influential stakeholders' views on their application.

The articles relate to the overarching project of investigating responsible assessments by commencing an exploration of how a research project in assistive technologies might be aligned to RRI. The normative demands for procedures and substantive themes in the RRI literature provides resources to discuss earlier assessment tools or frameworks. The broad approach to RRI applied in this research, gives an analytics through which these tools and frameworks might be adjusted to strengthen them towards increased responsibility. Lastly, a

modified version of these tools provides an insight into existing municipal assessment processes and a vehicle for reflecting upon where, why and how assistive technologies should be assessed.

5 Discussion

5.1 Discussion of responsible assessments

This project explores what assessments of assistive technologies mean in light of RRI and how they might contribute to the responsible assessment of assistive technologies. I believe it has contributed to this goal and has made some additions to the field of RRI and assistive technologies. One central contribution has been on how to translate and implement thoughts from RRI in the field of assistive technologies in particular and to the health and welfare field more generally. The application of the thinking and practice of RRI might be used to discuss different forms of product assessment or ethical tools or frameworks in order to see some specific RRI qualities of these assessment approaches. An equally important finding is how to identify spaces for systematically addressing value issues in municipal innovation processes. These spaces are either early in a process, where the municipality needs to know how to realise different values, or in an implementation phase, where there might be a need for structured debate concerning how different stakeholders' values are affected by a novel technology in order to make appropriate judgements.

I have now made a connection between RRI, responsible assessments and framework qualities by arguing that RRI implies a responsibility to obtain knowledge concerning how technologies alter and affect people's lives in order to be responsive to such changes. Furthermore, it is through systematic investigations of such changes, with a basis in values (which I refer to as assessment following Kaiser et al. (2010)), that knowledge ought to be obtained. What is also necessary is some measure against which to consider the quality of assessment and such measures were presented in the theoretical framework. I will now proceed to discuss how the Ethical HTA Matrix and the processes associated with creating and applying it perform according to these measures.

The discussion follows the structure of the theoretical framework, and relates to central themes in RRI, assistive technologies and qualitative research. It ends with a focus on the use of modified ethical approaches as comprehensive RRI approaches and points to some dimensions of RRI that might be under-represented when building on approaches from the field of ethics.

5.1.1 Discussion of inclusion of values

Two sets of answers are equally true and valid as to why I chose the Ethical HTA Matrix. The first is mainly pragmatic and the second relates to the quality of frameworks in relation to RRI. I start with the latter justification and then move to the former.

As analysed in *Responsibility for* the Ethical Matrix and the Socratic approach are complementary to some extent when it comes to covering both RRI keys and substantive themes, as identified in *Help at Home*.[34] Since, as argued below, there were no clear methodological reasons for not combining them, this should be a promising advance in the field of applied ethics. There is also a need to discuss briefly why *The Matrix* did not attempt to pursue either the HTA Core Model or the Ethical Impact Assessment (ETIA). Primarily, these two are not as complementary as the ones selected. Second, even though the HTA Core Model contains a vast range of possible social and normative issues, it is rather limited on specific normative issues. This is the opposite of the ETIA, which contains a vast range of topics and themes that would need to be reduced through some form of secretarial or research-based work (see Wright (2011)). Consequently, it would be difficult to maintain a high level of *throughput transparency* for some of the choices needed to make them both applicable. Third, and unique to the ETIA, it has been under development, among other places in the SATORI project (see Jansen et al. (2017)) from its first conceptualisations as a combination of a substantive and procedural approach (Wright 2011; Venier et al. 2013). Currently, it seems to be more of a checklist for the quality assurance of stakeholder involvement, and is thus purely a procedural tool (European Committee for Standardization 2017; Reijers et al. 2017). This latter point is not in itself negative, since the Ethical Matrix should also be considered procedural, but as an approach to RRI it falls short of providing substantive themes. One might qualify the current version of ETIA as a meta-framework for doing any form of applied ethics.

The ambivalence between the explicit extensive character of the ETIA and the implicit extensive character of the HTA Core Model, on the one hand, and the need to narrow in on or select on the other also has a pragmatic dimension. These are seemingly time consuming to apply, while the Socratic approach and the Ethical Matrix have a simplicity to them that seem to indicate less drudgery. There is a need here to remind the reader that the intention behind the articles was to produce or develop an assessment framework that could be used by decision-makers to select assistive technologies. In this context, it seemed inconceivable that

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[34] The RRI keys were gender/equality and diversity, open access, social justice/ inclusion, sustainability, science education, and ethics from Strand et al. (2015). The substantive themes in Thorstensen (2017c) were the good life, risks and benefits in use, distribution of risks and benefits, distribution of responsibilities, training, other possible impacts, contingency, systematic inquiry into ignorance, purpose of the assessment, health relevance, frugality, and social entrepreneurship.

a municipal employee would begin by reviewing all the issues and themes in the ETIA, and contrariwise that they would look for relevant questions throughout the complete HTA Core Model. In making this choice, I clearly have made certain assumptions about the user and the usability. As shown in *The Matrix*, the interviewees did not think that the Ethical HTA Matrix provided them with any clear direction. However, they sympathised with the value systematisations, which several reported as facilitating the evaluation of the decisions.

Assessing health technologies or assistive technologies is a moral and a value-based affair, as Hofmann (2005a) notes since health care activity is based on a moral view that health is good and suffering and ill-health is bad. This view is reflected in HTAs, which are based on a normative view that expert informed analyses are better than guesswork or experiences from practice. It also seems to take for granted that informed analyses is the preferred way to create a just and good health system. In a different article, Hofmann (2005b) proposed what has become known as the Socratic approach (Hofmann 2013a), the justification for which seems pragmatic: Since there is no way of agreeing what constitutes the right theoretical or methodological approach to the analysis of ethics or values in HTA, should one abandon trying to include ethics and values? Hofmann opts for a practical solution and presents a list of questions as a checklist, which are not claimed to be exhaustive or exclusive, and which might be irrelevant for some cases.

There is a reason why Hofmann does not use Beauchamp and Childress' principlism – on which the Ethical Matrix depends for its division and systematisation (Mepham 2000; Beauchamp and Childress 2013). Hofmann argues that principlism is disputed and that the health field is so heterogeneous that it might not be sufficient. I sympathize with Hofmann's ambition of presenting a lower-level method for performing ethical analysis for health technologies. The Socratic approach attempts to include several points of view from different ethical perspectives with a foundation in experiences from the health field. In contrast to principlism he includes some reflective questions (see Thorstensen (2019a)) and he anticipates some of the elements of Responsible Innovation in Health (see Pacifico Silva et al. (2018)) through paying attention to the producers, to other interested parties and to the health relevance of the proposed innovation. Where I differ from Hofmann's use of the Socratic approach in *The Matrix*, is in viewing third parties or producers as stakeholders who might be addressed in their own right, through an analysis with the same questions as Hofmann suggests for patients, health professionals and the health systems – where they make sense. I am not claiming that this is a superior way, but rather that it provides an additional

comparative element when structured through a matrix. In the next section, I will address a different issue to the content and the completeness of the questions relating to the inclusion of values, which is the accuracy of the method that led to the selection of the Ethical HTA Matrix.

5.1.1.1 *Framing effects on values*

The first principle in the Assisted Living project's RRI approach is needs and a central concern of the project was to document needs, "An important challenge so far has been to uncover real needs" (Forsberg and Thorstensen 2018: 22). This sort of framing of the lives of older adults as based on needs – even though we also looked into individual values and choices – could have had some effect on the process and the outcomes. According to Peine and Moors (2015) there are two opposite approaches to thinking about health technology and assistive technologies. On the one hand there is a *prosthetic strategy* consisting of three elements – personalisation, needs capturing and othering – through which, they claim, "the patient-consumer … re-emerges as a patient with a set of needs when processes of user involvement and their outcomes were discussed" (Peine and Moors 2015: 77). On the other hand is an *habilitating strategy* aimed at strengthening or focusing on "interactive individual agency grounded … in the practices of everyday life, and the way the robot engages with and changes these practices" (Peine and Moors 2015: 78). As Peine and Moors point out, to some extent these different strategies are followed by all kinds of experts and are not limited to technologists. One should note that Peine and Moors describe ideal-types, and that all practices involving an understanding of another with respect to changing or adapting the environment would include both prosthetic and habilitating strategies. The question I raise is whether, and to what extent, the Ethical HTA Matrix is capable of orientating itself towards assessing an increase or decrease in agency, as it is based on an early investigation into needs. If the Ethical HTA Matrix frames the user in a prosthetic manner, it signifies that the approach does not take into account the important aspect of values. As Peine and Moors discuss, agency is a condition for the realisation of values in everyday life.

During the interviews conducted for *The Matrix*, several informants highlighted the theme of dignity. For the stakeholder category of primary users, dignity in the Ethical HTA Matrix addresses the ability to make decisions and to create or uphold relations (Thorstensen 2019b: 22-28). As discussed in *The Matrix*, it seems that the Ethical HTA Matrix opens up the assessment of both social and medical dimensions of the case of GPS localisation for persons with dementia. This demonstrates that there are some prosthetic dimensions to the Ethical

HTA Matrix, but that it also displays how users might have increased or decreased agency, depending on the introduction of an assistive technology, that is, it has a strong habilitating aspect.

5.1.2 Discussion of multiplicity of viewpoints

The Ethical HTA Matrix includes values and it systematically included the participants' ranking of these values. However, there are some real difficulties when experts in ethics or social science want to represent these values and valuations.

5.1.2.1 Capturing viewpoints

As described earlier, the data for two of the articles are based on interviews and other discussions. Jerolmack and Khan (2014) point to the seemingly paradoxical situation that even though most social scientists are interested in what people do, scientists limit themselves to studying what people say they do, although there are often large discrepancies between what people say they do and what they actually do. They label this problem *the attitudinal fallacy*, "the error of inferring situated behavior from verbal accounts" (Jerolmack and Khan 2014: 179). Their point is that ethnographic research methods are better suited than verbal accounts or questionnaire studies to uncover or discover what people *do*. This criticism could affect the presentation of different viewpoints in *Help at Home* and *The Matrix*.

In the research undertaken with colleagues from the Assisted Living project on the engagement activities with older adults, called Dialogue Cafés, Jerolmack and Kahn's criticism seems salient and is a methodological challenge. In my view, the methodological work underlying the Dialogue Cafés can largely reply to their criticism even if oral accounts cannot completely replace lived life.

One might consider the Dialogue Cafés as small, informal and experimental technology assessment events since they all discussed technology in relation to values. [35] The Dialogue Cafés were organised to empower persons with mild cognitive impairment or dementia to express their views on technologies. As Kennedy and Ter Meulen (2016) document, such inclusion requires human, social and methodological care. They further recommend small groups and separating next of kin and persons with dementia in different groups to avoid undue influence from the former on the latter. In addition, the overall duration should be limited and with frequent breaks. In the Dialogue Cafés there were between three and four

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[35] A team from the Assisted Living project is currently producing an article on Dialogue Cafés.

participants in each group and sessions were a maximum of 25 minutes, and were carefully moderated. Meiland et al. (2014) have organised similar groups and found that such events give the opportunity for persons with dementia to express themselves and to relate to the viewpoints of others. Consequently, such formats might stimulate reflection and exchanges as well as learning about the discussed theme, which in itself is important in RRI, while providing researchers with different valuations of the discussed solutions. While these structural adaptations do not by themselves deflect the criticism from the attitudinal fallacy, they do open up for reflections on attitudes and values.

Jerolmack and Kahn's criticism is also pertinent to the interviews in *The Matrix*. To meet their standards, I should have applied the Ethical HTA Matrix together with a municipality or other procuring or producing institution and documented the trial. In a world where municipal health services have unlimited resources this might have worked. However, there are additional ethical and methodological reasons for pursuing interviews. Ethically it would have been a waste of resources to run a full-scale test before performing a pilot and discussing it with the intended users. Methodologically, it was valuable to learn about the differences in innovation thinking in the different municipalities. Through interviews with large, medium and small municipalities with different organisational structures, it became clear that there are central differences in public innovation approaches, which again affect for what purpose one might apply the Ethical HTA Matrix and where in the innovation chain it could be placed. However, there is still the possibility that respondents would have acted differently than they report. This challenge is not specific for this study.

5.1.2.2 Challenges in engagement

When it comes to why one should engage non-experts in the development and performance of an assessment of technologies, I draw upon Stirling's analysis of the *purposes for engagement*. Stirling builds upon Fiorino (1990), who argues that one can find three different types of argument for participation by the affected parties in technology development processes:

- A *substantive argument* is that lay judgments about risk are as sound or more so than those of experts. Non-experts see problems, issues, and solutions that experts miss

- A *normative argument* is that a technocratic orientation is incompatible with democratic ideals. […] The normative argument accepts, as an ethical presupposition, that citizens are the best judge of their own interests

- An *instrumental argument* is that effective lay participation in risk decisions makes them more legitimate and leads to better results (Fiorino 1990: 227–228).

As Delgado et al. (2011) convincingly argue, one tends to find a mixture of these motivations in applied engagement activities. They further describe the movement from "opening up" to "closing down" as a recurring difficulty when attempting to provide inputs to decision-makers. They label this difficulty as *the problem of closure*. One reading of Delgado et al. (2011) seems to imply that the problem of closure arises since there is a need to connect substantive engagements with policy objectives and these objectives might be more or less precommitted, as Owen et al. (2012) comment.

Help at Home is based on open engagements and the values obtained from these encounters laid the foundation for the later analytical and applied research. If this research has a bias towards the commitments of my research project, that might have negative implications for the later selection of, what I call, an Ethical HTA Matrix. One reason for suspecting such a bias can be found in *From Scratch* regarding the technological trial, "even if eight participants were willing to try out these solutions, it turns out that several of them do not actually have much need for them" (Forsberg and Thorstensen 2018: 22).[36] This discovery seems to indicate that I should vary the claims concerning the strength of my own analysis as it is based on similar methods. However, the conclusions in *Help at Home* are not solely based on the engagements with older adults or focus groups. As the research was meant to lay the foundation for a general approach to assessments of assistive technologies, it was also based on literature reviews, discussions in the advisory board and studies of other contributions on assessing new technologies. The major contribution to the selection criteria for an assessment approach, as discussed in *Responsibility for* from the engagements with older adults and with health professionals, was increased attention on the importance of learning how to use and maintain novel devices.

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[36] See Holthe et al. (2018a) for a description of the system the Assisted Living project proposed and installed.

5.1.2.3 Relevance of viewpoints

According to Coenen and Grunwald (2017) one should include relevant stakeholders and their viewpoints and not everyone with an opinion. There were some reactions in the interviews for *The Matrix* that care workers were not really relevant, but then again there were those who saw the Ethical HTA Matrix as a tool to be used with care workers. The inclusion of technology providers was also met with different attitudes, which indicates how different informants perceived the role of such providers in municipal innovation. Likewise, the introduction of climate and ecosystems was met with indifference or puzzlement, as this was a concern in standard municipal contracts – and distant from the respondents' concerns because they took the issue be sufficiently taken care of or simply because was outside of their sphere of influence. From a comparative and scholarly point of view, the inclusion of such stakeholders in the Ethical HTA Matrix provided an insight into how innovation takes place in the different municipalities. While this finding does not provide an answer to whether or not one should acquire a specific assistive technology, it provides a space for reflection on current practices.

A final potential criticism of both the Ethical HTA Matrix is that it seems to understand stakeholder groups as homogenous entities, although it is rather well established that they are not.[37] This diversity became visible in the validation phase of the application of the Ethical HTA Matrix, which displayed that in some themes there were large variations in valuations with regard to next of kin.

Accordingly, one should see the stakeholders more as categories than groups. According to Døving (2006), a group is a label for those with a common agenda and a minimum of organisation, whereas a category is a label for those with some common characteristics. There might be substantial overlap between these two, but persons with dementia, who have little in common in terms of agenda, cannot constitute a group but are a category. However, if they organise and present a range of demands, they become a group. Likewise for nurses, I would contend that when they organise as a union they are a group. However, when discussing ethics and technologies, Sandelowski (1997) has shown that the category of nurses contains two separate value approaches to assessing technologies in healthcare. The Ethical HTA Matrix

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[37] This issue of homogeneity vs. heterogeneity among stakeholders has been discussed in stakeholder theory for some time (Wolfe and Putler 2002; Fassin 2008), but up until now the stakeholder notion tends to emphasise homogeneity (Freeman 1984; Phillips 2003; Bonnafous-Boucher and Rendtorff 2016). A wider discussion of stakeholder homogeneity vs. stakeholder heterogeneity and its implications for RRI extends beyond the scope of this thesis.

attempted to solve this issue by having a measure of variation, but from the interviews one must conclude this additional element did not provide much clarity for the informants. It is possible to display different valuations in, for example, split cells in the matrix structure as an alternative practical solution. However, to represent a multiplicity of viewpoints inside the Ethical HTA Matrix, the underlying process (participatory or desk-based) needs to be attuned to such diversity. This theme is discussed further in Section 5.1.8 on the interactive quality.

5.1.3 Discussion of transparency

As presented in the theoretical framework, I have made a distinction between input, throughput and output transparency. The discussion on how the Ethical HTA Matrix relates to transparency starts with the input dimension on who was included and how inclusion took place. Some points are relevant for the discussion of input and throughput transparency in the discussion of multiplicity of viewpoints (5.1.2). These points relate to how statements from the participants methodologically were moulded into input. The main part of the discussion thematises output transparency as this aspect is central to understanding what assessments might contribute to in terms of governance.

5.1.3.1 Input transparency

The goal with *The Matrix* was to investigate how values might be included in municipal work with and for assistive technologies. Two themes are central. The first is how choices in *The Matrix* relate to input transparency and the second is how the Ethical HTA Matrix contributes to input transparency.

Input transparency refers to openness about all elements that are provided or collected to deliver substantive impact on the process. The validation phase of the values in the Ethical HTA Matrix is the central one since it is in this phase that persons in the stakeholder categories can give their views on what matters to them – and how much. In this research two different input strategies were selected – personal interviews and web-based questionnaires – which stood out as the most efficient means to gain a proximate validation of the findings from the literature searches, as described in *The Matrix*. What mainly mattered to the research was not the assessment of the GPS localisation system as such, but the assessment methodology and how and where to discuss values in innovation. To achieve this goal an assessment with a completed Ethical HTA Matrix was needed. Consequently, the technology partner in the Assisted Living project was asked if they had a product they wanted to assess in depth using the model developed for the Assisted Living project. They answered positively

that their GPS localisation system would be of interest, and put me in contact with a Norwegian municipality that had experience with their system.

To create an Ethical HTA Matrix based on the GPS localisation system that could provide useful information to the project partner, I decided to obtain information on the values in a stringent, but not representative manner, which translated into a cooperation with the municipality where I gained access to persons from the central stakeholder categories. The municipality had concerns over how much time they could dedicate to the validation effort. We therefore decided on the least time-consuming approach for next of kin, staff and decision-makers, which was an online questionnaire (see Appendix B). For the primary users, however, the municipality expressed concerns regarding their well-being and we co-developed a small set of questions that formed the basis for one-to-one conversations about their experiences with the GPS system. In total, two responses were received from decision-makers, four from staff and twelve from next of kin, and five personal interviews were performed. As becomes clear from the Appendix to *The Matrix*, this approach permitted me to find aspects of both agreement and disagreement and to identify some values as more important than others.

As a method, the Ethical HTA Matrix provides input transparency primarily by being clear about what the relevant questions are. These questions are given in Hofmann's (2005b) Socratic approach. As discussed above regarding framing effects and capturing viewpoints, there are challenges in turning talk into input. Likewise, there are challenges in using literature reviews as a basis for input since literature searches are demanding and might miss central elements. Understood in this light, input transparency depends on a range of conditions since it might be clear what the questions and the responses are, but the central element of how they were gathered might be unclear. In this case, one could ask how far back one needs to go along the chain of decisions leading up to the final value statements. On the opposite side, as Moula and Sandin (2015) mentioned, creating an excess of information might be detrimental to transparency. Consequently, it seems that full disclosure does not solve the problems with transparency (in addition to possible tensions with privacy). It seems that a method such as the Ethical HTA Matrix, which is clear concerning what stakeholder categories have been invited at what stage and for what purpose, and which also explains the methodology for obtaining their views, strikes a sensible balance that gives external parties access to what has taken place and an understanding of how the input has been obtained.

5.1.3.2 Throughput transparency

Throughput transparency offers an understanding of documentation and communicates how one step leads to the next. In the Ethical HTA Matrix one can follow an argument from the facts, through values, to a conclusion. By displaying this type of practical reasoning, the Ethical HTA Matrix seems to make visible what tend to be lacking in ethical analyses related to HTA, which is the operational process in making an ethical evaluation of a specific case (Legault et al. 2019). In the version presented in *The Matrix,* a summary of all the responses to the questions from the Socratic approach were systematised into a matrix format from the Ethical Matrix (Mepham et al. 2006). Both the affected value specification and an account of the expected consequences based on the literature were explained. Through the validation processes, as discussed above, these values and consequences were given weight according to their importance. The process, selection and outcomes were presented and discussed with the decision-makers concerning assistive technologies, and the underlying material was shared after anonymisation. This process qualifies as transparent since it is possible to follow the underlying arguments and to see that these values and consequences were products of the described engagement activities.

5.1.3.3 Output transparency

Output transparency refers to the degree of openness about the direct goods produced and their distribution. As already mentioned, there is a lack of precision in the definition of transparency and a lack of justification as to why transparency is important in the discussions regarding ethical tools. This taken-for-grantedness of transparency can also be found in the RRI literature, even though one of the most used definitions applies the term "transparent",

> Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society) (von Schomberg 2013: 63).

If one takes a different approach to transparency than simply seeing it as right in and by itself, and focuses on the consequences of transparency, Sunstein (2018) suggests that output transparency of political processes is more valuable than input or throughput transparency. Sunstein applies what he calls a "welfarist" perspective, where he sets benefits up against costs. He sees that increased output transparency increases political accountability through attention to the results of a policy and that it gives people the chance to pursue what they find

valuable and to avoid what they find undesirable. Whereas input transparency might come at the cost of people holding back information – also in public settings – since they want to avoid any negative sanctions related to holding opinions that might be controversial. What Sunstein (2018) focuses on as output transparency is the transparency of the implementation and administration of the results of the formal policy process, where increased transparency is needed to know who to hold accountable for what (Héritier 2003). Such a focus on output in RRI, has further been discussed by Lehoux et al. (2018) regarding fulfilling sustainable development goals through health policies. Likewise, Grunwald (2011b) explored how the ELSA research lacked influence on the larger research and innovation landscape.

One motivation in applying the Ethical HTA Matrix was that it has an intuitive strength in visualising how a change might affect different stakeholders. This output format seems to make the Ethical HTA Matrix superior to Beauchamp and Childress' principlism. An underlying drive in *The Matrix* was to investigate if it was possible to present an analysis of an assistive technology in a format that would appeal to decision makers, that is to fulfil Parson's (1995) requirement of usefulness. The justification for placing output at the centre of attention relates to discussions on ethics and their role in HTAs. I will now turn to this discussion before ending with a reflection if the Ethical HTA Matrix constitute an alternative.

Central to HTAs is the notion of methods. In an HTA theories are seldom rendered explicit, which gives it a veil of neutrality as a processor of facts. Seen from the theory of science, such a position could be understood as a form of positivism or neo-positivism (Refolo et al. 2016). If one applies the notions for the sociological studies on legitimacy, these methods should be understood as what provides the throughput legitimacy of the HTAs. Throughput legitimacy, as earlier mentioned, refers to how central stakeholders and – of course – the public perceive the legitimacy of the design of the process by the performers of HTA. These methods decide to a very high degree what forms of input are considered legitimate. Central to the analysis of the input is the quality assessment of how reliable and valid the inputs are.[38]

A range of very informed and highly useful discussions have taken place over the last 20 years on how to integrate social and ethical questions and themes into what has been a highly biomedical field. This discussion has only partially been taken up in the actual practice of

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[38] This quality is currently being estimated through the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which provides indicators for this quality ranging from randomised trials (high quality evidence) to observational studies (low quality evidence) (Guyatt et al. 2008).

writing HTAs, since surveys indicate that a minority of between 5% and 30% of HTAs take social, ethical and organisational issues into account (Velasco Garrido et al. 2010; Refolo et al. 2016). Nevertheless, there is little disagreement that normatively ethics should be a part of HTAs and that ethics should play a part in medical decisions. Furthermore, technologies are vital to our discovery and understanding of health or lack of health (Hofmann 2001). An interesting development, which extends beyond the scope of this thesis, is the integration of ethics and socio-cultural aspects into HTAs of complex interventions (see Lysdahl and Hofmann (2016); Lysdahl et al. (2016)).

In addition to the main concern of safety and security, a majority of HTAs seem to focus on clinical effectiveness rather than on the wider system of health delivery and its organisation, which renders them of little use to decision-makers and makes these latter depend on what has been called "colloquial evidence", understood as "anything that establishes a fact or gives reason for believing in something" (Lomas et al. 2005: 3). This dependence seems to be the result of HTAs that are too narrowly defined (Velasco Garrido et al. 2010). What seems to be typical of the discussions regarding the place of ethics and social aspects in HTAs over the last 15 years, is a focus on the suitable form of ethical throughput in the HTAs. Central themes in ethics and HTA discussions are what methods can be used to generate legitimate knowledge.[39] These and other suggestions on the input side have led to greater awareness and possibly to a better approach to ethical, social and organisational issues in HTAs. Clearly, work on the throughput and methodological side is important and should continue to establish practical and theoretically more refined approaches to the inclusion of social and ethical aspects of new procedures. *The Matrix* attempted to use a novel format for presenting the consequences, their likelihood, and their central critical factors when it comes to the introduction of novel assistive technologies. This application was not only an attempt to increase the relevance of HTA for decision-makers, but the epistemic equivalence between different value domains. The collection of *health effects* under *welfare* in *The Matrix* was an

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[39] Suggestions range across: a general broadening of disciplinary inputs to HTAs (Lehoux and Blume 2000); the inclusion of different forms of TAs in the European tradition (Clausen and Yoshinaka 2004; Hennen 2004); the role of ethical experts (Grunwald 2004); the use of the capability approach to bridge between economics and ethics (Kibel and Vanstone 2017); the introduction of a Rawlsian Wide Reflective Equilibrium as a process for stakeholder involvement on ethical issues (Daniels and Wilt 2016); the systematisation of ethical issues (Hofmann 2005a); the proper way of integrating ethics into HTAs (Hofmann 2005b; Lysdahl and Hofmann 2016). There are also contributions on novel and important aspects in the quality control of ethical inputs regarding the process of collection and the reliability of results (Scott et al. 2016; Scott et al. 2017).

attempt at both visually and methodologically claiming that effects related to *dignity* and *justice* are just as important as measurable physical effects. So, rather than subsuming ethics under effects, it subsumed effects under ethics (Hofmann et al. 2015). The idea of equivalence between the value domains can be justified through an approach to RRI that places these social values as the goal of research and innovation. However, there is the peril that this equalising effort makes the Ethical HTA Matrix a tool that becomes additional to established HTA practices, which Dreyer et al. (2017) see as a disadvantage of RRI in industry.

As the research scope was limited to the perceptions and possible uses of the Ethical HTA Matrix, I am not able to state that it actually provides increased output transparency, understood as insight into what happens with the advice, who uses it and how it is received. Nevertheless, several of the interviewees expressed that the Ethical HTA Matrix could be used as a tool to identify value-based gains. These values could subsequently be used to steer innovation in the municipality towards realisation. This finding indicates that the Ethical HTA Matrix could steer value-based innovation through a focus on the output of an innovation process. However, more testing and research is clearly needed.

5.1.4 Discussion of relevance

A central concern in the discussion on the qualities of a framework was how well or whether one might obtain policy-relevant normative considerations and arguments on the specific case. This demand is both an empirical issue and an invitation to investigate *policy* more. First, I will present how the Ethical HTA Matrix had relevance through its display of concerns and critical factors – as well as an increased focus on the role of health professionals. Second, I will explore if there are reasons to expect that policy has changed with respect to the policy context for ethical tools.

As shown in *The Matrix*, a majority of the interviewees found that the approach gave a structure for possible future analysis and, more importantly, that the GPS localisation system case provided a large overview, which might be useable in a changed format with less nuances and an improved information structure. This case analysis qualifies as relevant according to the theoretical criterion where validation can be made through meetings with policymakers or other stakeholders.

What the respondents wanted changed were largely my adjustments to the Ethical HTA Matrix, with the exception of the introduction of *critical factors* as a separate category to be placed after the value in question and the colouring of the cells to express a combination of

(or lack of scientific) knowledge and uncertainty of effect due to large variances in the research. Critical factors are those elements that need to be in place prior to use or that can severely jeopardise the (desirable) outcomes of a technology. The positive reception of the main content and the matrix structure was expected as both the Socratic approach and the Ethical Matrix have been used in different policy arenas (Forsberg and Kaiser 2000; Kaiser and Forsberg 2001; Hofmann 2008; Hofmann 2010).

The focus on critical factors in the Ethical HTA Matrix indicates how a health system needs to adjust to benefit from new assistive technology. This focus further addressed the criticism raised by von Schomberg and Blok (2018) of a narrow focus on technologies rather than contexts in RRI. Through attention to the system challenges, decision makers are able to identify how apt their local context is for the eventual implementation of an assistive technology.

The interviews identified that the Ethical HTA Matrix could be used creatively. Some informants used it and its content to reflect on its possible uses in the creation of novel health services involving assistive technologies.[40] The informants suggested two different uses. One use was as a mapping tool to give the health administration an overview of possible values and to use this overview as a structure to report on gains. The second use was as a framework to structure debates among employees and other stakeholders concerning experiences with assistive technologies. I would like to underline here that this was said in interviews and not tested in reality, but the creation of novel health services has a political character and there are two main reasons to support this understanding. The first is that creating novel health services affects the distribution of goods in a community, which is political in almost any understanding of political. The second reason relates to a different dimension of the political, namely health professionals' use of professional discretion as a part of policy processes. Health professionals in home-based services perform a range of services, some because of legislation. In Norway, the most central laws are *helse- og omsorgstjenesteloven* – Health and Care Services Act – and *helsepersonelloven* – the Health Personnel Act. Such acts confer formal control over some types of work to members of specific professions (Abbott 1988). The Health Personnel Act uses phrases such as *faglig forsvarlig* (professional responsibility)

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[40] Several other normative approaches might also have produced this effect so I am not claiming that this approach has any in-built superiority to those considered in *Responsibility for*. In the Ethical Bio TA Tools project, we found that preference for a specific tool could also depend on the local political culture (Beekman et al. 2006).

and *omsorgsfull hjelp* (diligent care) (Helsepersonelloven 1999: § 4). These phrases open up a field for professional discretion that decides how a health professional ought to implement formal decisions on healthcare or aid according to law. It is the health professional's own responsibility to perform a proper diagnosis and treatment of those in need. Accordingly, discussions among or between health professionals providing legally mandated aid or care might be considered as policymaking (see Lipsky (2010)). Furthermore, a discussion over what values should be prioritised in such an aid or care situation constitutes a central part of RRI.

A different point regarding policy relevance of the Ethical HTA Matrix, is the approach taken in the literature review underlying *The Matrix*. GPS localisation systems are seen as generic artefacts without relevant differences. Strictly speaking, assessments of one or two applications or artefacts presented as an assistive technology – in this case, a GPS localisation system – cannot be taken to be assessments of GPS localisation systems in general since evaluations and assessments of two artefacts with the same purpose are comparable, but they are not immediately transferable. Especially relating to questions concerning privacy, one should be careful in making such transfers between different artefacts since issues such as data safety and security might be fundamentally different between two products. To complicate matters further, one and the same assistive technology implemented in the same system for users with an identical diagnosis might yield very different results depending on a range of personal factors or co-morbidity (Øderud et al. 2017). Consequently, the general policy relevance of the assessment of a specific artefact may be limited. However, the relevance in the specific context is clear.

5.1.4.1 Changing policy contexts

The question explored in *Responsibility for* was what existing assessment frameworks might be used to assess assistive technologies, in line with the conclusions from the second article. Based on *Help at Home,* there are four candidates that could be considered as possible tools for assessing novel assistive technologies. These were the Ethical Matrix, the Socratic approach, Ethical Impact Assessment and the ethics part of the EUnetHTA.[41] Not one of them fully covers all the dimensions of RRI, as developed by a variety of authors and institutions,

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[41] There are several traditions for making decisions concerning health interventions. One prominent direction is multiple-criteria decision analysis (see Baltussen and Niessen (2006)). A balanced and in-depth discussion of this and other established methods extends beyond the scope of this thesis.

but they all contain valuable normative potential. However, what I do not discuss in depth is the assumption that tools or frameworks or other ethical methods constitute a solution. Furthermore, my theoretical framework presupposes that these frameworks provide improved normative content that will be relevant for policymaking, but there are good reasons to discuss the role of such frameworks based on the political contexts for their establishment.

As discussed above, there were political concerns behind the development of ethical tools. One such central concern was to understand the multitude of values and viewpoints on values in European society to avoid controversy around new and emerging technologies (see von Schomberg (2019)). I have already mentioned how practical philosophy has argued that there are several conceptions of the right and the good, which could all be designated as reasonable (Rawls 1993; Ross 2002). In Europe, there is still a variety of such conceptions. However, what I would like to raise is whether the political landscape has changed in ways that are significant with respect to how values are integrated into politics. From a sociological point of view, Roy (2019) concludes that the struggle over values in the European context is based to a large degree on political opportunism at the extremes (right and left) of politics that employs a traditional moral language to promote a strong individualism that departs from the communitarian values traditionally held by conservatives. Long and Blok (2017) are among several who see the rise of political opportunism, or populism, as a consequence of a poorly governed political development of technologies, leading to gross differences between rich and poor and a novel marginalised class of the perpetually unemployed. They further connect this political development to a popular contempt for the elites or experts who base their views on a political liberal agenda. These forms of novel moralism cannot be said to be tolerant towards what could reasonably be called, in Rawlsian language, comprehensive doctrines, which are characterised by underlying differences in values leading to similar political judgements (Rawls 1971).

With its foundation in proceduralism as a proper approach to achieving fair and balanced outcomes, the Ethical HTA Matrix might be unable to defend substantive democratic values in the political development and governance of new and emerging technology. As democratic values are at the core of RRI, such a flaw would diminish its political relevance for two reasons. First, political opportunism would make little political use of reasonable views that differ from their own. Second, if tools such as an Ethical HTA Matrix cannot substantively display why some democratic values should be given priority over intolerant values, then it fails to be a safeguard for a democratic system. There are then two consequences that follow

from these potential flaws. First, if assessment tools aim to be policy relevant for intolerant policymaking, then it is no longer RRI but it becomes irresponsible assessment. Second, if assessment tools wish to fulfil the democratic aspirations in RRI, they depend upon a distance from political regimes and a closer affiliation to sympathetic voices in the natural sciences and technology. What is unfortunate with this latter point is that both assessment tools and RRI lose their original aspirations connected to policy. Long and Blok propose a future for RRI in seeking legitimacy downwards with their suggestion "to recalibrate science, research, and innovation towards more authentic engagement, reflexivity, and responsivity" (2017: 68). One interpretation of this suggestion is to move RRI away from policy dependence, which also runs the danger of a move away from policy relevance. Science would become democratic, but the governance of science could move in any direction.

Consequently, it seems that the criterion of policy relevance is in itself mouldable and relates to several factors, including how states perceive the proper governance of science and technology. As both de Saille (2015) and Robinson and Mazzucato (2019) show, RRI was implemented under a policy regime that facilitates for innovation and business to create commercial solutions as answers to societal challenges. Policy relevance appears to be a positive criterion against which assessments should strive. However, as indicated above, what counts as policy relevant might be ethically or democratically problematic. The mutual dependencies and relations of such normative programmes as assessment tools and RRI on the larger sociological constellations of politics, people and power seem to be in need of further research.

For the purposes of this thesis, there are some systematic normative advantages in applying identical approaches to disparate solutions as a means of investigating social and moral changes, benefits and challenges. Nevertheless, one might be tempted to describe such frameworks as naïve if they present the main democratic challenge in assistive technologies as on a product level. In this context, other underlying assumptions could be problematic, such as the theme elaborated by Peine and Neven (2019), who find cases where products are the outcomes of socio-political processes that assume an interventionist logic where ageing is seen as a problem to be fixed by technologies.[42] This wider view of assessment finds support in von Schomberg (2019) who argues for a wider study of system changes from technologies.

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[42] In the context of RRI, Foley and Gibbs (2019) would refer to such assumptions as relating to macro-ethical failures in the problem definition.

I return to this point in the discussion concerning the relation between RRI assessments and ethical frameworks in Section 5.2.

5.1.5 Discussion of inclusion of ethical arguments

Ethical arguments are present in two ways. First, the dominant content of the Ethical HTA Matrix consists of specifications on what a principle means, related to a case and to stakeholders, while weighing its importance based on feedback from stakeholders. It would be correct to say that no arguments are spelled out in the Ethical HTA Matrix, but there is a clear connection to, for instance, why a GPS localisation system is ethically desirable or undesirable for the different concerned parties.

Second, and as argued in *The Matrix*, the Socratic approach adds a quality aspect to the Ethical Matrix when performing a desk-based approach. This quality aspect relates to the inclusion of relevant ethical arguments, as raised by Kaiser et al. (2007), and thus contributes to the fulfilment of this criterion.

5.1.6 Discussion of purposiveness

If we relate assessments of assistive technologies to the purposes describes in the TAMI table (Table 3.2), we observe the following. The main current purposes for conducting assessments of assistive technologies are to document: possible cost-effectiveness (see e.g. Melting and Frantzen (2015); Melting (2017)); technical features (see e.g. Calvaresi et al. (2017)); and independent living (see e.g. Hansen et al. (2017)). Current purposes relate mainly to scientific and policy aspects and there is little use of assessments to investigate the societal aspects of assistive technologies. Moreover, they relate to the cognitive and the pragmatic dimensions whereas the normative dimension is lacking. There is a range of ethical assessments of assistive technologies that tend towards a comprehensive overview of the consequences (see Körtner (2016); Topfer (2016); Ienca et al. (2017); Sánchez et al. (2017)). There are some noteworthy exceptions with a broader approach through their focus on wider normative and ethical issues (see Hofmann (2013b); Mort et al. (2015); Novitzky et al. (2015)). There is also extensive literature from Science and Technology Studies analysing how assistive technologies affect the lives of older adults (see e.g. Aceros et al. (2015)) as well as technology implementation processes (see e.g. Neven (2015)). Furthermore, there is one comprehensive scenario report on assistive technologies from a collaboration of different TA entities (Barland and Lovett 2014).

The tools one chooses must align with the purpose of the assessment. However, the methodology itself may have an effect not only on results but also on the main idea behind a technology – in this case assistive technologies. The scenario report shows how assistive technologies are a political phenomenon, while the cost-effect reports show how they are economic phenomena. It was simultaneously surprising and unsurprising that several respondents in *The Matrix* mentioned that the proposed matrix approach could have as a purpose at an early stage to get a broad view of the consequences and the knowledge status. It was unsurprising since this is the main purpose of a range of assessments and I would venture that providing wide-ranging views is what they expected assessments to do. It was surprising since one believes that they already possessed tools to initiate knowledge planning. Recall what Lomas et al. (2005) referred to as "colloquial evidence" as an important element in decisions regarding health interventions, which was "anything that establishes a fact or gives reason for believing in something". Based on the interviews from *The Matrix*, it seems that there are instances of such "colloquial evidence" approaches in early-stage introductions of assistive technology. Some informants addressed their experience of gaps between the purpose of the political decisions regarding health priorities in general and assistive technologies in particular, and their own mandate; stating that political decisions could be orientated towards quantitative goals, such as a municipality becoming a leader in the implementation of assistive technologies (or not being a laggard), or being seen as a political administration focused on quality through making popular decisions. Whereas the informants' own mandate was to provide quality health services through frugal spending – I should add that other informants experienced no such conflict. These conflicts could be addressed through an early-stage value analysis that informs a different purpose in the TAMI table (Table 3.2), namely societal aspects and increased visibility of possible conflicts or mediations. These informants' replies indicate that Hofmann et al.'s question in the Socratic approach "What are the reasons that this technology is selected to be assessed?"(2014) has a clear value in early-stage analyses.

A different reason for surprise was that they accepted structuration in a matrix approach where all the effects were given similar priority, regardless of the effects on health, economy, well-being, dignity or justice as relevant in early stages (see above). I was also surprised because the main effects in the official recommendations tend towards economic considerations (Melting 2017). This dimension of their replies connects to the policy

dimension of the TAMI table (Table 3.2) since it allows decision-makers to assess or evaluate a policy proposal with respect to selected values.

The second purpose, as mentioned by two informants, was the Ethical HTA Matrix as a facilitation tool for health professionals and care workers' experiences with assistive technologies in an introductory phase. This purpose is similar to the bottom-up use of the Ethical Matrix (Mepham et al. 2006). The informants emphasised a matrix's mediating function. The EFORTT (Ethical Frameworks for Telecare technologies for older people at home) project's primary recommendation was to discuss the implications for and changes in care work with the introduction of telecare (EFORTT 2011). Health professionals and care workers – paid and unpaid – experience changes in delivering care when health and assistive technologies become more dominant, to the point of changing how we conceptualise care (Roberts and Mort 2009). Structured evaluation and reflections among all stakeholders are further mentioned as key to successful implementation (Peek et al. 2016). In terms of innovation, Schultz et al. (2015) suggest that the work environment might be the neglected factor in health care innovation, through an analytical division of elderly care into quality of care, working environment (recruitment, management, organisation) and societal efficiency.

Neven and Peine (2017) suggest that there are three strong elements underlying the discourses supporting the introduction of assistive technologies. These discourses have aims and consequently purposes. The first element is a view on ageing as an imminent crisis, the second is technology as a vehicle for increasing quality of life and the third is technology as cost-saving. They understand this triple win as steering the development of assistive technologies, although the UK Whole System Demonstrator could not provide clear answers to any of these hypotheses (Gornall 2012). Consequently, if one reduces the purpose of assessments of assistive technologies to only document specific gains rather than seeing assistive technologies as agents of societal change, one not only suffers a loss of output legitimacy but also misses specific opportunities for gaining knowledge of how the municipality and its services could change for a successful implementation. There might be differences in the perceived norms and values among users and staff underlying the introduction of an assistive device. As discussed in *The Matrix*, there might be underlying institutional views in a municipality on the relation between employees and innovation or the role of technology companies in municipal innovation. Consequently, there could well be structural barriers to moving the experiences with one device in one municipality to a different municipality without reflecting on such contextual matters. In one sense, these

differences could call for assessments not only of the purposes of devices, but also on the implementation or innovation system in municipalities. For instance, if the purpose of an assistive technology is to innovate service delivery, then the object of an assessment should be the service delivery system as structured around technology rather than as a single assistive device.

These reflections on the purposes of assessments of assistive technologies show that there are a variety of possible purposes, but that only a limited selection seem to be addressed. The Ethical HTA Matrix has the potential to address the cognitive and the normative purpose dimensions in the TAMI table (Table 3.2) as it relates to experiences and might constitute a novel approach for discussing the values of assistive technologies more broadly and might consequently provide a basis for articulating goals that are difficult to quantify.

5.1.7 Discussion of user-friendliness and frugality

Kaiser et al. have stated that, "although the Ethical Matrix does not emerge as a very simple tool to use as a participatory ethical framework, it does show its potential to structure ethical concerns under varying conditions" (2007: 78). All informants found –as did Kaiser et al. – that information overload is a danger with the Ethical HTA Matrix. Some informants said that current forms for investigating value in assistive technologies, which only report on a few parameters, were already a strain for local municipalities to complete, and they found the Ethical HTA Matrix much more complex. Other informants said that one might use a matrix to discuss parts of an issue, such as dignity, or for one or two stakeholders at a time, while indicating that other issues are not neglected even though there is a focus on some.

 A different informant highlighted that any form of structured discussion among health professionals or care workers needed facilitation. Accordingly, care workers should not be the users of the matrix but should provide experience-based input to the matrix while a facilitator aids in the structuring. Such facilitation skills usually require time and training.

Over the last four to five years in Norway there has been a conscious political will to improve innovation processes throughout the delivery chain for assistive technologies. This development was mentioned by several informants in *The Matrix*. One of the more important structural changes has been the establishment of a Directorate for E-health. Even though there were mixed views on their work, they doubtlessly have taken up a central place in national initiatives on procurement, standardisation and assessments. Together with the Norwegian Association of Local and Regional Authorities and the Directorate for Health, the Directorate

for E-health runs a national assistive technologies programme, which covers all levels of government across the country.[43] Schultz et al. (2015) have already underlined the necessity of structurally including care workers and health professionals in innovation and I have already discussed the changing nature of care work. What is needed is to create the users of such reflective tools or frameworks – let us call them facilitators – through training, or a routine to acquire this competence when needed. As Rowe and Frewer (2000) pointed out, one of the criteria for successful implementation of participatory methods is that an adequate amount of resources is allocated to their accomplishment. Just as for other institutional changes in the health sector, the introduction of reflective tools or frameworks becomes a political question. With reference to Responsible Innovation in Health (Lehoux et al. 2019), it would seem that if one has a political ambition to introduce assistive technologies, then it should be accompanied by an approach that ensures basic values. It is the ambition of RRI to ensure basic values through innovation and research, but from this ambition follows the question of whether or not these values are assured through the suggested approaches in RRI.

Consequently, the different tools such as the Ethical HTA Matrix – and others – require facilitator competence. Accordingly, this facilitator needs to be created and/or inserted in innovation processes. However, such a change should take place if ,and only if, it leads to the realisation of some basic values. As Grunwald writes, "the main feature of ethical expertise in HTA is to uncover the normative structure of decision-making problems: to make the implicit explicit" (2004: 192). It is not the task of such a facilitator to establish the normative content, but to structure this content in the same manner as other disciplines involved in informing a HTA. As Shelley-Egan et al. (2018) underline, RRI has been developed outside the practical world of research and innovation. In the current context, the introduction of a competent facilitator into a municipal health system would most likely be helpful for the introduction of RRI understood as responsible assessment.

Practically speaking, implementations of assessment tools such as the Ethical HTA Matrix demand an increased competence in facilitation for value discussions in municipal organisations. Such a development could be coordinated through regional networks of facilitators with assistive technologies as their field of competence. As this research indicates,

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[43] The role of national initiatives and programmes for assistive technologies has not been an object in this thesis, but this role seems relevant for understanding how assistive technologies are researched, developed and implemented. Such programmes and initiatives and their effects and directionality should be researched on both national and European levels.

there is a need for further research into municipal innovation systems that provide targeted advice on where in a specific innovation chain such assessment tools would add to the normative quality of decision making.

As discussed by Pansera and Sarkar (2016), frugality is to draw upon meagre resources through specific (local) competences. Consequently, speaking of the frugality of an assessment without competent users or facilitators seems to be contradictory. Several of the interviewees in *The Matrix* discussed how the Ethical HTA Matrix displayed how qualitative and non-monetary gains could be realised through assistive technologies while simultaneously showing that spending would not decline (nor necessarily increase) in the selected case. In other words, the Ethical HTA Matrix might illustrate how health systems could become more frugal. Nevertheless, if the introduction and implementation of novel assessment tools in the health sector create additional costs, while the benefits are uncertain due to a lack of competence, such an introduction could qualify as irresponsible. A remedy would be, as discussed, to investigate how to create adequate competence in the health sector.

5.1.8 Discussion of interactive qualities

Pellizzoni (2018) notes that the practice and theory of RRI has a virtuous side, which is mirrored by a darker aspect. The strength in RRI perspectives, which consist in collaborative creation and development, is likewise a negative factor since it could disguise differences in agency between the parties involved. Large firms or research institutes with resources are portrayed as meeting users or voluntary organisations on equal terms – and with equal responsibility for potential outcomes. As Pellizzoni concludes, "the 'mutual responsiveness' of innovators and stakeholders is likely to result in a major disclaimer – we shared the choice, we share the blame" (2018: 209). What Pellizzoni points to here is a difference in power, which cannot be obliterated or equalised. Pellizzoni's point is relevant to the issue of procedural fairness of assessments, as a co-production of the results might be perceived as coming equally from everyone.

As noted above, the Ethical HTA Matrix depends upon interactions with the stakeholders and without their contribution, the validation phase fails. In bottom-up versions, where stakeholders participate in answering the questions in the Socratic approach, one is even more dependent on mutuality. However, as discussed in the context of user-friendliness, the informants signalled a need for competent facilitation in applying the Ethical HTA Matrix. An informant in *The Matrix* discussed how it allows dominating personalities to insist on some

85

themes but that as every other theme is already displayed these themes cannot be ignored. It seems to me that the responsibility for the failure of the Ethical HTA Matrix cannot be distributed evenly, but mainly resides in the hands of the facilitator. As the method also depends on the responsibility of the facilitator to provide research-based knowledge based on the Socratic approach, an uninformed Ethical HTA Matrix seems unlikely. However, Pellizzoni's criticism about creating a level epistemic playing field would constitute an additional demand on the facilitator.[44] As the development and the application of the Ethical HTA Matrix took as a point of departure the insights from Kennedy and Ter Meulen (2016) to give a voice to older adults in the Dialogue Cafés and in the validation phase of the Ethical HTA Matrix, I would point to this practice as a good practice. In this research, the Assisted Living project performed a preliminary study to map and understand the differences Pellizzoni thematises.

Usually, in settings where the Ethical Matrix is applied with stakeholders, such validation takes place in stakeholder workshops (Kaiser and Forsberg 2001; Kaiser et al. 2007). These fora have been criticised equally for not being representative or remaining unclear concerning the issue of representativity (Delgado et al. 2011). The issue of representativity could also be raised with regards to *The Matrix*. However, this is a different issue to interactive quality. As stated in the theoretical discussion, interactive quality should not be seen as a part of a tool in itself, but rather as conditioned by the application of the tool. In the GPS localisation case I adapted the methods for interaction that the municipal partner identified as fitting with respect to resources on the one side and the primary users' medical condition on the other. As discussed in *The Matrix*, this approach identified differences in valuations among the informants. In the follow-up meeting with the project partner, they valued an overview of the differences since it showed them sensitive areas and potential disagreements among next of kin or other stakeholder categories.

There are some specific concerns from the development and testing of the Ethical HTA Matrix that should be mentioned. The web-based questionnaires did not allow for much interaction between participants. Neither did they give any space for discussing the underlying agenda. However, it provided an equal opportunity for the participants to have their voice heard, which is a central element to the interactive quality.

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[44] The themes of epistemic equality have recently been discussed by Valkenburg et al. (2019) with reference to RRI, also see the work on epistemic injustice (see Fricker (2007)) – it is beyond the scope of this thesis to elaborate on these themes.

Regarding interactive quality, the methodology in *The Matrix* has some weaknesses. However, I still regard the overall approach as a strength, but that it could have been improved with a more stringent process in terms of research quality. Ideally, there would have been qualitative learning arenas for health professionals and next of kin with more nuanced data.

5.1.9 Concluding remarks

Through the Ethical HTA Matrix I have attempted to find a place within the municipal governance structures of innovation where substantive value debates, reflection and learning might take place.

Based on the four articles in this thesis I have found that the Socratic approach provides the Ethical Matrix with substantive themes, which creates an Ethical HTA Matrix. Such a strengthening is important since it provides more specific themes for investigation and a wider connection to health policy discussions. By taking Socratic-approach questions as a point of departure, the input becomes transparent. Furthermore, the matrix format provides a method for displaying the path from questions to valuations. Compared to other methods, the Ethical HTA Matrix has a concern for the output format, which seems to facilitate for improved insight into how the results are used at later stages.

There are inherent methodological difficulties in capturing people's values. To secure the validity of the findings, it seems advantageous to rely on several sources and also to discuss and reflect upon how these difficulties might have influenced the viewpoints. The Ethical HTA Matrix should be used in dialogue with the institution that will use the assessment to address the relevance of both methods, findings and interpretations. Its relevance is in opening up discussions regarding the future structure and content of the health services. There are uncertainties connected to the relevance of ethical tools if the policy context changes.

The use and implementation of the Ethical HTA Matrix is improved by creating competent users or facilitators, since it demands analytic expertise. However, it seems a promising approach to articulating what values are sought and realised through assistive technologies and it might work as a catalyst to focus on these values. The responsibility for the fair normative and epistemic use of the Ethical HTA Matrix lies with the process initiator. With its ability to present ethically relevant information in a limited space, it seems that the Ethical HTA Matrix has an inbuilt capacity for ignoring central values.

Section 5.2 returns to some of the central concerns in RRI related to assessments to investigate what might be missing through the reliance on a theoretical framework from applied ethics.

5.2 Ethical assessment tools vs. RRI assessment tools

This is the opportune moment to discuss this thesis's contribution to the larger ambitions of RRI. Since the theoretical framework in this thesis has come from the tradition of applied ethics, it seems reasonable to assume that there might be some differences between what ethical frameworks might provide against what would have been expected in a wider RRI context.

5.2.1 Assessments and cases

It is a well-established criticism that applied ethics has a limited horizon when it comes to the larger socio-political dimensions of technology and society. This criticism has been raised against the principlism tradition to which the Ethical Matrix belongs (Lucivero 2015). As mentioned above, there might be other and more pressing normative issues than how ethical or unethical a product might be, such as underlying understandings of ageing, technology or their combination, as discussed by Neven and Peine (2017). In this context Fraser (1989) describes how scientific assessments are typically the final stage in a process that starts with a social movement demanding rights or improved living conditions. To tame such social movements, experts enter the field and reframe the situation as based on definable "needs". Fraser sees the development of needs as moving from new social movements, which articulate an oppositional story of being in need of goods, protection or some form of intervention, to a discourse on reprivatisation, in which the powerful aim to re-articulate the needs as private or non-political concerns. According to Fraser (1989), different professions and disciplines have different conceptions of "need" according to their diagnoses, inferences and suggested treatments. The struggle ends as experts provide scientific assessments and go for a "problem-solving" approach – and through administering the needs that arise. Individuals then become "cases", rather than representatives of a social group.

Fraser's point is relevant for RRI, which also aims to democratise science, technology, research and innovation since it is an attempt at paying attention to social rights while opposing paternalism. This relevance is based on the possibility that there might be political or other normative issues related to ageing or dementia that can be ignored, overlooked or distorted by addressing ageing or dementia as cases – and consequently using technologies for solving these needs.[45] It is worth noting that the Assisted Living project's advisory board has

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[45] The assisted living movement started as a social movement to increase independence for older adults and give them a higher quality of life. As Thygesen (2009) pointed out, the

an explicit mandate to discuss the project's framing and situation analysis. However, the link between health system challenges, as a political challenge, and the focus on individual artefacts in the Ethical HTA Matrix could benefit from stronger mutual interaction in order to understand, and possibly influence, the dialectics between individual situations and the larger policy issues, as described by Lehoux et al. (2019) in health system challenges. The inclusion of the Socratic approach in the Ethical Matrix is a step towards addressing wider societal questions, such as medicalisation, under- and overdiagnosis, and under- and overtreatment. Nevertheless, a broader type of responsible assessment in health would discuss issues critically, for instance, three topics relevant in all wider assessments of assistive technologies, which are the influence of social understanding of ageing, the existing underlying assumptions about ageing and the public tender system for health services.

The Ethical HTA Matrix is consequently dependent on the context for its use to meet the larger demands in RRI. But as a responsible assessment that increases normative and epistemic reflection inside an existing innovation chain, the Ethical HTA Matrix has a legitimate place.

5.2.2 Constructive assessments

As discussed, there is a more constructivist school in RRI that investigates how technologies shape our values and valuations. While the Ethical Matrix and the Ethical HTA Matrix can show how the introduction of a novel technology or procedure might affect different stakeholders' values, it does not reveal how technologies could reconfigure the way citizens conceptualise values. As discussed in *Responsibility for*, such constructivist approaches do not systematically open up comparisons between different assistive technologies, but rather study them individually in a wider social context and typically through field work or imagined cases. Such a study would not have delivered an assessment tool for comparisons to the Assisted Living project. Furthermore, the inclusion of Hofmann's (2005b) Socratic approach invites the assessor to discuss ignorance, uncertainty and the potential moral implications of

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institutionalised thinking behind independent housing with access to health assistance emerged in the 1990s. One central step in this development was Keren Brown Wilson's Park Place in Oregon, which opened in 1983 and was called a "living center with assistance" where the residents were considered tenants and not patients and had their own apartments and full discretion over food, pets, furniture, indoor environment and so on (Gawande 2014). Wilson's project was designed to give decision-making power in the latter stages of life back to the individuals, "[w]ith 'assisted living,' as Wilson's concept become known, the goal was that no one ever had to feel institutionalized" (Gawande 2014: 111).

future changes through question 29, "At what time in the development of the technology is it assessed (and what are the morally relevant consequences)? What morally relevant challenges follow from knowledge gaps?" This is the place to discuss possible trajectories based on prior knowledge of technologies in healthcare. This inclusion might make the Ethical HTA Matrix more speculative than the standard Ethical Matrix, but it does open it up to a more constructivist way of thinking.

The Ethical HTA Matrix could include some aspects of constructivist thinking, but it is limited by the absence of a wider approach to how technologies might fundamentally transform societies. This points back to the notion of developing tools that are suitable for the task at hand, and the task for the Ethical HTA Matrix is to assist in a wide assessment of assistive technologies.

5.2.3 Assessments and time

A theme where an explicit focus on ethics could conflict with RRI is regarding the production of futures through assessment. Assessments are themselves engaged in producing futures through what Giddens (1982) has called a double hermeneutics, that is they influence the item that they study. As Coenen and Grunwald (2017) highlighted, part of the modesty of an assessment is its capacity to reflect on the limits of its own ability to project the present into the future. This hermeneutic and critical approach to the analysis of visions is part of an ongoing discussion on the role and place of anticipation in RRI. The various positions include whether anticipation is directed towards: knowledge of the future (Nordmann 2014); expectations of the future (Selin 2014); or to give meaning to the present (van der Burg 2014). This theme is relevant because, according to several actors in the field, assistive technologies have a strong transformative power on the health and welfare services (Novitzky et al. 2015). As many have noted, there are different approaches to discussing the orientation to the past and its meaning for an orientation towards the future (Thorstensen 2017a; Zimmer-Merkle and Fleischer 2017), and this last point calls for reflection on the production of futures through assessments.

In applying the Ethical HTA Matrix to decision making on the future implementation of an assistive technology, users will oscillate between past, present and future – based on earlier knowledge that is applied in the present for a future health system. As Neven and Peine (2017) have identified, the field of assistive technologies is marked by an optimism that is foreign to the critical tendencies in RRI, as described by Coenen and Grunwald. One response

to this criticism is that the Ethical HTA Matrix has a modesty in looking at one assistive technology and not the concept of assistive technologies. It will consequently point to arenas for future change and potential applications of the device rather than suggest a future where this change is already implemented. Furthermore, the inclusion of what I called "critical factors" is a reminder that the assessed solution depends on a range of contextual criteria to deliver the intended goods.

The proposed approach of the Ethical HTA Matrix could be combined with larger assessments that look at wider social, ethical, political and cultural dimensions of technologies for it to reflect on its own influence on creating futures and what they might mean. Such a wider contextualisation would depend on the purpose of the assessment, as discussed with reference to the TAMI project. If an application of the Ethical HTA Matrix is future-orientated with respect to norms or actions, then it would benefit from wider reflection. On the other hand, if the application of the Ethical HTA Matrix primarily has a cognitive aspect in the here and now, then two factors to discuss would be use of the past and the relevance or aptness of alternatives or the baseline.

5.2.4 Climate and ecosystems

The Ethical HTA Matrix emphasises ecological and climate sustainability, which are also central concerns in RRI. From the interviews to *The Matrix*, it becomes clear that the respondents did not perceive climate or ecosystem sustainability to be relevant as themes for the assessment in their daily practice. Furthermore, the literature review for the Assisted Living project did not identify sustainability issues as a theme in the assessments of assistive technologies (Thorstensen 2017b). The challenge is then how to include sustainability issues in the practice of the Ethical HTA Matrix as an assessment of assistive technologies in order to minimise the ecological and climate footprint of solutions that policymakers wish should play a prominent role in future care.

As discussed in Section 5.1.2. with reference to multiplicity of viewpoints, what is central is to have the relevant views present in the assessment process. Rivard et al. (2019) have studied closely the views of engineers, designers and others engaged in the production of health technologies, and they conclude that there are challenges in combining the sustainability goal with the goal of patient care. Their respondents seek coherent political priorities aiming to combine these goals. This finding resonates with the respondents in *The Matrix* who said that

sustainability issues were based on general rules in the municipal procurement system valid for all purchases.

There are two different challenges in relating assistive technologies to sustainability. The first challenge is to gain knowledge of how the lifecycles of these technologies affect ecological and climate sustainability. This domain seems under-researched and is a prerequisite for a fact-based assessment. The second challenge is, as Rivard et al. (2019) point to, to identify who has the responsibility to act in order to mitigate sustainability impacts. In the logic of the Ethical HTA Matrix, the policymakers that have as their respective domains care and sustainability would need to be included together with persons from the other stakeholder categories to discuss conflicting values and how to prioritise. The combination of different policy concerns into one matrix structure has previously been successful in the application of the Ethical Matrix (Kaiser and Forsberg 2001; Gough and Boucher 2013). Furthermore, in the context of older adults' use of technologies, there are indications that both use and non-use depend on identification with underlying values other than personal utility (Knowles and Hanson 2018). Accordingly, there should be a space for discussing the different values with specific attention to sustainability through the Ethical HTA Matrix among stakeholders, but this depend upon gaining more knowledge and focussing explicitly on the sustainability dimension.

6 Conclusion

This thesis set out to investigate "How can the resources in RRI contribute to responsible assessments of assistive technologies?" It has been an application of RRI in a concrete research and innovation setting with the intention to create, test and assess a product. The conscientious use of assessments as means to enhance a wider responsibility in the governance of assistive technologies has not been attempted earlier, to my knowledge. Neither has RRI's specific aim to produce social benefits through innovation been systematically addressed in assistive technologies.

The discussion of the Ethical HTA Matrix as a responsible assessment found that its strongest features relate to: a comprehensive inclusion of values; a greater degree of output transparency than in other approaches that integrate HTA and values; an inbuilt disposition to include a range of viewpoints; and a transparent process that makes explicit the ethical reasoning; although one needs to be careful in the methods used for obtaining these viewpoints. In decision- and policy-making the Ethical HTA Matrix is useful for assessing assistive technology applications, but there is a need for caution as there might be important differences between products. The research shows, however, that a competent facilitator may be important for the successful use of this tool. The frugality of the Ethical HTA Matrix depends on its competent use, but my research has shown the method's potential for assisting in improved articulation of what values (in terms of both financial savings/gains and non-economic values) are sought realised through the technologies.

The Ethical HTA Matrix is mainly oriented towards cognitive and normative purposes as it does not provide an impetus for action by itself. Its interactive quality is expressed through a display of the relevant concerns. However, the emphasis on and attention to these concerns depend on the skills of a facilitator and on an attention towards how to include a diversity of persons and views. In the application discussed in this thesis, such an attention was given high priority.

When analysing assessment through the notion of output transparency, attention is given to the RRI dimension of responsiveness. Responsiveness involves from the policy or decision-making side to be open for change based on improved understanding of the social valuation of a technology (understood as both system and artefact). As discussed, such a responsiveness depends on the existence of an actor (a body, institution or collective) that can implement

changes and, in addition, on the acknowledgment of the relevant public (or a properly mandated body) that the change was beneficial.

Given the limitations above, the Ethical HTA Matrix seems suitable to enhance the overall responsibility in assistive technologies. However, as became clear in the discussion related to RRI more generally in 5.2, there are some caveats as to seeing it as an independent assessment fulfilling a general RRI mandate. It has an inherent expert view on the challenge at hand and works through analysing the different factors into manageable units. Even if the Ethical HTA Matrix is holistic regarding values and stakeholders, it still isolates the technological artefact from other spheres of life and regard the artefact as a case. Moreover, the approach described here cannot take into account how the use of technologies might change the conceptualisations of values in the longer term. In addition, the Ethical HTA Matrix is immodest to the extent that it does not open for reflections on its own capacity to change or stabilise a situation vis-à-vis the future.

A general point about the municipal use of assessments of assistive technologies is that better consideration of sustainability issues seems to require new competence, but also a new knowledge base on the users' valuations, environmental effects as well as of the devices lifecycles.

When it comes to the overarching question of how to introduce RRI into the field of assistive technologies, the research and the discussion in this thesis indicate that there remain some challenges. This thesis has had an explicit orientation to values, which constitute an important part of RRI, but it remains a part. The attention towards values seems to have been an aspect that resonated well with all the stakeholders in the field; users, producers, workers, purchasers and implementers, all have a drive towards realizing also non-economic values. Furthermore, what seemed important to my respondents was the systematisation and the likely effects of a GPS localisation system on a range of values, but also the preconditions for realizing these values called critical factors. It seems safe to conclude that a focus on values is an approach that appeals to institutions and people connected to assistive technologies. A different dimension of RRI is related to knowledge assessment that can assert the quality of available knowledge. While this has not been an explicit topic in this thesis, a range of studies as well as the engagements in *Help at Home* and *The Matrix* indicates that there are several forms of division of epistemic, moral, physical and care labour in the healthcare sector that can affect the realisation of values negatively. Two examples related to assistive technologies are first how the maintenance related to the devices demands time and competence that are unevenly

distributed and, second, how allocations of assistive technologies depend on care workers' attention toward the user combined with their knowledge of technologies as well as the local health bureaucratic allocation system. This aspect of RRI and assistive technologies deserve more attention, and should be further studied.[46] A different dimension of RRI, the processes in the field in question, has neither received much attention in this thesis while I have indicated that the current processes could benefit from enhanced facilitation skills for a value-based governance. However, as discussed in *The Matrix*, it seems that the political goals with assistive technologies some times are the introduction of devices, such as a GPS localisation system. When goals are articulated in terms of a technological solution, this approach might conflict with solutions based on social approaches. These conflicts are even more probable if the underlying goal really is something else, such as living at home for a longer time or living a safer life. It seems reasonable to state that a value-based governance depends on value-based policies towards assistive technologies. As processes are goal-oriented – one initiates a process in order to achieve something – the premises for the process are decisive. If the policy premise is the introduction of a specific assistive technology, then the subsequent process will be orientated towards this specific goal. Consequently, there is a need for further research into how to make a policy-oriented RRI for assistive technologies, as Pacifico Silva et al. (2018) and Lehoux et al. (2019) have investigated more generally for health.

In the areas of values, innovation, assistive technologies and governance, there is a pressing need for further research, which should look at the full municipal innovation chain and at research and development processes in companies selling or providing assistive technologies in order to understand better how and where value-based assessments can be included as part of governance. As suggested in *The Matrix*, there are significant differences between municipalities, so the same approach might not be applicable everywhere. The role of national innovation programmes in this field needs to be analysed and understood in light of the realities in the municipalities.

A different dimension for further research is how to make RRI policy relevant and a propagator for the democratic governance of science when politics becomes opportunistic. As suggested towards the end of the discussion, the Ethical HTA Matrix is not a full-scale societal assessment of assistive technologies with an explicit focus on products. The creation of more encompassing assessments, perspectives and methods from other and more

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[46] See Holthe et al. (submitted) for an analysis of the experiences of care workers with assistive technologies.

sociological or cultural traditions should also have a prominent place. Consequently, there is a strong need for research into how technologies transform different people's lives in different manners. One example of such a transformation is how outdoor activities through GPS might create a novel set of risks for persons with dementia. Furthermore, studies are needed into how such technological solutions connect to existing overarching problems in medicine and health, such as loneliness, medicalisation, and over- and underdiagnoses for all age groups. Likewise, the impact of product lifecycles on ecological and climate sustainability should receive further attention.

In addition, the connections – or the mechanisms – between living at home, illness and quality of life are not well understood, as briefly mentioned in *The Matrix*, and ought to be the object for further study. Inclusion of these critical perspectives, however, should be complemented by significantly improved research into the health and well-being aspects of assistive technologies on all the levels indicated by Brey (2012). Without this knowledge, assessments run the danger of posing the wrong questions.

As a final reflection, an interesting avenue for future research is how the values, practices and knowledge from a sector, such as assistive technologies, could be used to inform the future development of RRI or similar approaches to the governance or democratisation of research and innovation in also other fields.

7 Appendices

7.1 Appendix A Interview guide focus groups

Intervjuguide til helsepersonell-fokusgruppe

Innledning

-Tusen takk for at dere vil bidra inn i dette prosjektet!

-Orientere om hensikten med studien som er å undersøke:

1) hvordan dere arbeider med velferdsteknologi i arbeid med *brukere med lette hukommelsesvansker*

2) hvordan dere vurderer behov og møter brukeres behov for teknologi som støtte i brukers hverdag

3) hvordan dere samarbeider med andre (f.eks.: den eldre, pårørende, utviklere eller andre) relatert til bruk av velferdsteknologi

-Dette er utgangspunkt for en frivillig samtale og dere deler det dere ønsker. Dersom dere vil avbryte samtalen kan dere gjøre det uten å oppgi noen grunn.

-Vi har en tidsramme på cirka time

-Vi ønsker å komme inn på følgende tema:

> *Velferdsteknologi som støtte for brukere med hukommelsesvansker i å mestre hverdagen*

> *Velferdsteknologi som en del av tjenestetilbudet*

> *Verdier og holdninger til velferdsteknologi*

-Kort presentasjonsrunde av deltakerne og med deres fagbakgrunn

-Da starter vi og evt sette på lydopptaker her.

Velferdsteknologi som støtte for brukere med hukommelsesvansker i å mestre hverdagen

> Har dere eksempler på teknologi som brukere med hukommelsesvansker anvender

> > o Støttespørsmål:

> > > ▪ Hvordan virker den inn på livskvalitet, verdighet, trivsel, selvstendighet, autonomi, privatliv etc.

> > > ▪ Eksempler på teknologi som er særlig egnet for personer med hukommelsesvansker?

> > > ▪ Suksesshistorie?

- Hvordan vurderer dere behov for teknologi?

- Hva er hensikten med teknologien?

- Hva kan hemme eller fremme at en bruker anvender teknologi?

- Får du spørsmål om å assistere brukere i bruk av teknologi?

- Hvordan samarbeider dere om teknologi hvis dere jobber i team?

- Hvis bruker har vært fraværende en periode(sykehus, reise eller lignende) hvordan bruker hun/han da teknologien?

Velferdsteknologi som en del av tjenestetilbudet

- Har dere eksempler på velferdsteknologi dere anvender i arbeid med brukere med hukommelsesvansker? (mobil, kalender, ipad etc.)

  o Støttespørsmål:

    - Hvordan hjelper denne teknologien dere med å gjøre jobben deres?

    - Er det noen ganger den hindrer dere i å gjøre jobben?

    - Er det noe teknologi dere drømmer om i fremtiden som kan assistere dere i deres arbeid?

Verdier og holdninger til velferdsteknologi

- Hvordan innvirker holdninger (egne holdninger, brukers holdninger, kollegaers holdninger) til bruk av teknologi?

- Hva synes dere om opplæringen dere får i bruk av teknologier?

  o Støttespørsmål:

    - Hvilken betydning har kompetanse om teknologi?

Er det noe mer dere ønsker å dele?

TUSEN TAKK FOR DERES BIDRAG!!!

7.2 Appendix B Validation questionnaires

Om SafeMate Family for pårørende

Side 1

Opplevde du at du også før du fikk SafeMate Family var delaktig i omsorgen for din(e) pårørende?

Ja / Nei

Hvor enig / uenig er du i de følgende utsagnene der 1 er «helt uenig» og 7 er «helt enig»,

	1 - helt uenig	2	3	4	5	6	7 - helt enig	Vet ikke
SafeMate Family setter meg som pårørende i en ny rolle								
SafeMate Family gjør det lett for oss pårørende å dele på ansvaret								
Jeg har fått mindre tid til egne aktiviteter etter at jeg fikk SafeMate Family								
Jeg bekymrer meg mindre for min(e) pårørende etter at jeg fikk SafeMate Family								
Jeg opplever at min(e) pårørende føler seg tryggere etter at vi fikk SafeMate Family								
Jeg opplever at min(e) pårørende føler seg friere etter at vi fikk SafeMate Family								
Jeg opplever lettelse ved at jeg vet om min(e) pårørende er hjemme når jeg drar på besøk								
Det viktigste med SafeMate Family er at min(e) pårørende er trygg(e)								

	1 - helt uenig	2	3	4	5	6	7 - helt enig	Vet ikke
Det viktigste med SafeMate Family er at min(e) pårørende selv kan bestemme turvalg og tid for å gå seg en tur								
Jeg er glad for at jeg bor i nærheten av min(e) pårørende slik at vi kan bruke SafeMate Family								
De som ikke har familie i nærheten av der de bor, vil ha større nytte av GPS-sporing enn de som har familie i nærheten								
Det er urettferdig hvis bare de som har familie i nærheten kan ha nytte av GPS-sporing								
Personer som liker å gå på tur har mest nytte av GPS-sporing gjennom SafeMate Family								
Jeg fikk god opplæring i bruk av SafeMate Family								
SafeMate Family gjør at jeg må velge mellom mitt eget arbeid og å passe på min(e) pårørende								

På en skala fra 1 til 7 der 1 er veldig viktig og 7 er helt uviktig, hvordan vil du beskrive viktigheten av

	1 - veldig viktig	2	3	4	5	6	7 - helt uviktig	vet ikke
trygghet for din(e) pårørende								
frihet for din(e) pårørende								
egen frihet								
egen sjelefred								

	1 - veldig viktig	2	3	4	5	6	7 - helt uviktig	vet ikke
egen trygghet								
GPS som avlastning								
å stole på at GPS'en viser rett posisjon								
din deltagelse i å lade og vedlikeholde GPS-senderen								
god opplæring i bruk av SafeMate Family								
egen jobb / karrière								
tid til øvrig familie								

	ufarlig	alvorlig	veldig alvorlig	vet ikke / har ingen oppfatning
Hvis SafeMate-senderen skulle vise feil posisjon, så er det				
Hvis SafeMate-senderen skulle virke dårlig innendørs, så er det				
Hvis det er steder i nærheten av brukeren med dårlig GPS- og mobildekning, så er det				

Har du noen ytterligere erfaringer til SafeMate Family eller kommentarer til spørsmålene?

Om SafeMate for responssenter

Side 1

I dette skjemaet, så er det brukt termene "bruker" og "pårørende". Her viser "bruker" til den som bærer med seg GPS-senderen, og "pårørende" viser til den som mottar eventuelle alarmer knyttet til GPS-lokalisering eller manuell aktivering av alarm.

	ja	nei	vet ikke / har ingen oppfatning
Vi hadde et samarbeid med pårørende før SafeMate			
Jeg opplever at vi får færre alarmer etter innføringen av SafeMate Family			
Jeg har opplevd dårlig lydkvalitet med SafeMate			
Jeg har opplevd å få feil posisjon for brukere			
Jeg har opplevd at brukere har vært uten GPS og GSM-kontakt selv om senderen er i orden			
Jeg har opplevd at Geofence alarmen har gått uten at brukeren har beveget seg utenfor sonen			
De fleste alarmer er falske alarmer			

	ikke viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
I min arbeidshverdag er færre leteaksjoner				
I min arbeidshverdag er mer tid til å gi helsetjenester				
I min arbeidshverdag er det å måtte respondere på færre alarmer				
I min arbeidshverdag er frihet til å utføre arbeidet mitt				
Å tilpasse rutinene for hverdagsassistanse til brukere med SafeMate er				

	ja	nei	vet ikke / har ingen oppfatning
Opplæring av helsetjenestene sammen med pårørende i SafeMate Family er			
Opplæring i hvem som har nytte av SafeMate er			
Trygghetsfølelsen SafeMate gir meg i arbeidet er			
At bruker forstår lovgrunnlaget for å ha SafeMate er			
At pårørende forstår lovgrunnlaget for å ha SafeMate Family er			
At pårørende forstår at de har taushetsplikt for informasjonen de får gjennom å ha SafeMate Family er			

Sideskift

Side 2

	ikke viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
At opplæringen i nye teknologier er enkel er				
Å forstå hvorfor en ny teknologi ikke virker er				
Å forstå alvoret ved en utløst alarm er				
Å hurtig spore opp en bruker ved en utløst GPS-alarm er				
Å få helseinformasjon om brukeren som har utløst en GPS-alarm er				
Å oppdage kognitiv reduksjon hos brukere av SafeMate er				

104

	ikke viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
Å oppdage forverret allmenntilstand hos brukere av SafeMate er				
For effektive tjenester, så er samarbeid med pårørende				
Reduksjon i antall alarmer er				
Å unngå falske alarmer er				
For å forstå hvor viktig en alarm er, så er lydkvaliteten i en eventuell samtale				
Å kunne stole på at Geofence-funksjonen virker er				

	ikke viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
At noen kontrollerer at en bruker har med seg GPS-sender er				
Kontroll av at GPS-senderen er oppladet er				
Å oppdage GPS-sendere som ikke virker er				
Å vite hvem som har ansvar for lokaliseringen av brukere er				
Å ha pårørende med til å svare på alarmer er				
Å ha pårørende med til å finne brukere er				
Hvis brukeren reiser bort, så er klare ansvarsrutiner for SafeMate				
For å tilpasse tjenestene til brukeren, så er SafeMate				

Sideskift

Side 3

	ja	nei	vet ikke / har ingen oppfatning
Det er enkelt for oss å rekruttere nytt kompetent personell			
Det er enkelt for oss å utvide kapasiteten til dobbelt så mange brukere av SafeMate			
Det er kostbart for oss å utvide kapasiteten til dobbelt så mange brukere av SafeMate			
Jeg synes at brukergrensesnittet til SafeMate Pro er godt tilrettelagt for vårt bruk			
Jeg opplever at språkbruken i SafeMate Pro er lett å forstå			

	ikke viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
Å få inn nytt kompetent personell i rett tid er				
Å ha systemer som kan oppskaleres er				
Hvis det er steder i nærheten av brukeren med dårlig GPS- og mobildekning, så er det				
For å levere gode tjenester, så er utformingen av brukergrensesnittet i SafeMate Pro				
For å levere gode tjenester, så er presis språkbruk i SafeMate Pro				

Sideskift

Side 4

	ufarlig	alvorlig	veldig alvorlig	vet ikke / har ingen oppfatning
Hvis SafeMate-senderen skulle vise feil posisjon, så er det				
Hvis SafeMate-senderen skulle virke dårlig innendørs, så er det				

	ikke noe problem	utfordrende	veldig utfordrende	vet ikke / har ingen oppfatning
GPS gjør det lett å vite hvor brukeren er, men ikke hva personen gjør. For meg er det				

	veldig negativt	negativt	vet ikke / har ingen oppfatning	positivt	veldig positivt
Jeg opplever økt fokus på vedlikehold, oppladning og oppsett av teknologier som					
GPS og SafeMate Family er en del av modernisering av helsetjenestene. Jeg opplever denne moderniseringen					
Inkludering av pårørende gjennom SafeMate Family opplever jeg					

Noen ganger kan det være uenighet mellom tjenesten, bruker og pårørende om tildeling av GPS. Har du opplevd slik uenighet?

Ja / Nei

Dette elementet vises dersom et av følgende alternativer er valgt på spørsmål «Noen ganger kan det være uenighet mellom tjenesten, bruker og pårørende om tildeling av GPS. Har du opplevd slik uenighet?»: Ja

Jeg opplevde denne uenigheten som

 veldig enkel å løse

      enkel å løse

      vanskelig å løse

      veldig vanskelig å løse

Når det kommer til bruk av SafeMate og GPS i tjenestene, så

	helt enig	litt enig	vet ikke / har ingen oppfatning	litt uenig	helt uenig
synes jeg at det fjerner stress i hverdagen min					
burde flere få tilbud om det tidligere					
gjør det at det blir større belastning på helsetjenestene					

Har du noen ytterligere erfaringer til SafeMate Tracker / SafeMate Family / SafeMate Pro eller kommentarer til spørsmålene?

Om SafeMate for helsetjenestesystem

Side 1

Ved innføring av et GPS-basert system som SafeMate Family, så er

	lite viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
utsatt behov for tilrettelagt bolig				
utsatt behov for sykehjemsplass				
mer aktive brukere				
mindre behov for praktisk bistand				
økonomiske innsparinger				
lenger botid hjemme				
reduksjon i antall ansatte				
det å gjenfinner personer hurtigere				
en mer effektiv organisasjon				
mer effektive tjenester				

	lite viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
mer effektivt samarbeid i tjenestene				
det å skape nye tjenester				
koordinering av tjenester med teknologi				
sikker kunnskap om utgiftsnivået				
sikker kunnskap om fremtidige innsparinger				
robust teknisk infrastruktur				
enkel oppskalering av antall brukere				

	lite viktig	viktig	veldig viktig	vet ikke / har ingen oppfatning
medarbeidere som behersker GPS-systemet				
samarbeid med pårørende				
økt livskvalitet for brukerne				
kvalitetskontroll av de GPS-baserte tjenestne				
tidlig innføring av GPS-lokalisering til alle som har behov for det				
samtykke fra bruker til GPS-lokalisering				
brukerbetaling for GPS-lokalisering				
lik tilgang til tjenester for alle innbyggere uansett sosial bakgrunn				

På en skala fra 1 til 7 der 1 = veldig god og 7 = dårlig...

	1	2	3	4	5	6	7
hvor god er opplæringen for pårørende i behandling av taushetsbelagt informasjon							
hvor godt fungerer dagens lovverk for inkludering av pårørende i helsetjenesten							

Har du noen ytterligere erfaringer til SafeMate Family / SafeMate Pro eller kommentarer til spørsmålene?

Spørreskjema for deg som bruker GPS i Bergen

	lite viktig	viktig	veldig viktig
1. Å komme meg ut synes jeg er			

	lite viktig	viktig	veldig viktig
2. Å kunne bestemme hvor jeg selv vil gå er			

	lite viktig	viktig	veldig viktig
3. At det er enkelt å få hjelp er			

	lite viktig	viktig	veldig viktig
4. Å være sosial er			

	lite viktig	viktig	veldig viktig
5. Å reise på ferie er			

	lite viktig	viktig	veldig viktig
6. Å vite at noen passer på meg er			

	lite viktig	viktig	veldig viktig
7. Å føle meg trygg er			

	veldig dårlig	dårlig	helt greit	godt
8. Å føle meg overvåket liker jeg				

	veldig dårlig	dårlig	helt greit	godt
9. Å føle meg ensom liker jeg				

	lite viktig	viktig	veldig viktig
10. Å kunne selv bestemme om bruk av GPS er			

	lite viktig	viktig	veldig viktig
11. Å vite at GPS'en virker er			

	lite viktig	viktig	veldig viktig
12. Enkel opplæring i GPS-bruk er			

	lite viktig	viktig	veldig viktig
13. At GPS'en er enkel å bruke er			

	lite viktig	viktig	veldig viktig
14. At GPS'en er pen er			

	lite viktig	viktig	veldig viktig
15. At prisen på GPS'en er lav er			

	lite viktig	viktig	veldig viktig
16. Å huske på å ta med GPS'en når jeg går ut er			

	litt brysomt	brysomt	veldig brysomt
17. Å sørge for at GPS'en er ladet opp er			

18. At bare de som har slektninger i nærheten kan bruke GPS med familievarsling er	litt urettferdig	urettferdig	veldig urettferdig

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Article 1

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Chapter 3
A Report from the Field: Doing RRI from Scratch in an Assisted Living Technology Research and Development Project

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Abstract The transdisciplinary Assisted Living project conducts research within ICT, health science, social science and ethics. The overall aim of the project is to advance responsible research and innovation (RRI) in the field of welfare technology. By adapting an RRI framework, the project aims to: (a) map how stakeholders and experts perceive the state-of-the-art of responsible welfare technologies, focusing on assisted living technologies (ALT), in Norway and internationally; (b) develop ALT solutions for users with mild cognitive impairment and dementia (MCI/D), through an RRI approach; (c) judge by an integrated HTA approach whether technologies introduced through an RRI process score better than currently implemented technologies; and d) create a wider dialogue on responsible welfare technologies for the future, reflecting on alternatives and options. In the project RRI is operationalized as involving four dimensions: (i) A specific focus on addressing significant societal needs and challenges, (ii) A research and development process that actively engages and responds to a range of stakeholders, (iii) A concerted effort to anticipate potential problems, identify alternatives, and reflect on underlying values, and (iv) A willingness from relevant actors to act and adapt according to 1–3. These dimensions are built into the project's design in different ways. The project, funded by the Research Council of Norway, started December 2015 and we have by now had substantial experience with working with these dimensions in practice. This paper will describe the experiences with including needs assessment, engagement, anticipation, reflection and responsiveness in the project, after 1.5 years operation. The paper will highlight several challenges that

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19

have appeared in the project when doing RRI in practice, related to transdisci-plinarity, communication, project planning and control, and quality. We believe that the challenges experienced in our project are typical of RRI projects, so it is important to create open discussions about the pros and cons of RRI projects in the community of RRI practitioners.

3.1   Introduction

Assisted living technology (ALT) is a generic term for a heterogeneous group of technologies, often used in care for persons with mild cognitive impairment or dementia (MCI/D), involving for example videophones, robotics, GPS technology and monitoring systems to enhance security and safety and enable people to live an independent everyday life at home and in the community. The political interest in ALT has been more pronounced than the actual use of these technologies, because of factors related to organisational culture among care providers, technological alienation among elderly, and a lack of anchoring of the technologies with the relatives of the persons with MCI/D (Calvaresi et al. 2017). In contrast, within a Responsible Research and Innovation (RRI) line of thought innovations should not be pushed *on* society, but rather be developed *with* society, to meet the needs *of* society. RRI has been interpreted as a comprehensive approach of proceeding in research and innovation in ways that allow all stakeholders at an early stage (A) to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and (B) to effectively evaluate both outcomes and options in terms of societal needs and moral values and (C) to use these considerations (under A and B) as functional requirements for design and devel-opment of new research, products and services (European Commission 2013a: 3).

However, even if there seems to be a need for RRI in ALT development, practising RRI raises some specific challenges in this field. Many of the main stakeholders (persons with MCI/D) will have problems discussing technology options with researchers and developers. An RRI approach will, therefore, have to adapt to this situation by facilitating communication at a level on which the user is able and comfortable to engage, and also involve other relatives or supports the user may have. Another specificity of RRI in assisted living technologies is an apparent technological alienation among the main users.

The still rather philosophical concept of RRI has been operationalised in the ICT field through projects such as *FRRIICT*, *ETICA* and *Framework for RRI in ICT,* and specifically for assisted living technologies in the *Responsible Industry* project. However, there is as of yet no commonly agreed upon procedure or governance framework for RRI, neither for research and innovation in general, for ICTs nor for assisted living technologies. There is thus a need for case studies and experi-ments with incorporating RRI approaches in technology development in this field, and the Assisted Living project amounts to an important contribution to such experimentation.

3.2   A Case Study in RRI

The Assisted Living project engages in development of technological solutions to needs defined by persons with MCI/D themselves in an RRI process specifically adapted to the capacities of such user groups.[1] By adapting an RRI framework, the project aims to: (a) map how stakeholders and experts perceive the state-of-the-art of responsible welfare technologies, focusing on assisted living technologies, in Norway and internationally; (b) develop ALT solutions for users with mild cognitive impairment and dementia, through an RRI approach; (c) judge by an integrated HTA approach whether technologies introduced through an RRI process score better than currently implemented technologies; and (d) create a wider dialogue on responsible welfare technologies for the future, reflecting on alternatives and options. The project is designed to be both an important contribution in the process of ALT innovation in Norway and to enrich and inform RRI in both concept and practice. The project is transdisciplinary and integrated, with project partners from nursing science, occupational therapy, automation and electronic engineering, sociology, philosophy, ethics and technology assessment (TA), and includes a smart home/welfare technology company and close collaboration with Oslo Municipality.[2] The overall aim of the project is to advance responsible research and innovation (RRI) in the field of welfare technology.

The technology intervention in the project is carried out in a housing complex in Oslo, where elderly that have certain needs, but are still able to live independently at home, can rent apartments in a building that also contains a restaurant, physiotherapy, exercise groups, etc. On the generic level, the technology solutions explored in the project will provide an automated environment to support the patient's everyday activities and provide a framework of safety. We incorporate existing sensor, telecommunication and automation technology and develop self-learning solutions that interpret, anticipate and intervene as required. The specific nature of the solutions explored in the project is determined as a result of user engagement and is therefore still under development. However, the long-term goal of the project is to develop self-learning systems (i.e. machine learning) that can provide useful cognitive support in accordance with individual values, choices, and needs.

This paper will give a brief description of the RRI method in the Assisted Living project's technology development project. The project started up in December 2015 and runs over four years, so we here only present the RRI design of the project and some preliminary results.

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[1]See https://assistedlivingweb.wordpress.com/. The project is funded by the Research Council of Norway, under the SAMANSVAR programme (grant no 247620/O70).

[2]See https://assistedlivingweb.wordpress.com/english/partners/.

3.3 Operationalising RRI

In the project we refer to Wickson and Forsberg's (2013) spelling out of what they argue to be common dimensions in most RRI approaches:
For research and innovation to be responsible it needs to include:

1. A specific focus on addressing significant societal needs and challenges,
2. A research and development process that actively engages and responds to a range of stakeholders,
3. A concerted effort to anticipate potential problems, identify alternatives, and reflect on underlying values, and
4. A willingness from relevant actors to act and adapt according to 1–3.

These four dimensions are then operationalised in different ways. In the remainder of the paper we will go through these four dimensions and present some preliminary reflections on their operationalisation in practice.

3.4 Addressing Significant Societal Needs and Challenges

The project inherently addresses the grand challenge of the aging population. In addition, we have designed a comprehensive process to better understand the needs of elderly. We do this in several ways;

1. a survey among elderly who receive home-based services
2. open dialogue cafés with elderly at the study location in Oslo
3. inclusion of a selection of elderly from the study location in a technology intervention study, including a thorough assessment of their needs
4. focus groups with employees in home based services
5. focus groups with next-of-kin to the individuals included in the technology intervention

At this point, we already have quite a lot of results from activities a) to d), but we still include more elderly in the survey, will organise more dialogue cafés and will include more individuals in the technology trials.

An important challenge so far has been to uncover real needs. We have so far organised four dialogue cafés where we first explored general challenges in elderly's daily lives, then explored generic technological solutions to some of these challenges, proceeding to explore pros and cons of some concrete solutions and finally to invite the participants to try out two solutions. However, even if eight participants were willing to try out these solutions, it turns out that several of them do not actually have much need for them.

There are several ways to account for this situation. One important reason is that the elderly at this location want to be positive and collaborate with us even if they don't personally need the solutions. Another might be that in the design of the dialogue cafés we asked the elderly to discuss generic user stories in order to avoid creating socially awkward situations where too much personal information was shared. This has resulted in feedback on generic situations, and not necessarily the individuals' particularities. We have also asked the elderly to be co-researchers with us, rather than insisting on them having certain needs we will solve in the project. This is an empowering research strategy, but does not guarantee that the project meets actual needs of specific individuals (even if there is evidence that elderly in general may have such needs). So in the project, we have uncovered challenges that probably are reasonably representative (see Zouganeli et al. 2017 for a list of these), but the first technology solutions to be tested do not necessarily represent solutions to needs experienced by this particular test group.

3.5 A Research and Development Process that Actively Engages and Responds to a Range of Stakeholders

In the project, we engage with elderly at the study location through dialogue cafés and technology trials, as described above. We also meet them through the survey in the home-based services. Through focus groups, we have also engaged with staff in the home-based services and we will engage with next-of-kin. These interactions help us outline the direction for the technology development in the process.

In addition to this, we engage with a broader range of experts and stakeholders to discuss the design of the research project as such, methodological choices, project activities and preliminary results. This group, called the ProjectSTEP group, functions as a combination of a steering group and a sounding board. An important function of the group is to discuss the situation analysis in the project and critically reflect on the framing of the issues and the plans and methods for developing and assessing the ALT solutions in the project. The group follows a version of the procedures of the so-called TranSTEP group as described in https://transtepapproach.wordpress.com/doing-transtep/ (see Forsberg et al. 2015).

Finally, we want the learning generated from the reflections in the project team, the ProjectSTEP group and dialogue cafés to be disseminated to and discussed with a larger group of national stakeholders. This will take place in two conferences; one focused on foresight and one on presenting and discussing the project's main learning points.

3.6 A Concerted Effort to Anticipate Potential Problems, Identify Alternatives, and Reflect on Underlying Values

As described above the mandate of the ProjectSTEP group is to help the project anticipate problems, identify alternatives and reflect on underlying values. In addition, such reflection has a dedicated slot in each consortium meetings' agenda. In this slot we specifically reflect on the learning processes in the project. In the kick-off meeting, we included the following reflection:

1. Write down 3 words that represent good transdisciplinary research cooperation for you
2. Any comments? Anyone who wants to explain their choice of words? Or comment upon others' choices?
3. How can we—and each one of us—ensure that these qualities are followed up in the project?

In the second consortium meeting we reflected on how much the different disciplines of the Assisted Living project need to understand of other disciplines and parts. Each team member was to fill in a three column set-up indicating what they believed they needed to know about other partners' research, what they would like to know and what they believed was not necessary for them to know.

In the third consortium meeting the reflective exercise was for each to fill in the following statement: When we present our solutions (as you envisage them) to the elderly, I expect […] because […]. The intention here was to explicate our assumptions and expectations about the elderly's relation to technology. As all project team members filled this out, it allowed us to better understand similarities and differences in assumptions and expectations within the consortium and reflect on these.

The fourth consortium meeting was a shorter meeting addressing a situation where it had become clear (referring back to the second reflection exercise) that some issues were elevated from being 'nice to know' to 'need to know', as they had implications for privacy questions, general research ethics and costs. The character of the technology research was here in focus and we discussed what characterizes RRI projects compared to other user-oriented research and development projects. A relatively unique feature of the Assisted Living project is that it is a technology development project lead by an RRI partner. In most integrated technology projects, the project leader is the technology partner and the RRI partner contributes in different ways to make the technology development process more reflective or responsive to societal concerns. In the Assisted Living project the balance between the partners—the technologists, the health researchers and the RRI partners—is tipped more in the direction of RRI, not least because there are four partners with RRI competence in the consortium.

These discussions are crucial, but challenging, as all partners need to reflect on their own roles, their own expectations to the project, assumptions about scientific quality, and wishes for project outcomes.

3.7   Responsiveness—A Willingness from Relevant Actors to Act and Adapt According to 1–3

The final dimension in the project is responsiveness. The project is designed to be responsive, and the funder,—the 'co-responsibility' program in the Research Council of Norway—has allowed for (and indeed encourages) flexibility to proposals from stakeholders during the project. An obvious expression of responsiveness is the way we have made decisions on technology solutions as a result of listening to the users.

Another expression of responsiveness is the project's policy with regard to input from the ProjectSTEP group. During the meetings in the ProjectSTEP group, the project team is not supposed to respond immediately, but rather listen (and explain, when this is necessary). After the ProjectSTEP meetings, the project team discusses what we've learned and responds systematically to the input. Some input we take simply for our information, other we adapt to, and some input we deem out of scope for the project. These responses are then published on the project's webpages (https://assistedlivingweb.wordpress.com/the-projectstep-group/), in order to transparently show how the project is responsive to input. An example of a change made from input from the ProjectSTEP group was to expand the project's focus from the MCI/D diagnosis to frail elderly in general, as the technological research in the project is not only relevant for those with a diagnosis.

In addition to these planned responsiveness measures, we have also learned the necessity of being responsive to unexpected practical issues that affect the research, especially related to the engagement of the elderly at the intervention site. In order to be successful, the project must be sensitive to social dynamics at the site, to practical particularities of the individual elderly's home, daily routines, varying health conditions and wishes, and to technical challenges related to sensor equipment, data transfer, etc. This makes it clear that the flexibility of such an intervention project is crucial. This flexibility also implies that ethical considerations cannot simply be carried out ex-ante, at the planning stage, but must be a continuous reflection as the project evolves.

3.8   Concluding Remarks

We are still in the very beginning of the technology trials in the process. These trials will give us more quantitative and qualitative data on de facto technology use among the elderly. Working with technology implementation in the field will also

likely bring up further issues concerning the transdisciplinary interaction in the project. These results will be discussed as the project advances.

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Article 2

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Responsible Help at Home: Establishing Indicators for a Product Assessment Methodology

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Abstract. Responsible research and innovation (RRI) seeks to expand the governance of innovations through including social values and beneficial impacts throughout the innovation process. This chapter presents an attempt at addressing how to use insights from RRI in establishing a method for assessment of assisted living technologies. In a current research project, we aim to compare assisted living products developed through an RRI process with such products developed through a different approach. I argue that product assessment is a central part of responsible research and innovation, albeit a less developed part than the procedural dimension of RRI. Based on the literature of assisted living technologies and socio-ethical issues and on a range of stakeholder engagement activities in the research project, I document substantive values and themes that should to be included in an RRI assessment of assisted living technologies. These themes and values are systematised with the aim of aiding in selecting a product assessment methodology.

Keywords. Responsible Research and Innovation, Assisted Living Technologies, Assessment, Stakeholder Engagement.

11.1. Introduction

Governments and transnational institutions alike aim for policies and activities that can lead to fulfilments of the ideals of 'active ageing', 'healthy ageing', and 'successful ageing' (Lund and Engelsrud, 2008). Assisted living technologies are often held to be crucial in addressing these challenges. Such technologies are generally based on Information and Community Technologies (ICT), and are specially developed for assisting persons such as digital calendars, videophones, medicinal dispensers, location and tracking devices, or purpose built robots. However, the adaptation of such technologies is a slow process due to several factors such as 'technology push' (Novitzky *et al*., 2015), emphasis on caregivers' needs rather than users' needs (Topo, 2008), conflicts between the health professionals' aim to empower the elderly and the political goal of solving demographic challenges (Pols and Willems, 2011), and lack of training of users (Dahler *et al*., 2016) or training of health professionals (Saborowski and Kollak, 2015).

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Governments and transnational institutions have also recently called for increased responsibility in research and innovation, to the extent that Responsible Research and Innovation (RRI) has now become a well-known acronym. RRI can be interpreted in different ways, but many agree that the overall philosophy is captured in the following formulation:

> '[RRI] is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation' (European Commission (EC), 2014:3),

> and is specified as having a focus on the following principles: anticipation, inclusion, reflection and responsiveness (Stilgoe *et al.*, 2013).

In the context of a project addressing both the overall societal challenges related to ageing the call for RRI, researchers and PhD students from nursing, nursing ethics, occupational therapy, and ICT, as well as researchers on RRI, have repeatedly visited a facility for independent living in Oslo, Care +, in order to discuss assisted living technologies together with residents and health professionals. The higher goal of these encounters was to develop assisted living solutions in a process conforming to such established RRI dimensions. Prior to these meetings, researchers in the Assisted Living project had studied and planned how to engage persons with Mild Cognitive Impairment (Kennedy and Ter Meulen, 2017) and reviewed literature on RRI and assisted living technologies (Thorstensen, 2017).

The Assisted Living project is a novelty in RRI studies since it poses a fundamental question in RRI: Does an RRI-based process actually improve the product?

The Assisted Living project has in total three aims:

1. to produce a solution –a product– through a developed RRI process

2. to assess whether this product is deemed better (or not) by its users as compared to a non-RRI baseline study, and

3. to assess the project's working process to see how it fulfils the criteria for an RRI process it has set.

This chapter is a first step in fulfilling the second aim of the project: How can we assess a product in assisted living technologies according to RRI ideas and practice? Consequently, it is useful to start answering this question by reminding ourselves of some of the thoughts within RRI on product assessment. Thereafter, I will present two normative sources for the selection of an assessment approach: first, concerns, findings and values expressed in the literature on RRI and assisted living technologies; and second, the valuations of prospective end-users, health professionals and the stakeholder-based reference group of the Assisted Living project. Thereupon, based on these sources, I will specify the concerns under Stilgoe *et al.*'s (2013) questions for assessments of products.

11.2. RRI and product assessment

The relation between an RRI process and its outcome is not mechanistic. Kupper *et al.* described commonly acknowledged process requirements in RRI and have suggested that:

> '… it should not be lost out of sight that fulfilling those process requirements is no guarantee that RRI outcomes will be achieved. When it comes to assessing R&I practices, then, this also means that outcomes weigh in on the question of whether or not they meet the standards of RRI' (Kupper *et al.,* 2015:30).

It thus seems that an assessment of what constitutes a good outcome has an important place in RRI independent of the process. Stilgoe *et al.* (2013) proposed the following list of questions concerning the product, process and purpose dimensions of RRI.

Table 11.1. Lines of questioning on responsible innovation

Product questions	Process questions	Purpose questions
How will the risks and benefits be distributed?	How should standards be drawn up and applied?	Why are researchers doing it?
What other impacts can we anticipate?	How should risks and benefits be defined and measured?	Are these motivations transparent and in the public interest?
How might these change in the future?	Who is in control?	Who will benefit?
What don't we know about?	Who is taking part?	What are they going to gain?
What might we never know about?	Who will take responsibility if things go wrong?	What are the alternatives?
	How do we know we are right?	

Source: Stilgoe *et al.* (2013:1570)

As illustrated by Table 11.1. Stilgoe *et al.'s* (2013) articulated concerns for the consequences of products' positive and negative effects–as well as their distribution. Since the questions are in the future tense, it seems fair to assume that they are questions technology developers should ask themselves prior to launching a product. Likewise, these questions can be asked when assessing a product either at an early phase or even after years of use.

From a different perspective, von Schomberg (2012) articulated RRI as an integrative concept for assessment traditions and separates the process from the product dimension. In addition, von Schomberg (2013) saw the basis for the product dimension to include normative anchor points that should constitute the basics of a product assessment. These normative anchor points are that products should be (ethically) acceptable, sustainable, and socially desirable.

Since my colleagues and myself at a later stage will conduct an RRI-inspired assessment of the product solution from the Assisted Living project and compare this

solution to an existing relevant 'non-RRI' product, this chapter focuses mainly on identifying the specific RRI content for an ex post product assessment.[2]

In section 11.3., I will briefly explain the methodology for my literature review and elaborate on how the findings from the review can serve to articulate concerns that should be taken into account in the assessment of a product. In section 11.4., I present results from our dialogues and focus group interviews. In section 11.5., I analyse these concerns in order to identify what will constitute the specific RRI approach as a prerequisite to selecting a method for product assessment at a later stage in the Assisted Living project.

The reviewed literature consisted of in total 94 articles, theses, reports and other documents collected via cross searches in sets of databases, snowballing from these searches, reading of project documents from current projects in RRI on ICT, ageing or health, and two recent reviews (Hofmann, 2013; Novitzky *et al.*, 2015) of ethical dimensions in assisted living technologies for people with dementia.[3]

11.3. Key concerns in the literature

A central conclusion from the study of the literature on RRI and assisted living is Hofmann's (2013) argument that there is a dearth of information on how people live with assisted living technologies. His position can be illustrated with Pols and Moser's (2009) comparison of two robots: a playful and humorous dog versus a serious and factual cat. It turned out that the users preferred the whimsical dog even if (or because of) it did not serve any strict purpose other than companionship. Furthermore, Hofmann was critical towards the lack of high quality evidence of assisted living technologies' efficiency and effectiveness. Vines *et al.* (2015) suggested that the elderly themselves might be included in deciding the success or efficiency criteria. Topo (2008:29) finds a 'bias toward caregiver needs' and suggested that this is because caregivers are the main source of information in describing the lives and challenges of people with dementia.

In order to address a future demographical change with an increasing number of citizens depending on health services, Prescott *et al.* (2012) wrote that the different factors constituting the needs or challenges must be articulated. Ertner (2016) pointed

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[2] The Assisted Living Project is still in its development phase and it is too early to decide the features of the product.

[3] The searches had two themes and a conjunction, and included two main search strings: one for a narrow search and one for a wider search. Both search strings were used on EBSCO, Web of Science, and Science Direct on 2 February 2016. Since these there databases to a large degree contain articles that are not open access, I also searched the Directory of Open Access Journals on 21 April 2016, as well as Google Scholar that also points to open access articles. In addition, Google Scholar also encompasses PhD and Master Theses as well as research reports–and what is called the 'grey literature'. The narrow search was ('Responsible research and innovation' OR 'Responsible Innovation' OR 'Social studies of science' OR 'Science and technology studies') AND ('Ambient living' OR 'Ambient assisted living' OR 'Welfare technology' OR 'Welfare technologies'). The wide search was ('Responsible research and innovation' OR 'Responsible Innovation' OR 'Social studies of science' OR 'Science and technology studies') AND ('ICT' OR 'Sensor*'). I included inputs based on reading the abstract, and in some cases the concluding section. As space is limited, I will only refer to one source per claim even if this claim is substantiated by others.

to the fact that today's users are different from future users, and Mort *et al.* (2009) argued that ageing as a societal challenge should be examined by addressing how such a framing affects the understandings of ageing, and which solutions are sought: What is the relation between the users of the products and the sense of urgency? (Bachinger, 2015). Other framing effects, such as the opposing ideals of 'active ageing', suggesting a healthy and outgoing person, and 'ageing in place', connoting a frail person (Aceros *et al.*, 2015), as well as constructing elderly's relation to technology, as opposed to younger persons' usage as based on aptitude (Mort *et al.,* 2009). Novitzky *et al.* (2015) warned that technology push is likely to be greater than demand in that technologies might be developed without concrete users in mind, as was illustrated by Barlow *et al.* (2006) in a case where professional knowledge encountered business funding without any connection to local policy needs. On a different level, Constantinides and Barrett (2006) documented how unresolved intellectual property rights contributed to the failure of a tele-health product.

Tinker and Lansley (2005) documented that older people welcomed assisted living technologies to the extent that it addressed a need, but when planning for assisted living technologies, it is vital to know how many persons live in housing with sufficient health and safety standards so that they can benefit from these technologies (Tinker *et al.*, 2013).

'Will it actually work?' is an obvious question to ask, and a hard one to answer. Largely, the degree of certainty of the answer depends on the research quality behind the product and the assessment criteria for this quality, and these should both be thoroughly investigated (Barlow *et al.*, 2006). Another important element is training of professionals and users. Training of health workers can be done by letting them use the products themselves (Nielsen *et al.*, 2013), but since employees and technologies interact, the employees need a situational understanding of the technology–consequently the most fitting learning environment is the workplace (Hellesen and Bisgaard-Nøhr, 2013). However, when involving persons with cognitive impairments, the assessment design needs to be particularly sensitive to their predicament in order for them to be able to speak freely (Meiland *et al.*, 2010).

Both the testing and the implementation of assisted living technologies need to be based on informed consent, and the health professionals should adhere to norms for professional ethics during test periods in order to protect their clients (Nickelsen, 2013). In cases in which there is doubt about competence to give consent, the procedures must be scrutinised with care (Novitzky *et al.*, 2015).

Use of assisted living technologies in public settings might be stigmatising and cause isolation (Novitzky *et al.*, 2015). Likewise, assisted living technologies can cause alienation through medicalisation of the home or introduce an instrumental rationality into homes and peoples' lives in a manner that challenges fundamental values such as care, dignity and vulnerability (Hofmann, 2013).

According to the Ethical Issues of Emerging ICT Applications (ETICA) project, the main ethical issues for emerging ICTs are privacy, security, trust, liabilities and digital

divides (Stahl, 2011).[4] The issue of privacy and security reoccurs in all ethical reviews, and accountability in this regard needs to be addressed and solved (Novitzky *et al.*, 2015). Since these issues are distributed among several stakeholders, there is a risk that those in need of care are burdened with most of the disadvantages and are deprived of privacy while others–such as health workers, next of kin or the health service providers–gain (Hofmann, 2013).

Assisted living solutions might create novel risks, especially through false alarms and malfunctioning products (Pritchard and Brittain, 2015), and/or change the lives of the elderly through expected alignment with the services (Aceros *et al.*, 2015). In line with this, Tinker *et al.* (2013) systematised a range of housing alternatives and supplements to assisted living technologies, such as home sharing, retirement villages etc., which should be considered for the system transformation to meet the demographic change. When analysing telecare, Roberts and Mort (2009) found that the traditional notion of 'care' as performed by humans in close proximity to a receiver has been rhetorically compartmentalised into three different forms of care: monitoring or checking, physical care, and socio-emotional care. This has implications for the relations between users or patients and formal and informal caregivers.

Peine and Moors (2015) saw it as vital that assistive living technologies actually empower the elderly in terms of agency. Similarly, Pols and Moser (2009) argued that successful relations to technological devices depend upon the technology being 'scripted'[5] so as to allow the user to create an affectionate bond with the device, and this depends on the extent to which the device can *bring something of value* to the user. Peine and Moors (2015) suggested here that it is of greater interest to reflect on the processes through which users estimate or value something than what they value.

In a study of a sheltered housing scheme for elderly, Roberts and Mort (2009) found that women experienced loss of coping and receiving care as losing independence whereas men saw assistance as loving care. They also address gender as an aspect in the changing nature of care work since female informal caregivers and low-paid females perform this work. Dahler *et al.* (2016) identified gender as one central factor in adapting education and training to professionals and end users.

11.4. Stakeholder events

In order to determine important parameters for product assessment, we did not only consult the literature, but the elderly themselves and other stakeholders. We did this by asking what experiences do current users, health professionals and central experts have with assisted living technologies? In this chapter, I put an emphasis on what was valued–both positively and negatively–by the different stakeholders, professionals and users. I use these valuations as normative criteria for how assisted living technologies ought to

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[4] The ETICA project identified ethical issues from emerging ICTs and their possible applications and produced recommendations for addressing these issues. See: http://www.etica-project.eu/

[5] Madeleine Akrich explains the notion of a 'script' by comparing it to a film script: 'Thus, like a film script, technical objects define a framework of action together with the actors and the space in which they are supposed to act' (1992:208).

be. The Assisted Living project has the responsibility to answer to these concerns. In the last section, I will look closer at which concerns are central in an RRI approach, and use this at a later stage as input to what kind of product assessment the Assisted Living project should apply.

This section encompasses the valuations from two engagements (dialogue cafés) with prospective end users, five focus groups with different health professionals and two meetings with the Assisted Living Project's advisory group. I present here the parts that are relevant for assessing the output of the innovation process. This information is gathered from the transcripts of the events and from the internal reports produced by the consortium.

The setup and the analysis of the different stakeholder engagements were similarly conditioned by RRI: We emphasised that everyone should be able to speak; we were unambiguous concerning the purpose of the event; we took specific note of values and uncertainties; and we returned later with replies to issues raised or questions asked. We held two arrangements of the 'World Café' type with the residents at Care +, two roundtable meetings with our reference group, and five focus groups in Oslo with health professionals.[6] We wrote thematic reports from the events with the residents and full transcripts from the other events.

11.4.1. Dialogue cafés

The Assisted Living project reviewed previous studies on how to engage with persons with cognitive impairments in research (Kennedy and Ter Meulen, 2017). The project team then organised two World Café type events at the Care + facility, and called them *Dialogue cafés*. They were structured as to respect the residents' contributions and served to efficiently facilitate discussions between the residents and the research team. We held two events with residents at the Care + facility. The first event aimed to map residents' daily challenges, and in the second event, we presented some general use cases.

The residents emphasised how technological solutions could both include monitoring solutions and solutions of assistance in their daily lives. High on the list of priorities are safety alarms and fall detection, and safety at night with a possibility to control the lights. Everyone had a range of routine situations such as going to sleep, eating, cooking, shopping, going outdoors, watching TV, calling relatives, or receiving visits from friends or care workers. Such routines might require assistance. Furthermore, a good solution should empower the user to feel that she or he is in control of the situation and amplify positive situations, such as socialising and reduce negative situations such as, for example, forgetting one's wallet, pin codes or passwords, credit card, handbag, hearing aid and/or keys.

New technologies call for sufficient training. Every solution might have difficult settings with an array of buttons. Training is not just technical instruction, but adaptation to a person's full life situation. People whom they perceived to be responsible for a

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[6] Please note that these are only the events in 2016 and that the Assisted Living project continues with engagement activities with these and other stakeholders throughout the project.

device or happenings do not always assume this responsibility. Technologies and care services alike can waste the elderly's time, and technologies should facilitate for communication, for example between services and users. Several of the participants expressed that it was useful with prompts and reminders in the daily life. However, this latter point was contested by others who saw such prompts produced by technological devices as potentially stultifying since they enjoyed training their memory through daily tasks.

The technology itself should be safe and secure. When discussing safety technologies, the elderly emphasised that they need to know that someone will respond to alarms or distress signals. The combination of bodily and mental frailty creates new fears and new safety and security challenges. Solutions should be moveable or useable from a distance; if solutions are fixed in position, a person might not be able to reach them in the event of a fall or accident elsewhere.

On a general level, we in the research group had the impression after the first dialogue café that the residents did not have specific concerns regarding privacy. This, however, was proved wrong in the second dialogue café when we introduced a scenario in which their next of kin could be notified of falls through video and alarms. Here, several of the groups objected strongly to involving their relatives since they perceived them to be too busy or that they would become upset–and that it was a task for the public services. Others saw this solution as having only benefits, and felt that video surveillance could be installed in all rooms as long as they had some say in who could access the video. Some mentioned that it would be an advantage if the images were blurred.

There were several objections to a scenario of notifications on a tablet showing who was present in the cafeteria, as such notifications could be used to 'pry'. They also had concerns regarding who decides what kind of information is distributed where. Furthermore, they wished to be in control over this process of information gathering and distribution. Rather than digital remote surveillance, some wanted night watch and locks that could be opened by others in case of emergency.

11.4.2. Advisory group

The project's advisory group consists of representatives from user organisations, academia, municipalities, government, professional groups and businesses connected to assisted living technology. Due to the mixed composition of the group, there are two main perspectives on assisted living technologies: as part of the health and welfare services and independent of these services.

Relevant for both perspectives are considerations regarding what will happen when a product is scaled up either to the market or as part of the services. Are there strong regional differences in digital literacy or service provisions that might be of importance? A hermeneutic aspect is how to adjust for differences in expectations (and possible disappointments) among users, professionals, service providers, and the public. In line with its central function, the advisory group underlined several important aspects regarding the innovation and implementation process, such as the set-up of the

research and innovation process in order to become aware of similar solutions under development.

Some members of the advisory group challenged us to investigate if we have become too reliant on today's views on technologies and solutions rather than trying for more radically novel solutions that might fit better with a situation ten years from now. Every technological solution has a life span. An important point in the assessment will be to try to characterise the expected life span of the different components of a solution. Likewise, the organisation of the services will influence the life cycle of a solution.

Even though the members of the advisory group separated their remarks between technology as integrated with and independent of the services, they are of the opinion that ideally solutions should be compatible for use independently of or integrated into health services. This necessitates that the solution adheres to certain standards.

Future technologies should not only empower citizens to be self-reliant, but ideally also include the networks surrounding the users, such as family and friends. Solutions should ideally be fun and stimulate the users mentally and physically: prevention is preferable to treatment. One of the largest barriers to use is that users find the products ugly–and that taste varies between individuals.

When it comes to developing solutions for use in the health services, the advisory group felt that there is a need to envisage how to integrate the solution into the services as well as to create training opportunities. Training should teach health professionals to work differently, but also how to set up and administer the solution and to train the end users. With deteriorating cognitive capacity, training end-users becomes more challenging, but it is important to activate and train remaining capacities. However, for persons with diminished cognitive functions, smart technologies that can anticipate and assist decision-making are valuable.

The advisory groups asked if there are specific factors characterising our test group as opposed to our target group–people with reduced cognitive abilities. One particular issue they have raised in this regard is if there are regional and/or cultural differences between our test users and the remaining population that might limit the applicability of the results.

11.4.3. Focus groups

The participants in the five focus groups had different professional backgrounds, but all worked in the home services in Oslo. The sessions lasted for one hour each, and were transcribed afterwards. They mainly emphasised the relations between users, next-of-kin, professions and suppliers; safety; user and professional empowerment and efficiency; and usability.

The health professionals primarily perceived assisted living technologies as increasing personal safety, but there are several ways of assuring safety. In all the focus groups, they mentioned how the next of kin (friends or relatives) are key to co-operating with and on behalf of users, discovering anomalies in disease and/or technology, and in facilitating prolonged independent living:

'because it's not only to receive these assistive devices, but who's in charge for support and can the next of kin follow through in the use–one thing is to get them, but who's seeing to that they're used?' (focus group participant #R1-2, 9 June 2016).

Consequently, any solution should be assessed as to how it facilitates involvement of non-formal caregivers. In order for this to be realised, training is necessary, as well as clear distributions of responsibilities: it seems that doubt, insecurity and inefficiency can occur in the quadrangle between users, next-of-kin, professions and suppliers especially when new equipment is installed, something breaks down or just has incorrect settings or functionality for the user:

'But then there are the companies, for many companies are responsible for their equipment, so if I fiddle with the equipment of someone else, then I do something I'm not allowed to … it's about guarantees and different things … but it would be nice to have the same knowledge as the user' (focus group participant #R2-12, 9 June 2016).

A central feature is then how good the training is. In many instances, a product cannot be assessed on its own without connection to the training procedure. Furthermore, as is touched upon in the quote, health professionals (and next of kin) are often the first who are asked to fix malfunctioning equipment. They should then have competence in basic troubleshooting and repair. Training should also include sensitivity training in order to uncover whether changes in the user's condition render the product irrelevant to the user.

An important idea is that good technology saves time for the professional and empowers the users at the same time. As is illustrated in the following quote, several members of the different professions saw possibilities for increased efficiency using technologies that can activate the users:

'That you could have a big screen with fitness and exercise programs in the homes of several different people at the same time instead of the physiotherapist having to make all those visits' (focus group participant #R2-10, 9 June 2016).

Technology creates individual and social habits. Some professionals hold some habits to be virtuous, especially those promoting safe behaviour and/or that give the users a feeling of freedom and independence, while others hinder social interaction or movement. Such changes to an individual's life should be considered both according to the degree of change and the quality of that change.

11.5. Systematising values for indicators

Stilgoe *et al.*'s (2013) overarching theme regarding the distribution of risks and benefits is a central issue that reoccurs in several of the sources for this chapter (see, for example, Hofmann, 2013). Consequently, the Assisted Living project would benefit greatly from an assessment methodology that can differentiate between a range of topics and open up for a potential deliberation around them. My central issue in this section is to systematise the different factors that we found to be given importance so that the Assisted Living project knows what the central values are before deciding upon a methodology for assessing assisted living solutions.

11.5.1. The good life

First, what is needed is a methodology that allows for a reflection with the stakeholders on what constitutes a benefit. These are concerns that pertain to the sphere connected to autonomy and dignity–and to the wider question of living a good life. An assessment should open up for a reflection on what form of value (amusement, service, exercise) the user receives, and how the product might connect affectionately to the user (Pols and Moser, 2009) or the health professionals' experiences of how technologies influence or alter social relations. In a similar vein, Hofmann (2013) underlined that technologies might cause medicalisation of the homes where devices replace social solutions, that they instrumentalise the homes and create alienation. The participants in the dialogue cafés saw such an instrumentalization as potentially stigmatising. A necessary question to ask here is whether this form of 'care' is the preferred form of 'care', and how this novel type of care affects the other dimensions of care, such as the physical and socio-emotional aspects (Roberts and Mort, 2009), or if the new care constellation comes from a technology push (Novitzky *et al.*, 2015).

11.5.2. Risks and benefits before use

Before a product is tested with users, one can seek evidence for the product's security as well as what are the most likely privacy issues (Stahl, 2011). The participants in the dialogue café also expressed a wish to control for what kind of information that could be collected and where and how it is distributed. Furthermore, one should investigate the evidence bases for the product (Barlow *et al.*, 2006; Beedholm *et al.*, 2016), and the health professionals highlighted the need for evidence for its user-friendliness (focus groups). Likewise, one should seek evidence for economic, social and ecological sustainability (von Schomberg, 2013), as well as for potential institutional sustainability (Dahl *et al.*, 2013) Both the stakeholders in our advisory group and the health professionals emphasised the value of early analyses of expected costs and relations to the services for the possibility for up-scaling. Along a different dimension, an assessment should take into account if the research was conducted according to ethical codes (Nickelsen, 2013). There are also juridical and soft law practices that might influence the practical possibility to implement a system such as intellectual property rights and standards (Constantinides and Barrett, 2006; Advisory group).

11.5.3. Risks and benefits in use

In the context of assisted living technologies, it is central to determine what form of predicament is envisioned targeted through the use of the product (Aceros *et al.*, 2015), how and whether this change also empowers the elderly in terms of agency (Peine and Moors, 2015) and how else this change will benefit the elderly, as pointed out in the discussions in the advisory group. They further emphasised that important dimensions for prolonged living at home is both bodily control and cognitive training. In addition to discussing the importance of daily cognitive maintenance through remembering and performing quotidian tasks, the participants in the dialogue cafés also raised the topic of increased social participation as a central benefit. They held the possibility of social encounters as one example of positive situations in a wider sense than just receiving

technical task assistance, and brought forward the view that benefits and risks should further be understood as *situations*, i.e. the benefits and risks should be understood in a wider context. A situation where a person sounds an alarm, but without receiving any notification that help is underway, was mentioned as a negative situation even though they receive help in the end. In this case, the benefit is not primarily for the user, but a new risk has been created (Pritchard and Brittain, 2015).

The story suggests a bias towards caregivers' needs which in general seems to be an issue (Topo, 2008). The health professionals also discussed who is the main beneficiary of the increased effectiveness of new assistive devices. This suggests that assessments should be able to distinguish between how different stakeholders are affected. The health professionals warned that devices might cause confusion and that a central goal should be an increase in experienced independency for the primary users.

In the dialogue cafés, the participants saw both experienced and actual safety as central dimensions. Since health professionals in many cases will interact with the users and their devices, the advisory group discussed how the impact on the professionals also should be assessed, whereas the health professionals themselves emphasised that they needed to have training in and access to adjusting the products or performing easy maintenance. The health professionals highlighted the need for proper adjustments or personalisation to individual users as a prerequisite for enjoying the suggested benefits.

11.5.4. The distribution of risks and benefits

The distribution of risks and benefits should be informed by normative criteria. In the reviewed literature and the engagement practices, we found that the following concerns are raised. First, the distribution depends on the alternative to the technological solution: If there exists a safer and less intrusive method of providing assistance, then the transferal of risks to elderly should be properly justified (Tinker *et al.*, 2013). A central question is also the scope of reach, or how many persons and what groups that can be expected to employ the technology (Tinker *et al.*, 2013). Roberts and Mort (2009) discussed how men and women might have different experiences when it comes to being in need of aid. Hence there might both be a subjective dimension as well as a gender dimension in adjudicating what a fair distribution could be. Likewise, there is also an objective dimension to the distribution, such as Stahl's (2011) observation that digital divides should be addressed.

11.5.5. Distribution of responsibilities

The distribution of risks and benefits can be said to be mirrored in the issue of the distribution of responsibilities among the service providers and/or researchers. From Stahl (2011) and from the focus groups I retain that the distributions of responsibility among all the involved parties for all the elements of the assisted living technology should be explicated and understood by everyone.

11.5.6. Training

Reading through all the normative issues, the continuous emphasis upon learning and training among the stakeholders is striking. The stakeholders in the project refer to training and learning as instruction. Instruction can well be a social event with individualised aspects, but also include manuals or videos. Of course, training is not integrated into a product in the same manner as a processor to a computer so it seems problematic to include training into criteria for product assessment. At the same time, it is difficult to imagine that a person installs a device at home in order to increase safety, coping, and/or quality of life without any introduction. Consequently, I find it legitimate to include instruction into the product assessment.

11.5.7. Reflections

I primarily see the last three questions from Stilgoe *et al*. (2013) as reflexive questions. One way of trying to include these, as reflexive exercises, would be to connect them to some central themes from the literature, such as framing effects (Mort *et al.*, 2009), reconfiguration of trust (Stahl, 2011), the procedural aspects of valuation (Peine and Moors, 2015), and the difference between today's users and future users (Advisory group). Do such issues provide reflection among the assessors? We will open up for discussing these issues with users, health professionals and next of kin in the Assisted Living project.

11.6. Conclusions

One of the next steps for the Assisted Living project will be to select an existing assessment approach that can accommodate for–and be enriched with–all the concerns above, and simultaneously provide grounds for comparison between different products. Based on the findings above, the possibility to include contextual factors and different stakeholder perspectives are two of the important features in a future assessment methodology.

The limitations of this study have to do with the completeness of the reviewed literature and the framing and the context of the fieldwork. For the literature review I have searched for and read only material relevant for a combination of assisted living technology, ICT, ethics, and Science and Technologies Studies, there is a danger of circularity in the interpretation of the material and the systematisation of the findings. We conducted the fieldwork in an open but structured manner in a socially privileged part of Oslo. This means that we gave much space to persons who might not be representative of the national population of elderly as such.

We addressed these challenges by presenting as openly as possible all the perspectives in the empirical material. This form of grounding of the hermeneutical intuition might help the research project, readers and myself in gaining insight into what is of value and why. Furthermore, these findings have been discussed with project partners so the interpretations have been filtered through their backgrounds as well. Here, the debates on how to understand and proceed with every issue in the process have

been discussed intensively based upon both professional and personal logics before we have acted upon them and presented the next step to our partners in Care +. One central challenge for improving lives through technologies is to translate the project members' internal learning into useful products. Such insights might come at different times to individual members: if we close down too soon, then we will not reach the pinnacle, and if we keep everything open too long, we will not provide users and business with anything at all.

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182

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Article 3

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Responsibility for Assistive Technologies: Product Assessment Frameworks and Responsible Research and Innovation

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The approach to innovations known as Responsible research and innovation (RRI) aims to move the innovation system towards creating products that strive to realize social values along with economic benefits. This paper discusses the systematic assessment of assistive technologies in order for them to meet the aims expressed in RRI. A central issue in the discussion is how to facilitate an integration of insights from the discourse on RRI with more established assessment approaches such as Health Technology Assessment (HTA). Based on the literature on existing socio-ethical assessment tools, I investigate how these tools can be combined with HTA and how they can add perspectives from RRI that might increase the socio-ethical value of assistive technologies. Through a discussion on how to understand RRI, HTA, assessment and integration, I suggest a list of four possible approaches that have the potential to be applied as assessment approaches that integrate insights from RRI and HTA. These are then evaluated on their ability to address issues that have emerged from a literature review on RRI and assistive technologies, on empirical studies in this technology field and on their product focus. In conclusion, I argue that the Ethical Impact Assessment, the Socratic approach, the Ethical Matrix, and the HTA Core Model seem to be the most promising methodologies, but that these need adjustments to cover substantive themes from RRI.

Keywords: responsible research and innovation, assistive technology, methodologies, product assessment

Introduction

Worldwide we see a proliferation of assistive technologies in hospitals, institutions and homes, ranging from high-tech robots to low-tech analogue alarms. There are high hopes for assistive technologies in policy circles as part of an approach that might empower people with disabilities of all ages to reside at home longer, as opposed to living in different kinds of institutions. In the last 25 years, researchers,

policy-makers and health professionals have especially focused on older adults in order to accommodate smart homes for this group (Thygesen 2009). The vision behind this practice has been to increase older adults' independence and self-esteem, while reducing both health care expenses and an increased number of employees in health care delivery. In addition, several technology firms are launching solutions promoted as meeting these policy objectives. In the field of assistive technologies, we then encounter both *policy pull* and *technology push*, as von Schomberg (2011) calls them. Seen from a socio-ethical perspective, concerns over assistive technologies relate to issues such as how *care* is perceived, experienced and given (Roberts & Mort 2009), the possible medicalization of homes (Hofmann 2013), focus on caregivers at the expense of users (Topo 2008), and possible conflicts between empowerment of older adults and the larger goal of addressing ageing as a demographic challenge (Pols & Willems 2011).

The Assisted Living project is a research project using insights from Responsible Research and Innovation (RRI) in order to research and develop assistive technologies. The project consists of a facility for independent living, an SME for developing assistive technologies and smart home solutions, technology assessors, and researchers in technology assessment, ethics, ICT, nursing, and occupational therapy. We compare the assistive technology developed in the RRI-based project to an existing assistive technology developed in a project that is not based on RRI. The intention is to obtain information on the possible influence of process on product.

In the health technology field, Health Technology Assessment (HTA) is a common denominator for different policy advice formats on novel products or solutions. Consequently, this approach has high legitimacy and high policy relevance. In order to make RRI relevant and legitimate for decisions regarding health policy, I will explore how different assessment frameworks used for socio-ethical assessments of health technologies reflect the core components of RRI. A number of such assessment dimensions have been identified in the current context in a previous paper (Thorstensen 2017b). I will then focus on evaluating assessment approaches, but this study does not claim to exhaust all the possible socio-ethical approaches that might be combined with HTA and also resonate well with RRI.

This paper argues that Ethical Impact Assessment (ETIA) (Wright 2011),[1] the Socratic approach (Hofmann 2005b; Hofmann, Droste, Oortwijn, Cleemput, & Sacchini 2014), the HTA Core Model (Lampe et al. 2009), and the Ethical Matrix (Kaiser & Forsberg 2001) are relevant candidates for assessing assistive technologies in line with HTA and the central thinking in RRI. In order to reach this conclusion, this paper begins with a general introduction into RRI and product assessment, followed by an explication of what a product assessment methodology of assistive technologies in line with RRI should contain. Based on literature that assesses health technologies and RRI and assistive technologies, I present the possible candidate methodologies and relate these to the aforementioned criteria.

Responsible Research and Innovation

Responsible Research and Innovation (RRI) is a term used for research policy, for a cross-sectorial approach to science and innovation governance, and for an intended practical approach to research and innovation (Ribeiro, Smith, & Millar

2016). For the Assisted Living project, the last term of the phrase RRI applies. When conceived of as a method for innovation, Assisted Living project utilizes a conception of RRI as containing:

1. A specific focus on addressing significant societal needs and challenges
2. A research and development process that actively engages and responds to a range of stakeholders
3. A concerted effort to anticipate potential problems, identify alternatives, and reflect on underlying values, and
4. A willingness from relevant actors to act and adapt according to 1–3 (Wickson & Forsberg 2015: 1164)

The Assisted Living project understands itself as responding to the "Ageing society" as a "societal need or challenge." The justification for using RRI in assistive technologies lies in the connection between RRI and these societal challenges (von Schomberg 2013).[2] In addition, all four points above constitute the normative foundation for establishing how to assess a product in line with RRI.

Part of the novelty in the Assisted Living project, is the use of RRI as a guiding principle for doing research and innovation in practice. RRI has a novel normative approach to research and innovation in its study of the moral purpose of innovations. This approach aims to combine central value aspects in societies with the social and economic benefits of research and innovation through close links with industry (Pacifico Silva, Lehoux, Miller, & Denis 2018). Different approaches and RRI both include affected parties, users, stakeholders and policy-makers. However, they differ somewhat in that von Schomberg (2011) has tried to explicate how to conceptualize these values whereas Owen, Macnaghten, and Stilgoe (2012) tend to emphasize that these values should be sought among the participants, and operationalized towards application in research (Owen 2014). Wickson and Forsberg (2015) strive to combine these two approaches.[3] In the European Union, RRI has been presented in relation to the research policy areas (the so-called "keys") of *public engagement*, *open access*, *gender*, *ethics*, and *science education* (and earlier also *governance*).

Product assessment

A more specific meaning of the term "product assessment" is conditioned by background and discipline. In an early contribution to RRI, Stilgoe et al. mention some questions that are relevant for a product assessment:

- How will the risks and benefits be distributed?
- What other impacts can we anticipate?
- How might these change in the future?
- What don't we know about?
- What might we never know about? (Stilgoe, Owen, & Macnaghten 2013: 1570)

von Schomberg (2011) argues from a different perspective that in RRI, products should be evaluated through their ethical acceptability, sustainability and social desirability. When it comes to assistive technologies for the elderly, products must have acceptable functioning and design in line with the users' and central stakeholders' values and preferences, how they relate to quality of life, and general ethical principles. Central to the overall idea of RRI is to reflect on the purpose of research and innovation (Owen et al. 2012; Stahl & Coeckelbergh 2016).

The concept of a "product" needs further clarification.[4] My understanding follows Brey (2012), who suggests three relevant levels for an ethical analysis of technology: 1) the technology level, 2) the artifact level and 3) the application level. With solutions at the application level, Brey refers to "the concrete use of a technological artifact or procedure for a particular purpose or in a particular context, or a specific configuration of an artifact to enable it to be used in a certain way" (Brey 2012: 311). In the present case, "application" would thus refer to an artifact being used by elderly individuals with diminished cognitive capacity in their homes in order to perform certain tasks or sets of tasks. Brey's distinction between technology, artifact, and application makes it possible to distinguish different aspects of product assessment and to differentiate it from Technology Assessment – which has as its focus Brey's "technology" level. I follow Brey in this article, and by "product" I refer to Brey's *application* level that includes a specific purpose and the configuration surrounding the application in order for it to achieve this purpose.

Recently, researchers from the Responsible Industry project presented an approach where they argue that effective RRI should be assessed according to "certain identifiable consequences" (Stahl et al. 2017). These consequences are derived from the RRI "keys" of the European Commission (2012) as well as from an expert group on suitable policy indicators for RRI (Strand et al. 2015). Stahl et al. have employed the keys together with the process criteria from RRI, as listed above, to create a project self-assessment tool to monitor the RRI quality of a project or an organisation (ORBIT 2017). The ORBIT tool and similar *RRI process evaluation tools* fall outside the scope of the meaning of product assessment in this article.

Health Technology Assessment

The historical background for HTA is similar to that of the different forms of Technology Assessment (TA). They both originated in and through the same impulses that created the U.S. Congressional Office of Technology Assessment (OTA) in 1972 and with the same focus on efficiency, understood as the cost-effectiveness of a given health intervention. Traditionally, pharmaceuticals, vaccines and medical equipment have been easier to assess through HTA, while different types of health care practices have been more challenging to assess due to their interlinked and complex nature (Banta 2003). Adding to the complexity, studies reveal a lack of clear definitions in the literature on how value is or should be defined (Antoñanzas, Terkola, & Postma 2016).

Currently, the INAHTA (International Network of Agencies for Health Technology Assessment) defines HTA as follows: "Technology assessment in health care is a multidisciplinary field of policy analysis. It studies the medical,

social, ethical, and economic implications of development, diffusion, and use of health technology" (INAHTA 2016). This expands the scope of the original use to include social and ethical aspects in a systematic manner. HTA still has as its main purpose to assist in decisions related to policy. Now, the policy context can be at any level, including at the low level of a hospital or the higher level of a municipality assessing new interventions.

With respect to RRI and HTA, Cuijpers and van Lente (2015) present a strong case for how HTAs do not allow for different sets of logic or values. In a similar vein, Moors and Peine (2016) argue that HTA assumes a perspective that downplays solutions enhancing individual agency and promotes medicalization. The integration of the social and ethical dimensions has suffered from being analyzed independently of the other epistemological dimensions in the HTA. As a remedy to this dissociation, suggestions have been put forth that mainly serve to add complexity to the procedure while subsuming social and ethical issues under general effectiveness research. (Refolo et al. 2016). Another dimension that has rendered this integration problematic has been that the specific methods have been immature (Hofmann 2005a). The EU-funded project Integrate HTA suggests including assessments of socio-cultural dimensions into HTA, in addition to or in parallel with an ethical assessment (Lysdahl et al. 2016; Mozygemba et al. 2016). Including other normative issues seems to be in line with the move from ELSA (Ethical, legal and social aspects) to RRI. Since HTA is by definition an interdisciplinary endeavour and since RRI revolves around continuously discussing and reflecting on assumptions, inherent values and responses, the preferable mode of integration in the product assessment approach and the HTA would seem to be those of *coordination* and of *interaction*, as defined by Hofmann et al.:

- Coordination: Ethics is still an independent part of the HTA, but the role and weight might differ depending on contextual factors. The results from the other parts of the HTA will influence the input to the ethical parts, but not the methodological choices of the ethicists.
- Interaction: Ethics and other disciplines will be in a continuous exchange of viewpoints and results with possible redefinitions of the policy question, methods, and relevant comparative cases for all disciplines. (Hofmann et al. 2015: 131-132)

This means that there should be some form of interaction between an assessment method based on socio-ethical concerns and monetary and health concerns in an HTA.

Indicators for choosing an approach

In an earlier study based on a review of the RRI and assistive technologies literature as well as dialogues with stakeholders in the current project, I documented that a range of values ought to be taken into account when developing assistive technologies (Thorstensen 2017b).[5] I will now recapitulate the central findings

from this article. A central concern is that a product assessment approach used in an RRI project should be able to incorporate these points.

The good life:
A central issue for the assessment of assistive technologies is that the stakeholders are included in thinking about and reflecting upon what constitutes a benefit in the particular case. These benefits should not be reduced to utilitarian concerns but should also include social relations, values such as exercise and amusement, and reflect modifications to the lived environment through devices and a novel type of care. Including the stakeholders' own understanding of benefit can be carried out as a part of the assessment (when interviews or other qualitative approaches are used) or in phases prior to the actual assessment.

Risks and benefits before use:
The above concerns should be used in a solid and complete pre-trial (i.e. ex ante) testing of a product. Such testing should also encompass privacy, safety, security, information collection and sharing as well as a thorough review of the evidence base of the product. Assessments of the product's economic, social and ecological sustainability ought to constitute a part of this evidence base. However, this criterion will be disregarded for the present purpose, since we are striving for an assessment method that is applicable both to products made in an RRI process and other products (without any possibility to conduct an ex ante assessment), where an assessor or an assessing body lacks information about the process.

Distribution of risks and benefits:
An assessment should include considerations about the distribution of risks and benefits. In particular, one should be aware that assistive technologies might entail a transfer of the risks towards the elderly. If such a transfer seems to be the case, alternatives to the solution should be explored or the transfer needs to be justified in terms of other types of benefits.

Distribution of responsibilities:
As with the distribution of risks and benefits, the distribution of responsibilities regarding the product should be well understood, but also open for discussion. This relates particularly to the division of responsibility among the different operators in the service provisions connected to a product.

Training:
A final concern is that the assessment also investigate how users are introduced to the product, since health professionals and users alike identify didactical approaches (or their absence) as key aspects in the process.

These criteria overlap to some extent with the previously referenced product assessment question posed by Stilgoe et al. (2013), who mention the distribution of risks and benefits. The dissimilarities, however, have to do with future impacts and changes in such impacts. As Cuijpers, van Lente, Boenink, and Moors (2014) point out, the future orientation inherent to RRI demands a responsibility towards

an imagined or assumed future. In order to fulfill this demand, I believe that an assessment approach would also need to include an exploration into *contingency*, in order to assess plausible changes (Stilgoe et al. 2013). Recently, Pacifico Silva et al. (2018) investigated *Responsible innovation in Health (RiH)* in a policy setting, and they argue that this should encompass five value domains consisting of nine dimensions.[6] Their addition to the themes above are the health relevance, the organizational dimension and frugality. Health relevance relates to the innovation's intent to address neglected or under-prioritized disease or adding to incremental benefits for the more affluent. The organizational dimension studies how or if the producer – inspired by the literature on social entrepreneurship – seeks to provide additional values to society. The frugality dimension is rooted in the literature on health economics showing the pressures on the health system by novel technologies and focuses on whether greater value is produced through fewer resources. Regarding the RRI qualities of the frameworks, I use *frugality*, *social entrepreneurship* and *health relevance* as parameters based on the consideration of the frameworks suggested by Pacifico Silva et al. (2018)

The following criteria are central in analyzing how to address the quality dimension of ethical assessment approaches: *comprehensiveness* and a broad inclusion of values, *user-friendliness* and *transparency* (Beekman et al. 2006; Forsberg, Shelley-Egan, Thorstensen, Landeweerd, & Hofmann 2017; Kaiser, Millar, Thorstensen, & Tomkins 2007). In practical terms, this translates to an assessment that includes a broad range of relevant values and other ethical aspects. The ability to practically operationalize these criteria is key, so that other persons (users, stakeholders, decision-makers or the public) can understand how conclusions follow from the relevant values and other ethical aspects.[7]

The values proposed by the desired assessment approaches should at least encompass a good life, risks and benefits before use, risks and benefits in use, distribution of risks and benefits, distribution of responsibilities, and training within a fixed and transparent framework that allows for case-relevant and socio-ethically relevant aspects and arguments. Stilgoe et al. (2013) supply the criteria of other possible impacts, future changes of impacts and systematic inquiry into ignorance, as well the purpose of the innovation. From Stahl et al.'s (2017) substantive list of product assessment criteria I retain gender/equality and diversity, open access, social justice/inclusion, sustainability and science education – and here ethics should be added for systematic purposes. Based on Pacifico Silva et al. (2018), I use health relevance, frugality and social entrepreneurship as criteria. In terms of the process criteria of governance and public engagement from the European Commission's six "keys," I believe that governance is covered by distribution of risks and benefits and distribution of responsibilities, while public engagement is covered by comprehensiveness and a broad inclusion of values, since these presume the inclusion of a variety of perspectives and viewpoints.

Discussion of assessment approaches

Several scholars have recently studied in detail some of the possible candidate frameworks (Forsberg et al. 2017) and their relation to HTA (Hofmann et al. 2015; Lysdahl et al. 2016). I will use their work as a point of departure in addition to my work in the literature review for the Assisted Living project to present the possible

frameworks that may be suitable to apply as an RRI product assessment framework. I have selected the frameworks and methodologies discussed here based on whether they appeared in the reviewed literature or if they have been discussed in relation to HTA and socio-ethical issues.[8] Some of the approaches reviewed by Assasi et al. (2014) propose a variety of a literature reviews, but these will not be considered as they constitute what Hofmann calls an "add-on approach."[9]

According to Hofmann et al. (2015) and Lysdahl (2016), the possible interactive and coordinated approaches between HTA and socio-ethical assessments are Social Shaping of Technology (SST), Axiological (Socratic, EUnetHTA), Constructive Technology Assessment, Interactive Technology Assessment (iTA), and the Ethical Matrix. These authors also mention utilitarianism, discourse ethics and wide reflective equilibrium as interactive ethical approaches. However, these approaches would not qualify as frameworks in the sense that they provide practical guidelines for addressing ethical quandaries. Since utilitarianism is a theory of normative ethics, discourse ethics is a way of justifying and legitimizing moral judgements, while wide reflective equilibrium is an approach that might well be used in order to analyze or to develop coherence between principles and judgements (Forsberg 2007c). Of the methods or frameworks discussed in the mentioned literature review (Thorstensen 2017b), only the Ethical Impact Assessment has the potential to focus on an application (Forsberg et al. 2017), whereas the remaining ones are mainly used in planning and/or interventions.[10]

Constructive Technology Assessment (CTA) is not a form of product assessment, but an approach to identify societal impacts of technology developments early, in order to make these impacts as beneficial as possible (Schot & Rip 1997). Interactive Technology Assessment (iTA) shares the same purpose as CTA and does not include interaction between stakeholders, but is limited to interviews and analysis (Reuzel 2004). Social shaping of technology (SST) is explained by Lysdahl et al. to be a position that sees

> technology as the product of societal processes within industry, research institutes, governmental bodies, and society at large, rather than an independent artefact that has a certain, measurable impact on its target. Therefore it is important to understand the engagement and strategies of various actors, and the way various problems are defined and resolved (2016: 64).

SST's strongest asset is its ability to create novel insights as to the interaction between society and technology, which is invaluable. The challenge of this approach is that it lacks structured resources to guide an assessment towards specific topics, which limits its comprehensiveness and transparency (Forsberg et al. 2017). Consequently, the approaches I will address in more detail in this paper are the HTA Core model, the Socratic Approach, Ethical Impact Assessment and the Ethical Matrix.

The HTA Core model

The HTA Core model is in itself a synthesis of a range of HTA practices developed by the European network for Health Technology Assessment (EUnetHTA), and it is currently online in its third version.[11] Ethical analysis is a separate chapter of the HTA Core model. The nineteen isolated ethical questions cover six topics,

seemingly derived from Beauchamp and Childress' principlist approach and expanded to include legislation and ethical consequences of conducting an HTA.[12] Since the HTA Core model is structured by questions in the form of a checklist, it provides many opportunities for different types of comparison between health technologies. However, limiting the selection of questions to only these nineteen socio-ethical elements seem unnecessary, since the full HTA version of the HTA Core model contains several highly important normative questions that are likely to affect the uptake of health technologies, such as, "G0001 How does the technology affect the current work processes?" This theme is highlighted as important by Wouters, Weijers and Finch (2017) and is reinforced by actual practice where the EUnetHTA (2017b) has investigated potential organizational changes. Even though the list of ethical questions might be found lacking, the total HTA Core model rectifies these shortcomings to some extent. The total HTA Core model further examines resource uses and social aspects such as health relevance, but does not directly include a value-enhancing business model despite addressing market conditions and aspects of ownership.

An investigation of the practices in EUnetHTA's published reports shows that patient involvement does not seem to be an absolute criterion, since they in one instance write "no response from patients has been received" (EUnetHTA 2017c: 49), but in other instances conducted focus groups with patients (EUnetHTA 2016b). This point is also raised by Lysdahl et al. (2016). Evidence of the quality assurance of the possible ethical impacts is also variable (EUnetHTA 2017d). In one instance the ethical aspects are addressed by the first author but not reviewed, but they are checked in another instance (EUnetHTA 2016b). Good practice of HTA further depends on a range of extra-disciplinary factors that relate to the practice of assessment rather than science. These variations in application practices imply that there is room for adjusting and improving actual practices. The HTA Core model is highly transparent due to its specificity.

Since the HTA Core model accounts for ethical, cultural, social, legal, and normative issues in the form of a list, it has a large degree of transparency Furthermore, the compatibility with HTA is a given. The HTA Core model is reflective in its normative valuations because questions allow for discussion of central normative assumptions in the framework. However, the practical application of the full HTA Core model does not appear to include the more reflective questions, and how socio-ethical issues are integrated varies greatly. However, the openness of the framework to including such elements is a strength in this context.

The Socratic approach

Hofmann et al. (2015) group the Socratic approach and the HTA Core model together in terms of how they can be integrated with HTA. Hofmann (2005b) presented the Socratic approach as a methodology to systematically include ethical issues in HTA without giving preference to any ethical theory. In 2014, Hofmann et al. revised the 2005 approach, because the 2005 version was not exhaustive, lacked issues related to screening, lacked a method for balancing harms and benefits, had shortcomings in the treatment of distributive justice, and included some questions that were unclear and needed modification.

In what follows, I primarily address the 2005 version and view the 2014 amendments and additional modifications as indications of the flexibility of the approach (see for example Hofmann (2017b)). Procedurally, the Socratic approach identifies the purpose, the stakeholders and the relevant moral questions; investigates, analyzes and discusses the identified moral questions; and finally summarizes the central findings (Hofmann et al. 2014).

The original 33 questions are listed and approached from different perspectives: the technology (i.e. application) itself, the user group, human dignity or personhood, social aspects, consequential aspects, other stakeholders, the implementation, the assessment process and governance issues (Hofmann 2005b, 2017b). This form of perspectivation is one of the appealing features of the approach since it addresses the contextual reality of the technology in use. The Socratic approach seems to be unique in asking the question, "What are the moral consequences of the HTA?" which allows for reflection on the purposes of the assessment. Question 17 addresses health relevance, while frugality and enhanced social benefits seem to be lacking.

Hofmann (2017a) provides an application of the modified Socratic approach. Here, the modified Socratic approach shows itself to be reflective in its normative analysis, with questions related to the normative assumptions in the technology assessment methodology. Hofmann's mastery of his own method impresses a reader. However, the recent application of the Socratic approach to smart houses as assistive technology (Sánchez et al. 2017) lacks such reflective discussions on the promissory nature of assistive technologies. Such a difference in use opens up questions regarding the skills necessary to apply the method. Hofmann (2013, 2017a, 2017b) makes extensive use of literature reviews and provides rich presentations, but more participatory approaches could be useful to receive input in areas where the literature remains silent or where there are controversies.

Ethical Impact Assessment

In the FP7 Prescient project, Venier et al. (2013) present an Ethical Impact Assessment (ETIA). The approach is structured around Beauchamp and Childress' (2013) principlism approach with an additional section on privacy and data protection. Wright (2011) identifies a range of possible Beauchamp and Childress principles relevant to ICT assessments.[13] In the first paper on the ETIA, Wright (2011) specifies questions on several themes related directly to health and technology.[14] As with the modified Socratic approach, the ETIA is a stepwise approach starting out with a threshold analysis (European Committee for Standardization 2017), but the ETIA steps move in time whereas the modified Socratic approach moves along themes.[15] The central procedural steps in the ETIA are the involvement of stakeholders in identifying risks and solutions, the production of the report and the independent audit of the report (Wright 2015).

ETIA draws on the development of ethical tools as well as the Constructive Technology Assessment (CTA), and the specifications of the questions are derived from studies of CTA and other assessment methodologies (Wright 2011). The ETIA does have a clear function as an ex ante assessment approach, like the CTA, but additionally has lists of questions that can be used to address the application and artifact levels of technologies. Brey (2012) supports ETIA's substantial list of questions but finds that Wright lacks a clear method for forecasting. Since the

scope of this article is to address previously developed products, Brey's criticism is valuable but does not in any way undermine the use of the ETIA as a possible product assessment framework.

ETIA provides the transparent procedure that Forsberg et al. (2017) found lacking in principlism. However, Reijers and colleagues characterize ETIA as an "intra assessment method," which is used "at the stage of an R&I in which conceptual ideas are being translated into a concrete technology design, and in which prototypes are made and tested" (2017: 14-15). In this way, the ETIA cannot be seen as solely an ex post product assessment. Furthermore, Forsberg et al. have argued that the ETIA has a versatile quality and a process that is "clearly described in a number of steps which can be easily followed – and crucially, adapted – by the user according to application-specific factors, contextual conditions and assessment purpose" (2017: 50). If an assessor wishes to adapt the ETIA to an ex post assessment, the whole process stands out as transparent for decision-makers, stakeholders and the public.

Given Wright's (2011, 2015) rich descriptions of the ETIA as a process tool and Reijers et al.'s (2017) presentation of the ETIA as an intra assessment method, is it viable and justifiable to apply the ETIA as an ex post product assessment? Based on practice, it seems that the reply is yes. Dittrich et al. (2013) apply a different form of Ethical Impact Assessment (Kenneally, Bailey, & Maughan 2010) to a hypothetical botnet. Wright and Friedewald (2013) highlight the similarities between Kenneally et al.'s form of Ethical Impact Assessment and their own. Eventual uses of the ETIA as an ex post assessment need to address how the ETIA might change when used as an ex post assessment rather than as an intra or ex ante assessment.

The ETIA is a comprehensive approach, but is it too comprehensive? The Socratic approach with its original 33 questions seems more manageable than the countless specifications of the ETIA. Rodrigues et al. (2016) present the ETIA as it was applied in the FP7 PULSE project. Here, Rodrigues et al. show that the ETIA is a valuable tool that is capable of analytically identifying threats, vulnerabilities and risks to ethical, social and legal principles so that mitigation measures might be put in place.

The literature lacks a study that looks at the possible integration between ETIA and HTA, even though Flaming (2017) states that ETIA is a valuable method for an ethics review in a discussion where HTA figures.

However, since the ETIA operates on the basis of a checklist, in the same manner as the Socratic approach and the Core HTA Model, there should not be any formal problems with such an integration. The working method design in the ETIA is characterized by quality checks in the same systematic way as the HTA. In addition, the emphasis on direct stakeholder inclusion seems to move beyond the desktop approach signaled in the Socratic approach.

The Ethical Matrix

The Ethical Matrix is a structured approach for analyzing impacts of technologies according to stakeholder groups and the ethical principles of fairness, autonomy and well-being (Kaiser & Forsberg 2001). The Ethical Matrix draws on Beauchamp and Childress' (2013) principlism for these principles. The Ethical Matrix displays

how these principles are conceptualized for a set of stakeholders in a two-dimensional matrix.

In Kaiser and Forsberg's structure of the Ethical Matrix, the number of stakeholders may vary from case to case, since the relevant stakeholders are connected to the issue at hand, and the conceptualization of the principles allows for flexibility. In a related manner, Kaiser et al. (2007) suggested experimenting with a bottom-up version where the participants also decided on the principles.

Furthermore, the Ethical Matrix can be carried out in two stages. In the first stage, the users define what the principles signify in this case for their respective groups, and in the second stage, the impacts of a novel technology are then assessed as they relate to these significations (Mepham, Kaiser, Thorstensen, Tomkins, & Millar 2006). The Ethical Matrix originates from ethics in biotechnology but has been applied to other cases as well, such as carbon capture and storage and radioactive waste management (Boucher & Gough 2012; Cotton 2009).

As Reijers et al. and Cotton point out, the Ethical Matrix could well be supplemented with structured stakeholder selection in order to avoid overlooking important stakeholders (Cotton 2014; Reijers et al. 2017). It would seem that the Ethical Matrix assumes that all members in a stakeholder group will assess the impact of a novel artifact in the same manner, and/or that the adherence to a stakeholder group is decisive for a valuation (Cotton 2014). Even though the Ethical Matrix simplifies the issues at stake by locking them into a matrix, Kaiser et al. found that "although the Ethical Matrix does not emerge as a very simple tool to use as a participatory ethical framework, it does show its potential to structure ethical concerns under varying conditions" (2007: 78). A main advantage of the Ethical Matrix is thus the assessment of how specific technological interventions affect the values from Thorstensen (2017b) . This assessment can be done through weighting or through assigning numeric values. However, "[t]here is no hard algorithm for such balancing, but the matrix structure will make the trade-offs appear much more clearly" (Forsberg et al. 2017). Nevertheless, deciding how to proceed depends on the group or a decision-maker to provide a verdict (Kermisch & Depaus 2018).

Neither ETIA nor the Ethical Matrix includes elements such as frugality, health relevance or social entrepreneurship directly. These could be introduced as dimensions under well-being and fairness in the Ethical Matrix.

In Table 1, I present an attempt at characterizing the strengths and weaknesses of the approaches discussed above in a numeric fashion. It should be obvious that Table 1 is a heuristic tool for the author and readers. It does not display an objective evaluation of these approaches and any form of summarization to reach a final score constitutes a misuse of the displayed information.

Table 1. Strengths and weaknesses of the reviewed approaches related to the indicators for selecting an assessment framework

RRI keys

	Socratic Approach[16]	Ethical Impact Assessment[17]	HTA Core Model[18]	Ethical Matrix[19]
gender / equality and diversity	2	3[έ]	3[έ]	3[έ]
open access	0	0[ʊ]	0[γ]	0
social justice/ inclusion	3	3	3	3
sustainability	0	3	0	3
science education	0	0	0	0
ethics	3	3	3	3

Framework quality

	Socratic approach[16]	Ethical Impact Assessment[17]	HTA Core Model[18]	Ethical Matrix[19]
comprehensiveness	3	3	3	3
transparency	3	3	3	3
usability[ά]	2	1	2	1

Substantive themes

	Socratic approach[16]	Ethical Impact Assessment[17]	HTA Core Model[18]	Ethical Matrix[19]
the good life	3	3	3	3
risks and benefits in use	3	3	3	3
distribution of risks and benefits	3	3	3[έ]	3
distribution of responsibilities	3[β]	0[λ]	3[β]	0
training	3[ι]	3	3	0
other possible impacts	3	3	3	3
contingency	3	0	0	1
systematic inquiry into ignorance	3	0	0	0
purpose of the assessment	3	0	0	0
health relevance	3	0	3	0
frugality	0	0	3	0
social entrepreneurship	0	0	0	0

Legend

3	Specifically mentioned in the model	ά	A model's own claim to ease of use is not considered to be sufficient documentation.
2	Solid evidence in application	έ	Not specific on gender but on equality between groups
1	Some evidence in application	ι	Training is a topic in the HTA Core Model which is a resonance for the Socratic approach
0	No mention	ʊ	Focus on anonymity – prerequisite for open data
		β	Theme on how professional roles change & patient roles
		γ	The EUnetHTA provides an open access archive.
		λ	Focus on liability

What seems to differentiate these socio-ethical assessment frameworks from RRI is the lack of reflection on purposes – with the exception of the Socratic approach. They differ from RiH on frugality and social entrepreneurship. With respect to the RRI keys – and with the noted exception of "open access" and "science education" – the four frameworks are rather similar except for the lack of inclusion of sustainability in the Socratic approach and the HTA Core model. The lack of sustainability issues in assessments on technologies outside the fields of biology and chemistry was also a finding in the EST-Frame project (Thorstensen et al. 2013) . This poses a challenge for RRI practitioners on how to incorporate such aspects into a product assessment. On a more general note, it may be possible to supplement all the methods listed above with novel elements, to the extent that these do not interfere substantially with the inherent systems in the approaches.

Based on the arguments above, ETIA, the Ethical Matrix, the HTA core model and the Socratic approach all have different virtues, in addition to some downsides. In terms of the different criteria, the approaches are all transparent and they all seem comprehensive with a strong emphasis on including different points of view. Furthermore, they all address the concern of other possible impacts in a structured manner raised by Stilgoe et al. with respect to a reflection on future impacts, but only the Socratic approach allows for changes in such impacts and reflections on ignorance. The Ethical Matrix is the only approach that does not have a specific focus on training or an element pointing towards distribution of responsibilities. Otherwise, all the candidates allow for assessing the substantive themes.

Conclusion

In order for ETIA, the Ethical Matrix and the HTA core model to be fully developed into RRI tools, they need to be adapted to include uncertainties and ignorance. Methodically, they could all achieve this by modifying their output structure to highlight these elements. I would assume that fulfilling the goals of science education depends to some degree on convincing the technology developers or the natural scientists to accept the methodology and to include the results in curricula in order to connect to *praxis* (Mejlgaard et al. 2018). Open Science – or Open Access – presupposes discussions regarding ownership and distribution of the whole epistemic scientific endeavor and has a series of meanings in different contexts (*Opening science* 2014). This necessitates widening the concepts of who benefits (*cui bono*) and distributive justice to include the epistemic dimensions in addition to the material ones.

RRI and HTA are both future-oriented with respect to the process dimensions, as they typically concern some level of policy-relevant advice. The structure of HTA outcomes might well inform RRI in the clear division of epistemic domains, whereas RRI might inform HTA in highlighting that one cannot assume that the medical epistemic or the risk epistemic should have superior value compared to other epistemic domains (Refolo et al. 2016). HTAs make more modest claims than RRI when it comes to addressing "significant societal needs and challenges" since it is oriented towards a single item and its comparators. RRI can supply HTA with clearer reflections on the *purposes* of an assessment, the social meanings of both cure and care, and alternate framings of illness and disease (Cuijpers & van Lente

2015; Moors & Peine 2016). RiH contributions regarding the business model, frugality and, especially, health relevance are welcome specifications from RRI to HTA. They share a commitment to reflection on alternatives, but this has a more solid foundation in HTA due to the inherent demands for evidence of the novel technology's superior effect. Consequently, the meeting between these two processes might be mutually beneficial.

Regarding user-friendliness or usability, the modified Socratic approach and the Ethical Matrix seem to have the simplest structure, while ETIA and the HTA core model pose a range of very specific questions with several sub-questions. However, practice has shown that the ETIA lists could be reduced to a set of specific issues to be investigated further. The Socratic approach and the Ethical Matrix are intentionally very general, but this does not in itself indicate ease of use, as documented by Kaiser et al. (2007) with respect to the Ethical Matrix.

It is fair to say that the Socratic approach covers all aspects of the health research life cycle and has great utility in comparing how products might differ in an ethically robust manner. ETIA, on the other hand, targets innovations in ICT far more specifically, and the questions it poses make little sense outside of this precise field. The HTA Core model provides a custom fit between the socio-ethical dimension and the effectiveness study. The Ethical Matrix provides a systematic and comprehensive overview of conflicts and commonalities between stakeholders or issues.

Consequently, the Ethical Matrix, the Socratic approach, the ETIA and the HTA Core Model could all serve well as product assessment methods within RRI. The choice is then left open to the assessors to determine the main concerns for the assessment. The Socratic approach and the Ethical Matrix have an appealing accessibility, whereas ETIA and the HTA Core Model are more comprehensive. ETIA has a particular emphasis on privacy and ICT, whereas the Socratic approach and the HTA Core Model have a general orientation towards health and health technologies, and the Ethical Matrix is a generalist approach. The HTA Core Model has a systematic and structured integration into HTA, whereas the Ethical Matrix, the ETIA and the Socratic approach might challenge some of preset structures in an HTA.

Selecting an assessment approach for a specific project and product thus needs to take into account the particulars of that project or product. In the context of the current project, we should keep in mind Stilgoe et al.'s statement, that "the (often implicit) evocation of the highest principles that engagement might ideally fulfil can make it difficult to acknowledge and pay serious attention to the varieties of engagement that are very much less than perfect but still somehow 'good'" (2013: 1572). Whereas the Socratic approach and the Ethical Matrix encompass the ethics in their own way and in a multiperspectivistic manner, the ETIA and the HTA Core Model include the different topics from the literature and the stakeholder engagement in a very structured but theoretical way. Especially the prioritized emphasis on privacy, the inclusion of elements on empowerment and a clear social dimension make the ETIA well suited for being applied as an RRI framework on assistive technologies. The ETIA also adequately covers standard HTA topics such as economic efficiency and implications for services, making it compatible with this already established approach in the health field.

Acknowledgements

Notes

[1] Wright (2011) abbreviated Ethical Impact Assessment as EIA, but in my view, this might be misunderstood as referring to Environmental Impact Assessment, hence the choice of ETIA in this paper.

[2] For a description on how the Assisted Living project meets the process criteria listed here, see Forsberg and Thorstensen (2018).

[3] Such a synthesis should, theoretically speaking, be feasible as the two parties seem to share what Rommetveit et al. (in press) call a system-based style of reasoning.

[4] See Koops (2015) for further analysis on the meaning of "product" and "process" in RRI and how these terms relate to the underlying approach to RRI.

[5] The full references for all the claims can be found in Thorstensen (2017b).

[6] The domains and the dimensions are: Population health (Health relevance, Ethical, legal, and social issues, and Health equity), Health system (Inclusiveness, Responsiveness, and Level of care), Economic (Frugality), Organizational (Business model), and Environmental (Eco-responsibility) (Pacifico Silva et al. 2018).

[7] Reijers et al. (2017) point out that ex post assessment should have a methodological solution for solving value conflicts as well as more general guidance on how to choose among different socio-technical alternatives. As I understand Reijers et al., this first demand is a move from evaluation to recommendation – or from assessment to appraisal in the HTA terminology (Sandman & Heintz 2014). However, in a transdisciplinary project such as the Assisted Living project, we would strive towards providing advice, such as laid out by Jan Schmidt in his work on interdisciplinary work, "it does not solve the problems itself: It supports a decision but does not provide the actual decision" (Schmidt 2011: 259). As for the second recommendation, Reijers et al. note that "ex post methods offer inadequate guidance on how to choose between sociotechnical alternatives or courses of action based on an ethical analysis" (2017: 22). This recommendation might be a possible criterion, but if all the methods developed to date share this flaw, it seems unlikely that any candidates would meet it.

[8] I will not argue that this selection is exhaustive, but I believe that it encompasses the main approaches suitable for product assessment of assistive technologies. See Thorstensen (2017a, 2017b) for details on the reviewed literature.

[9] Hofmann writes that, "moral aspects are frequently viewed as an 'add on' to 'the real thing,' that is, systematic reviews [of effect]" (2005b: 2).

[10] The remaining frameworks were Real-Time Technology Assessment (Guston & Sarewitz 2002), ETICA framework for ethical issues in ICT (Stahl 2011); EFORRT

project's ethical framework for home telecare (EFORTT 2011), Value Sensitive Design (van den Hoven 2013).

[11] https://meka.thl.fi/htacore/

[12] The ethical questions in the HTA Core Model are:

1. What are the symptoms and the burden of disease or health condition for the patient?
2. What are the known and estimated benefits and harms for patients when implementing or not implementing the technology?
3. What are the benefits and harms of the technology for relatives, other patients, organisations, commercial entities, society, etc.?
4. Are there any other hidden or unintended consequences of the technology and its applications for patients/users, relatives, other patients, organisations, commercial entities, society, etc.?
5. Are there any ethical obstacles for evidence generation regarding the benefits and harms of the intervention?
6. Is the technology used for individuals that are especially vulnerable?
7. Does the implementation or use of the technology affect the patient's capability and possibility to exercise autonomy?
8. Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?
9. Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?
10. Does the implementation or use of the technology affect human dignity?
11. Does the implementation or use of the technology affect the patient's moral, religious or cultural integrity?
12. Does the technology invade the sphere of privacy of the patient/user?
13. How does implementation or withdrawal of the technology affect the distribution of health care resources?
14. How are technologies with similar ethical issues treated in the health care system?
15. Are there factors that could prevent a group or person from gaining access to the technology?
16. Does the implementation or use of the technology affect the realisation of basic human rights?
17. Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?
18. What are the ethical consequences of the choice of endpoints, cut-off values and comparators/controls in the assessment?
19. Are there any ethical problems related to the data or the assumptions in the economic evaluation?
20. What are the ethical consequences of conducting the technology assessment at this point of time?

[13] The SATORI project, satoriproject.eu, and the European Committee for Standardization (2017) uses the term "Ethical Impact Assessment" denoting a general process for ethical evaluations according to the steps listed by Wright (2011, 2015).

[14] The full list of themes is: *informed consent, safety, social solidarity, inclusion and exclusion, isolation and substitution of human contact, discrimination and social sorting, universal service, accessibility, value sensitive design, sustainability,* and *equality and fairness (social justice).* For *Privacy and data protection* Wright specifies the areas of: *collection limitation (data minimisation) and retention, data quality, purpose specification, user limitation, confidentiality, security and protection of data, transparency (openness), individual participation and access to data, anonymity, privacy of personal communications: monitoring and location tracking, privacy of the person,* and *privacy of personal behaviour.*

[15] See Wright (2015) for the full list of steps.

[16] (Brinch 2003; Droste, Herrmann-Frank, Scheibler, & Krones 2011; Hofmann 2008a, 2008b, 2010, 2017a, 2017b; Hofmann et al. 2014; Hofmann, Haustein, & Landeweerd 2017; Holte 2007; Lauvrak et al. 2012; Sánchez, Taylor, & Bing-Jonsson 2017; Vist 2007)

[17] (European Committee for Standardization 2017; Rodrigues et al. 2016; Shelley-Egan, Wright, & Wadhwa 2016; Venier et al. 2013; Wright 2011, 2015; Wright & Friedewald 2013))

[18] (Assasi, Tarride, O'Reilly, & Schwartz 2016; EUnetHTA 2016a, 2016b, 2017a, 2017b, 2017c, 2017d)

[19] (Beekman et al. 2006; Boucher & Gough 2012; Cotton 2009, 2014; Forsberg 2007a, 2007b, 2007c; Forsberg & Kaiser 2000; Jensen, Forsberg, Gamborg, Millar, & Sandøe 2011; Kaiser & Forsberg 2001; Kermisch & Depaus 2018; Mepham 2000; Mepham et al. 2006)

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Article 4

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Stakeholders' Views on Responsible Assessments of Assistive Technologies through an Ethical HTA Matrix

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Abstract: Assessments of novel assistive technologies for use in home-based services has been documented to be performed in a variety of ways and often with a rather narrow focus on safety and effect or effectiveness. In order better to understand the place for wider forms of assessments of assistive technologies, the current study presents a combination of the Ethical Matrix and the Socratic approach for assessment of health technologies—the Ethical HTA Matrix. This matrix was filled with content based on a case of a GPS localization system, which was validated by stakeholders. In a next step, central decision-makers in assistive technologies and stakeholders were interviewed concerning their views on this methodology. Mainly, the matrix was seen as very comprehensive, but too detailed with an abundance of information. Nevertheless, some informants suggested concrete uses of the matrix in their organizations. Some understood the matrix more as an epistemic tool aiming at providing an overview of the state of knowledge, while others identified a normative potential in the matrix that could be implemented in health innovation processes for the home-based services, in particular when discussing novel solutions and working methods with health professionals and care workers.

Keywords: responsible research and innovation; assistive technologies; ethical matrix; health technology assessment; GPS tracking; ethics

1. Introduction

Communities, municipalities, counties, regions, countries, and supranational structures all attempt at successful integration of assistive technologies into care for persons with disabilities and older adults with needs for assistance. At the same time, a range of disciplines from medicine, nursing, and manual therapy on the one side to engineering and informatics on the other side have conducted and will continue to conduct research, development and innovation in assistive technologies. In addition, there is a substantial contribution from the social sciences and the humanities to the social, ethical, cultural, and legal dimensions of ageing, technology and assistive technologies. The main purpose of research and innovation in assistive technologies is to increase the number of people who might live in their own homes for a longer time. This purpose has two underlying rationales: (1) People prefer to live in their own homes rather than in some form of institution; and (2) Societies might avoid significant increases in costs when or if fewer persons live in some form of institution.[1] These two rationales have a weighty normative content. The first point to the good life and the second refer to the survival of the political and geographical entities mentioned above through a control over spending. I believe that

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[1] Both of these underlying rationales might be questioned. According to Oswald, et al. [1] and Wahl, et al. [2] the view that belonging is the main factor for quality of life needs to be complimented with an understanding that housing-related agency is just as central for maintenance and construction of identity. For the second rationale, Okunade and Murthy [3] and Fineberg [4] have shown how technological systems are drivers of cost in the healthcare system.

it is of importance to underline that the introduction of ICT-based solutions as measures to provide prolonged residency has existed since the beginning of the 1990s. Furthermore, the uptake of such solutions could best be characterized as hesitant [5].

In this contribution, I will present, examine and discuss one possible approach to assess an assistive technology in an integrated manner. My objective is to provide a tool for decision-makers responsible for acquiring assistive technologies and for developers of assistive technologies that can serve as a structuring device for assessing costs and benefits at the same level as the wider social, ethical, cultural, and legal aspects. Through a series of interviews with central stakeholders and persons whose daily work is to be the mediator between the political ambitions in assistive technologies and the concrete implementation in the services, I aim to not only find their opinions on the tool, but also aim at finding possible places for the approach in the municipal health innovation processes, which is a field with relatively few studies [6].

The normative context of Responsible Research and Innovation (RRI) provides the frame for the current research. Here, the importance of integrated assessments has been underlined by von Schomberg [7], while a related care for the future impact of new and emerging technologies has been voiced by Owen, et al. [8]. Relevant to my argument is the demonstration by Fitzgerald and Adam [9] of the fragmentary decision-making landscape in Europe for assistive technologies, the lax and seemingly arbitrary approaches to testing of assistive technologies [10,11], and the recent report from the European Parliamentary Research Service Scientific Foresight Unit (STOA) voicing concerns over lack of proper assessments of assistive technologies classified as consumer technologies, which constitute the large majority of the marketed products [12]. Hopefully, my contribution might serve as a first brick in a bridge between the hasty, short-spanned, and profit-based logic in industry and the careful, person-centered, and budget-based logics of the health sector, as proposed by Demers-Payette, et al. [13], through the use of similar assessment instruments.

In this article, I introduce and discuss the concept of responsible assessments based on recent work in RRI and assessment methodology of new and emerging health technologies [14–21] before presenting a methodology, which is a combination of the Socratic approach to ethical analysis of health technologies and the Ethical Matrix [22–25]. I apply this methodology, the Ethical HTA Matrix, on an assistive technology currently on the market in several towns and municipalities in Norway and with increasing use, and present the results from the analysis to decision-makers in assistive technologies. Bruijnis, et al. [26] have already applied the Ethical Matrix in the context of RRI and they see it as contributing to the realization of RRI as presented by Owen, Stilgoe, Macnaghten, Gorman, Fisher and Guston [8], with a caveat for responsiveness. What is my main theme in this article is the feedback from the decision-makers on the Ethical HTA Matrix. Based on these presentations and the ensuing discussions, I make recommendations for future changes and contribute with more general comments as to the possible places, desired formats and content for such assessment.

2. Materials and Methods

The concept of responsible assessments is based on the thinking and practices of RRI. The current approach to RRI has attempted to remain open as to what it signifies to perform research according to RRI. The explicit intent in this paper is to bring the voices and concerns of users and stakeholders closer to the political processes of producing and acquiring assistive technologies with the aim of shaping innovation processes through a normative model. Here, I aim at highlighting other societal processes and concerns that might have an impact on the usefulness, but also on the acceptability of the proposed assistive technology. A central theme in the discussion is precisely at what time in the policy process, on the one hand, and in the innovation processes, on the other hand, the Ethical HTA Matrix might be beneficial for the respondents. Such a link between the political processes and stakeholder events has been described as a "strong RRI approach" by Coenen and Grunwald [27]. Underlying this search, is an interest in how research and innovation in assistive technologies might be

governed in a way that makes the products available to users with special and specific needs both more acceptable and desirable [28].

2.1. Background

In RRI, the quest for the right impacts is a central theme [7,29,30]. Such right impacts are notoriously difficult to define precisely, but they should consist of the realization of social values and contribute to the preservation of public goods and maybe even enrich the latter. In the European context, von Schomberg [30] has suggested to connect the values to those of the Treaty of the European Union, while the public goods relate to the protection of the environment, human health, and sustainability. As indicated in the introduction, there is a large policy pull to realize assistive technologies, and simultaneously, there is a strong technology push to introduce these in home-based services. von Schomberg [7] has proposed that assessments might be used in RRI as a moderator between the search for the right impacts and the push and pull forces. Since assistive technologies in the homes to a large extent fall under the regulation for consumer goods rather than for medical devices, there are no set procedures outside of technical functionality and absence of harmful components regulating the products. This situation indicates that there is a large political space for discretion and a variety of possible methods for assessments. The mentioned STOA report suggests narrowing this gap through a more nuanced classification system [12]. However, the question remains how to moderate and how to narrow these gaps. In this respect, Forsberg, Quaglio, O'Kane, Karapiperis, Van Woensel and Arnaldi [20] have introduced the concept of responsible assessments for assessment approaches that meet the normative ambitions of RRI as described by Wickson and Forsberg. They present a view where the responsibility of research and innovation can be described by its ability to

1. address significant societal needs and challenges;
2. engage a range of stakeholders for the purposes of mutual learning;
3. anticipate potential problems, identify available alternatives, and reflect on underlying values; and
4. respond, act and adapt according to 1–3 [31].[2]

My scope in this article is to provide an assessment for responsibility, which refers to "the support that the assessment apparatus can provide for responsible development and governance of science and technologies" [20]. I present a method that I investigate whether could be used in order to align governance with Wickson and Forsberg's 1–4 above. However, in order for an assessment to be fully responsible, the process of creating the substantive content of an assessment methodology in this field has to be conducted with responsibility, i.e., in a manner that meets the four requirements and that might be applied to an existing product.

In order to find what the right impacts might be in the case of an assistive technology in a Norwegian setting, a transdisciplinary groups has used fieldwork, user workshops and literature studies to approach how and why users and different stakeholders value assistive technologies [16,32,33]. A brief summary of the main areas of concerns and that any assessment should address are the good life, risks and benefits in use; risks and benefits before use; the distribution of risks and benefits; and the distribution of responsibilities and training, in addition to opening up on the changing nature of future impacts of assistive technologies. These findings informed a survey and evaluation of different assessment methodologies for new and emerging technologies [17]. A central theme here was further the applicability of the methodologies in the health domain and more specifically on assistive technologies.

The proposed methodology, the Ethical HTA Matrix, is based on a combination of the Ethical Matrix [24,25] and the Socratic approach for ethical analysis of health technologies [22,23]. These two

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[2] This description encompasses what Owen, Stilgoe, Macnaghten, Gorman, Fisher and Guston [8] have presented as Responsible Innovation, namely anticipation, inclusion, reflexivity, and responsiveness, but adds what von Schomberg [30] has described as "grand challenges".

were primarily selected to address a wide range of concerns that an RRI assessment should include for assistive technologies [17], and in addition they have been widely used to analyze ethical and social impacts of novel technologies [10,14,19,21,22,24,26,34–50]. The reason for combining these two is that the Ethical Matrix can best be characterized as a general-purpose tool for practicing applied ethics, whereas the Socratic approach is highly specified towards the health field. The Ethical Matrix serves well to illustrate how the same technology or product can affect different stakeholders in different ways, which is a less visible feature in the Socratic approach. The Socratic approach then provides the concrete questions whereas the Ethical Matrix gives the structure to discuss how the issues influence the relevant stakeholders.

2.2. Methods

The object selected to make a test case for the Ethical HTA Matrix (hereafter, the Matrix) is a GPS (Global Positioning System) localization tool that includes next-of-kin as primary responders, but with the public health system as a secondary responder. This GPS system is a commercial system currently being used by a number of municipalities in Norway. The GPS system is mainly used for persons with dementia or other sever cognitive conditions. The decision to implement a GPS system has to take place with the consent of the person being tracked (hereafter the user). If the user lacks capacity to consent, a legal decision is needed to implement GPS tracking for the user. The GPS system consists of three basic components: a tracking device to be carried by the user so that she or he is possible to locate, a steering system keeping track of all users and relating users to the ones responsible to locate the tracking device (and the person), and a smart phone application to be installed at the phones of those with a legal right to participate in tracking and with a corresponding obligation to act as a first responder. These latter are often family members and will be referred to as "next of kin". The tracking device might activate an alarm if the device moves outside of a predetermined geographical area (a so-called geofence) and if the user triggers the alarm physically. It further has the possibility of two-ways communication since it is based on both GSM (Global System for Mobile Communications) and GPS. If the first relevant next of kin does not respond to an alarm, the alarm can be routed to a different next of kin, and in the last instance to the health services. Hereafter, I will refer to this system as "the GPS system".

What is of interest here is how the different values in the Matrix, as specified by the Socratic approach, are affected by the introduction of the GPS system: Will a primary user experience that she has more freedom to move? How important is it for her to move? How sure are we that our knowledge is correct? And: How much money will the health system save? How important is money-saving for the health system? How sure are we of the savings? These are the types of questions the Matrix will attempt to display.

2.2.1. Completing the Matrix

The first step is to identify the stakeholders affected by the introduction of the GPS system and place these in the matrix structure (cf. Table 1).

Since the Socratic approach seems both relevant and complete concerning novel technologies in health, the next step is to identify which questions from the Socratic approach could be placed where in the matrix (see Appendix A for completed Matrix with questions from the Socratic approach).

The Matrix might be used in several different ways, but there are two main approaches. The first consists in finding all the values for the different stakeholders together with them or with their representatives. A different approach is based on desk research on what the research literature and other policy-relevant documents say about these values [35]. In this article, I have chosen the second approach. The key to applying the Matrix consists of two main phases: (1) document the relevant values at stake for the different stakeholders, and (2) validate the impact of the technology for the relevant values with the stakeholders. The force of these impacts can be described in different manners, but often one applies a scale that might be a 2-point (important, very important) or along a range

−5 to +5. When having completed a Matrix, the full material is presented to a decision-making or policy-making body either in order to reach a decision or to inform on a subject matter.

Table 1. Stakeholders[3] affected by the GPS system.

	Well-Being	**Dignity**	**Fairness**
Primary user			
Health professionals			
Health delivery system			
Technology providers			
Next-of-kin			
Climate			
Ecology			

One central underlying idea in this assessment experiment has been to place the values "effect" and "cost", which are central to decision-makers as well as to HTA, under the heading "Well-being" in the Matrix. The rationale for this choice is that these values, which often are given a very prominent place in the decision-making process, should be placed on the same level as other values (see Refolo, et al. [51]).

2.2.2. Validation of the Matrix

A central aspect in the work with matrices as methods is to obtain some form of validation from the relevant stakeholders. My field of investigation here does not center on how the different stakeholder groups value, see or understand a GPS system, but rather how the decision-makers involved with assistive technologies perceive the Matrix as an instrument for making decisions. Consequently, the validation phase has been somewhat briefer than the full participation through workshops to weigh the different values or consequences [34,35]. Maybe the most important stakeholder category, the end users, are people with dementia. For these respondents, I employed a brief questionnaire developed in cooperation with the dementia center that they attend daily. Drawing on recommendations from Kennedy and Ter Meulen [52], I conducted individual interviews in familiar settings for a duration of maximum 20 min where we had the GPS tracker between us and talking about different situations where the GPS tracker figured. From these five interviews, there were some points where the respondents disagreed and some points where they all agreed—see Appendix B, The validated Matrix.

For the remaining stakeholder groups, I developed questionnaires distributed by email by a local municipality to next of kin, health professionals, alarm center employees, and health services officials. In this case, I similarly settled for a smaller number of respondents in order not to place too large a burden on the time of health workers in the municipality.

2.2.3. Interviews

In order to obtain views and opinions on how the Matrix is perceived among those working daily with making decisions concerning assistive technologies, I made arrangements for interviews with two representatives from civil society organizations, two technology developers and nine representatives from health decision-makers or advisors working for or with mandate from towns, municipalities and government in March 2019. They were selected based on experience with assistive technologies from their respective perspectives. The interviews lasted between one hour and two hours and were recorded with written consent from all the respondents. Prior to the interviews, I sent the Matrix (Appendix B) to all interviewees with an explanation about the project and methodology.

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[3]   The last two stakeholders, the climate and ecology, are stakeholders to the extent that these are entities affected by technology. In traditional applications of the Ethical Matrix in biotechnology, the ecosystems play a central part. Pacifico Silva, Lehoux, Miller and Denis [18] argue that RRI in health need to take into account how the health system affects the climate.

In each interview, we were between one and three persons. I began the session through a brief presentation of myself and the Assisted Living project, and asked them how they understood the acceptance, uptake and use of assistive technologies in their context. Mostly, this served as a method to start the conversation and make the interviewees talk about their experiences. These experiences are relevant because the methods for product assessment need to also be relevant within their local challenges and for their professional tasks. This interview strategy is what Spradly calls task-related grand tour questions [53].

Interviews with experts in the field, such as my informants, presuppose an active interviewer well-orientated in the field pursuing an open approach to the theme based on general topics [54]. To introduce the experts to give their own narratives, such as grand tour questions, is recommended in order to provide insight into more unreflective or tacit knowledge dimensions [54].

Following this overview, I turned the attention to the assessment of the GPS system as presented in Appendix B in order to establish a common ground for the discussion of the Ethical HTA Matrix.

I further used material from earlier interviews and suggestions and positions from these towards the end of the interview in order to hear others' opinions and judgments of the previous informants' views. This methodological position places the researcher more as an active part in the creation of knowledge and spreads and disseminates thoughts and insights between the informants. Furthermore, given the wide discussion in the introducing themes, I wished to investigate where in the innovation process an RRI method could provide additional value, thus reflecting the debate on the place of responsibility in innovation processes [55]. As Reijers, Wright, Brey, Weber, Rodrigues, O'Sullivan and Gordijn [15] point out, there are several possible points for normative intervention in a decision-making process which also affects the choice of method.

2.3. Stakeholders' Values

Since I have selected to start with desk research and validate the impacts with stakeholders, the first step was to identify relevant literature. Fortunately, there have been a range of development and research projects conducted in Norway on different aspects of GPS tracking technology as an assistive technology in the period from 2012 to 2018. For the purposes of developing and testing the Ethical HTA Matrix, I took these reports as a point of departure and worked backwards in the approach called "snowballing", i.e., searching for relevant references in the reports [56]. This limitation to Norway might be questioned, but it simultaneously avoids the problems inherent in comparing between national health systems and, furthermore, several of the studies from the snowballing cover a wider spectrum of contexts.

2.3.1. Primary Users

Concerning the effects for the primary users, GPS systems seem to increase mobility and daily activity, but only for users who are already active [57–59]. Users stop benefitting from GPS systems when they are no longer capable of going outdoors [60]. GPS systems further contribute to faster location and retrieval of the users when they trigger an alarm or they are missing [59]. When it comes to the possibility to live at home for a longer period of time, studies indicate that a GPS system can be beneficial [61], but for a minority of the users (15–20%) and for a period of 3 to 8 months on average [62,63].

In general, GPS systems increase freedom of movement and experience of freedom [61,64] as well as increase interpersonal contact and maintain friendships [60]. In addition, a GPS system including a geofence system would be even more adaptable to individual preferences and to avoidance of neighborhood dangers than a simple tracking system [60]. The fit between user and device might be problematic due to the illness or to malfunctioning of the GPS system [59,62,65,66].

One connected risk element is that GPS systems might create a false sense of security when users lose the ability to dress for cold or rainy weather [64].

A remedy to some of the risks is to invite users to start using GPS tracking at an earlier stage in order for the users to master their devices [63] and open up for learning and experimentation [66]. This solution, however, might create opposition and will place temporarily increased stress on the health system in addition to creating possible legal challenges as the current use is based on health needs [67].

Some of the trackers might be experienced as stigmatizing [57,63]. The issue of surveillance and privacy is challenging when it comes to GPS tracking for users with cognitive impairments [68]. In addition, the users' privacy is affected and even more so if the system also included a geofence function [69,70]. Even though the large majority of the users do not feel surveyed [63], some report tracking as affecting their privacy [61,69]. To complicate things further, users might feel surveyed even if they do not report it [71], and a majority of the users report that they primarily use GPS for the sake of the peace of mind of others [57,61,64]. It is consequently a need to secure that consent is non-coerced [69]. As the alternative to GPS tracking in some cases is drugs or physical restraint [59,61,62] or being admitted to a health institution or assisted living facility [71], voluntary consent becomes even more difficult to assess. Most users report increased independence and higher quality of life [64] while not experiencing a loss of authority over their own lives [57].

Concerning matters of fairness, it seems that the introduction of GPS systems favors those already co-residing with someone [63], and that a GPS system with next-of-kin as first responders would favor those with next-of-kin nearby. Likewise, it is reported as easier to give training to and maintain the use of GPS for persons living with others than those living alone [64]. Specific efforts are needed to target persons residing alone [60,63], and these are the ones who would benefit the most from using GPS tracking [64]. As should be clear, GPS systems might primarily benefit those capable of walking around on their own [72].

2.3.2. Health Professionals

The main value of GPS systems for health professionals is a workday with more focus on health-related tasks. This effect has its causes in less searches for people because they are missing or because they are not at home when the health professionals have an appointment to see them [61,72,73], but also in fewer alarms interrupting daily planned routines [74]. An increased feeling of safety among health professionals is widely reported [61,62,64].

The maintenance and charging of trackers, as well as reminding users to carry them with a tracker, are reported as novel tasks and an increase in workload [63,64,73]. An additional task is to assess users in order to understand if they might benefit from GPS [64], as well as monitoring and assessing these benefits [63], and how to include relatives in healthcare [69]. Internally, among health professionals, GPS systems could create the need for new workflows and novel forms of cooperation [73,74].

When it comes to health professionals' performance in their work, such remote-sensing technologies deprive health professionals from continuous contact and might impede observations of deteriorating condition [73] and novel challenges arise as the health professionals know where a patient is, but not what she or he does [61].

Furthermore, the involvement of relatives and the facilitation of contact with relatives might be reducing the need for care services [57]. The involvement of relatives might introduce conflicts over the suitability of a tracking device for a person between health professionals and next-of-kin [69]. In terms or fairness or justice, the health professionals might find themselves in novel legal territory if GPSs are implemented earlier to persons without direct health needs but who are at risk of developing such a need [67]. From the literature, it seems that the physical aspect of care is delegated to the domain of female informal caregivers and low-paid females [75].

2.3.3. Alarm Center

For the staff at the alarm center and the alarm center as an organization, the ability quickly to find people outdoors without extensive searches is the main effect [61,72,73]. The main costs relate to upscaling from a limited number of users and to integration between other possible alarm systems

of databases [72]. However, there are some uncertainties relating to the effect. In the cases where one seeks to talk to the users to assess the seriousness of an alarm, the sound quality is a critical factor [72]. A puzzling factor here is the large number of false alarms. One report estimates that 90% are not real alarms [63]. However, studies point to such false alarms as a positive social experience for the users [75] Related to the issue of upscaling mentioned above, is also the challenge of recruiting competent personnel [72], and related to the user interface, one study mentions that the language and expressions used there might influence the personnel's perception of the users [76].

Pertaining to fairness, one study indicates that more time and resources are dedicated to persons using mobile alarms than immobile alarms [72].

2.3.4. Health System

The two main purposes of a GPS system for the health system is to provide better quality of life for the users and to reduce the costs of healthcare services. In addition, there is the specific RRI concern of *frugality*, i.e.,: "Does the technology deliver greater value to more people using fewer resources? Does the technology presuppose a larger technological infrastructure?" (see Pacifico Silva, Lehoux, Miller and Denis [18]). In one way, the distributed nature of a GPS system with next-of-kin as first responders is lessening the pressure on health services, but if the infrastructure becomes more complex due to the involvement of new parties, then the criterion of frugality is not met.

The health delivery should become more effective and the staff less stressed with more active users [72], and it is not likely that the number of health professionals will be reduced through a GPS system [61]. In addition, the health service delivery chain and work practices would need at least some reorganization for large-scale implementation [57,63,64,77]. A central feature of a GPS system is to prevent persons going missing. Estimates show that half of those with dementia missing for more than 24 h die or are seriously injured, and the cost of a missing person search was estimated to be in 2012 between £1325 and £2415 in the UK [78].

More active and mobile users should overall give less stress on the services [57] and the professionals would spend more time on health delivery [63]. However, the most significant uncertainties regarding costs is the lack of systematic studies and consistent methodology on the one side [60,79,80],[4] and insight into which patients that will benefit from GPS systems on the other side [64,83], as mentioned above under Primary users.

When it comes to fairness considerations for the health system, one central question is whether the benefits from a GPS system with next of kin as primary responders are distributed fairly. Such a system benefits those who are already active and who have next-of-kin available [72]. The legal situation is further unclear whether or not users should pay, and this might be practiced differently between cities or municipalities [63]. There is further a need for a legal framework that can cope with the challenges of making next-of-kin responsible for health services and safety [84].

2.3.5. Next of Kin

Next of kin are already first responders to GPS, but with the introduction of a phone-based application one is no longer dependent on living together with someone in order to maintain this role [57,72]. Overall, next-of-kin report experiencing more safety for their loved ones [72], increased freedom for themselves and the users [60,62,64], and a general peace of mind [69]. It seems that the role of first responders change the prioritization of next-of-kin. The prioritization of family caregivers change from an emphasis on safety when they are responsible to an emphasis on autonomy when the professional caregivers are responsible [69]. In addition, there is a possibility that the introduction of

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[4] This lack is widespread in the whole sector of assistive technologies for prolonged residency at home. Franck, et al. [81] found very few validated studies for long-term effects. As demonstrated by Steffensen [82], cost-utility analyses in small municipalities are very sensitive to small fluctuations in staff.

next-of-kin might cause disagreement between users, next-of-kin and health professionals regarding the suitability of both the decision to track and of the tracking device [69].

2.3.6. Technology Developers

The studies included here did not pay much attention to the values of the technology developer. In general, I would state that in assistive technologies, the technology providers or developers remain rather understudied.[5] In order to understand better what the values of a technology company in this field are, I approached the producer of the GPS system for an interview. Seen through the dimensions of the Matrix, the ability to make income to the firm and avoid huge expenses with uncertain gain are the main factors under well-being. The more interesting findings I have categorized under dignity and fairness. With regards to dignity, I had the impression that recognition of providing a valuable service is central, but, in addition, they felt very distant from the goods that they deliver to the patients or to the users. The public calls for tender with a too-high degree of technical specificity made it both difficult and tiresome to respond to since the space for novelty is very limited and because it violates a "natural" division of labor between the health services who should be experts on health needs and the technology developers who should know best how to technically configure such a solution.

In the considerations over fairness, too-detailed calls for tender were not considered fair since they more or less then gave preference to one firm over others. Consequently, the ability to compete on fair and even terms seems important and is connected to a view of professional pride in how best to solve the task. The public procurer should also be careful in applying the total of its purchasing power since the public is the single most important possible purchaser in this domain in Norway.

2.3.7. Climate and Ecology

Even though the public are the dominant purchasers of assistive technologies in Norway, there is little evidence—or more precisely no evidence—that municipalities or the state considers ecological impacts. According to the Norwegian government, both the environment and climate figures as goals to be realized also by the health sector [87], but the responsibility is placed on hospitals and regions and not municipalities who are responsible for assistive technologies. Other national strategies [88,89], recommendations [62,65], and procurement guides [77] for assistive technologies do not reflect the government's ambition of a more climate friendly or ecofriendly healthcare. A recent Canadian study found that 27 out of 92 requests for proposal for medical technologies included environmental concerns as evaluation criteria [90]. Seen from the perspective of Responsible Innovation in Health [18], an absence of use of monopoly power would qualify as irresponsible especially since there is a large amount of studies documenting the negative life cycle impacts of mobile technologies [91].

2.4. A Value HTA Matrix

Based on the concerns identified for the different stakeholders, I arranged the central values at stake into a Matrix (see Appendix B). These values are then expressions of how different stakeholders might be affected through the implementation of a GPS-based tracking system with next of kin involvement. One challenge I experienced in reviewing the literature, was whether to differentiate graphically between the uncertainties and the variations of the effects in the Matrix. Take for example, the finding that almost 50% of the users seemed able to benefit up to 1 year from a GPS tracker when it comes to independent living. It seemed to me untenable to present the value of "Living at home for a prolonged time" with the same certainty as "Being found when lost". Here, I chose to identify the level of certainty with a range of colors from red (uncertain hypothesis) over yellow (some level over certainty) to green (documented consensus). Through this choice, I conflate two

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5   This is in contrast to other aspects of health technologies. See Brown and Webster [85] and Lehoux [86] for extensive studies and overviews into technology production and policy processes of medical and health technologies.

different elements: variation and uncertainty. However, at the same time, I assume that variability and uncertainty both relate to the expected effect [92]. Consequently, for the persons making a decision with respect to a desired function, the inside of the black box of the GPS-based tracking system with next of kin involvement might not matter too much, but this assumption will be investigated during the encounters with the decision-makers.

When filling in a Matrix, it is customary to insert what are the likely positive or negative consequences for the different stakeholders following the introduction of the technology [36]. However, when working with the findings from the literature, it became apparent to me that there are a range of important prerequisites that need to be in place or that might even affect the likelihood for the realization of one or several values.[6] Returning to the example of "Living at home for a prolonged time", the literature indicates that one important condition for this value to be realized is that those receiving a GPS tracker are properly diagnosed both with respect to their internal and external capabilities [60,94]. Knowledge of these conditions are important for decision-makers and consequently they should be presented together with the affected values.. At first, I considered presenting two different versions to the informants; one with values and consequences and one with values and necessary conditions. However, I rather listed the conditions calling them "critical factors" and discussed the format with the informants.

3. Results

In the current section, the results are grouped according to general comments, views on the applicability of the Matrix on the case of GPS localization, views on the approach chosen to apply colors and fonts through literature review and external validation, and finally suggestions for where in the municipal innovation processes or working flows such a Matrix could be used. The version of the Ethical HTA Matrix used in the interviews is presented in Appendix B translated to English from Norwegian by the author. In order to provide some context, I start the presentation with some of the general challenges and continue with what the informants presented as some of the main changes in the innovation landscape of assistive technologies.

3.1. Innovating Assistive Technologies

Several of the informants had been working with assistive technologies either as producers or procurers—or simply as interested parties—since 2011. This year marks the start of the current period of interest in assistive technologies, which started with a White paper [95]. All parties told a story of testing technical solutions in rather limited scope with little or no attention to the integration of these assistive technologies into the services. Largely this period was characterized by a technology push with small firms on the one side and enthusiasts in the services on the other side and politicians with ambitious goals above. A change started to manifest itself around 2015 with sharper focus on the services and lower confidence that the technologies by themselves would revolutionize health. Such a change presupposes increased competences in implementation and workplace innovation. With the creation of the Directorate for e-health in 2016, the whole field has become more professionalized on the one side and now follows centralized guidelines for procurement, but on the other side, this centralization has been advantageous for larger companies that can use smaller technology developers as subcontractors delivering standardized solutions that municipalities implement. Several of the informants saw clear benefits of this change, but others expressed concern that it might stifle technological innovation when smaller firms just become suppliers rather than developers. In the larger municipalities and towns, informants told of changes in workflows, routines and organization as a means to achieve both

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[6]　One of the criticism levelled against some bioethical approaches has been the uncritical acceptance of optimistic technology futures [93]. Through underlining the necessity of specific factors and conditions necessary for realizing the intended goods, I believe the current approach meets this criticism.

implementation of assistive technologies and improved care. In smaller municipalities, there was a struggle to prioritize organizational change in parallel with technology implementation, and thus it is difficult to achieve innovation as the working routines remained the same. As some informants told me, in smaller municipalities, everything tends to depend upon a few central persons for securing the routines and if these are absent for 1 week, the routines return to the old ways.

3.2. An applicable Matrix?

I introduced the Matrix to the participants through the case of the GPS system. First, they were asked if they had any initial reactions. The clearest and unequivocal response to the Matrix was that the suggested approach did not provide an easily accessible overview of the GPS system because of the high level of specifications. The additional outcomes of the discussions might be separated along two strands: One pragmatic strand where the display of information and the applied case is considered, and a different strand where the Matrix is seen as an RRI-tool (see Wickson and Forsberg above). I will commence with the latter strand.

When it comes to the how the Ethical HTA Matrix is related to RRI, several of the respondents gave the impression that it opened up for reflection on problems, mutual learning and value analysis. What characterized all meetings with municipal decision-makers was extensive discussions regarding the red and orange colors in the well-being column for the stakeholder category Health system. They all expressed that the economic effects of introducing assistive technologies are real and substantial, but that there are methodological difficulties in asserting or quantifying these effects due to expected gains in other sectors in addition to those in the home-based services. Most interviewees agreed that even if this latter factor is taken into account, systematic knowledge concerning economic gains is scarce.

One could note an ambivalence regarding care workers and health professionals' roles in innovation processes. Some informants saw their primary role as adapting to the needs of the health system and the users, whereas others regarded their contribution as constitutive of any municipal innovation process. A third view was to rethink the whole organization of the services based on the introduction of assistive technologies. I would venture that there might be different models for innovation underlying these conceptualizations of health professionals as stakeholders. The first approach connotes a view on the care workers as in a principal/agent relation [96], whereas the second moves towards the opposite outlier where one departs from the local experiences and professional values of care workers and health professionals in order to arrive at innovations [97]. The third approach seems managerial with a solid belief in planning and structuring to facilitate for innovations [98].

There is a conflict in the literature between a view on assessments as in need of proper resources and a view suggesting that assessment frameworks should be cost-minimizing [99,100]. This tension could also be found among the interviewees with some highlighting that complexity is a value in itself and one needs to dedicate the proper resources, and others who expressed that municipalities need facile and simple procedures throughout an assessment or procurement process. A different line of comment addressed that what is needed is a closer examination of the localized understanding and a systematization of existing practical knowledge. This line of thinking seems to suggest an additional place for bottom-up approaches or ethnographic studies. The latter might be difficult to reconcile with the procedural thinking in the Ethical HTA Matrix since it emphasizes rich context and local cultures [101] whereas the former approach has been used in several instances [24].

Contrary to the usual practice of using an Ethical Matrix, I have chosen to display what I refer to as Critical factors for the realization of potential values. This dimension addresses the non-use of assistive technologies and barriers to use of assistive technologies (see e.g., Scherer [102]) and the point raised by Hofmann, Droste, Oortwijn, Cleemput and Sacchini [22] regarding the morally relevant challenges of assessing *ex ante*. They expressed that a link between the different levels of critical factors and the realizations of the relevant values is a valuable contribution.

Regarding mutual learning, nearly all the respondents recognized the different stakeholder groups and saw them as relevant with the exception of the climate/ecosystem. The exception to this was a

position where only the health system and the user ought to count. The climate and the ecosystem were not in themselves considered irrelevant, but more out of scope of what decision-makers in assistive technologies might influence. Decisions on these matters are taken at a political level and implemented as general procurement rules, and form part of the calls for tender.

Several informants raised the issue of uncertainty and knowledge as central. However, there were differences in opinion on what counted as knowledge. In the matrix, I relied on published sources whereas some informants added that they had much knowledge—and this lead to a discussion on what counts as knowledge in assessments. Some municipalities conduct a range of studies by themselves, and there is a significant amount of information-sharing concerning assistive technologies between municipalities.

A related discussion to the status of knowledge were the views on who should count as the most relevant stakeholders. In this regard, the technology developers expressed interests in all stakeholder groups but with a clear orientation towards users and next of kin. On the opposite side of the spectrum, an informant from the municipalities said regarding the technology developers, "Finally, they are experiencing our power" whereas a different municipal interviewee saw co-production of services with the technology developers as crucial in fitting solutions to the actual context. The technology developers' orientation towards users and next of kin seems to make sense since these categories constitute their end-target group and it fits their rationale. However, the divergent orientations towards technology developers as a stakeholder group indicates either that large parts of the customization of the solutions takes place in the municipalities or that these municipalities are able to make very specific orders from the technology providers. Regardless which interpretation is correct, there is a peril of little feedback from the municipalities to the technology firms. However, in the opposite case with a large degree of cooperation, this feedback would seem to be secured. These differences were raised directly in the interview with one view held that the technology firms for too long have played a strong part in the implementation of assistive technologies. Whereas a different view was to see the long relation with select technology developers as the municipality's strongest asset in successful implementation and seeing other municipalities as not allocating adequate budgets to transform an "off-the-shelf" device to a functional assistive technology in cooperation with the technology developer. It is of interest to further research to investigate what separates the municipalities emphasizing contracts and those that emphasize collaboration as a means to successful implementation of assistive technologies.

Analysis of values created the main discussions, especially the column dignity in the matrix-produced reflections. I experienced that the informants accepted the division into utilitarian and fairness concerns easily, but the line regarding dignity was more problematic and more valuable at the same time. The problematic aspects consisted of different conceptions of dignity among the interviewees, but also among those working with assistive technologies, according to the informants. Several informants expressed that the column dignity had content that was at the core of their efforts in the health services, and likewise one technology developer said that this form of documentation of how an assistive technology might affect quality of life is central to their planning and sales as a technology firm. Dignity expressed the types of change that several of their customers sought.

When discussing the Health system as a stakeholder, one informant said that what mattered in this time of technological hype was to be frugal. Since frugality is one central concept in the recent proposal for Responsible Innovation in Health [18], I pursued this theme and asked why she used the word *frugal* and what she meant by it. She replied that one has the responsibility to ensure that patients and users receive proper care, something that cannot be left uniquely to technologists and that when spending large amounts of public money, one has the responsibility to ensure that these funds are spent well. I raised the theme if one should replace the heading welfare with the heading *frugality* in the overall Matrix, but she said that while it made sense for the stakeholder of the Health system, it did not apply well to the other stakeholders.

Regarding the case and display of information, one interviewee expressed skepticism if this GPS system was a valuable case to study as an example since GPS localization currently was not seen as

only unproblematic—contrary to the situation 5 or 10 years ago—but also highly desirable by everyone. In all the interviews, I had different discussions regarding specific interpretations of the content of the cells, but no one expressed that any of content was erroneous even though some were surprised or suspicious to the content of one or two cells. Displaying the knowledge status for an intervention with assistive technologies was conceived as valuable, both as providing the specific state of affairs and as a general approach. Several informants engaged in discussion if I had presented the right critical factors and of the internal links between the critical factors as well as their sequence and placement in the matrix.

In addition, we had discussions concerning the layout and the presentation. In general, the interviewees agreed that one should attempt at diminishing finer nuances and limit the presentation of the potential consequences as certain, uncertain, and ignorance. The weighing should likewise consist of the categories very important, important, and unimportant. I will not pursue the issues of layout and graphics further in this paper.

3.3. Places for Responsibility

As mentioned above, the general view was that it is too complex—at least at first sight. However, the Matrix contained elements the informants found useful, and, in addition, they mentioned concrete places for using the matrix in the working and innovation processes in the municipalities as well as potential for dialogues within the municipalities and between those implementing assistive technologies and those external to the process, such as policy-makers and firms.

Some informants expressed that one potential place in the municipal innovation chains was to employ the Matrix with health professionals or care workers in order to discuss their own experiences with existing solutions under testing or prior to deployment. One informant had recently been involved in a project where care workers filled in diaries or logs to document how a new assistive technology was used in homes. This exercise garnered an impressive amount of information regarding both the home-dwellers and the care workers interactions with the devices and with the elderly, and also regarded the organization of the services. However, what they lacked was a method that could structure what affected welfare, dignity, justice and fairness when they all discussed their individual experiences as a collective. The informants mentioned the utility of structuring discussions with care workers, however, they did this in earlier phases in order to structure concerns, thoughts and interests over novel solutions. Such dialogues are necessary and useful, but they have a tendency to be dominated by a few central themes to the detriment of less acute problems that may be of lower significance to some, but that does not mean that the themes are irrelevant. In addition, a possible use could be to investigate the relations between and experiences or views of different categories of health professionals or care workers in the home-based services.

All informants who took the perspective of using a matrix as a structure for dialogue between care workers also raised the theme of facilitation. They expressed concern that facilitating would need to be based on some specific skill set. However, this is not different from other situations where one wishes to use input from employees in developing the workplace.

A different perspective was to see the potential value of the Ethical HTA Matrix as a planning and documentation tool to prepare for the introduction of an assistive technology and structure the discussion with technology suppliers as well as mapping potential pitfalls. A similar, albeit somewhat different approach, was to apply the matrix as an intermediate mapping tool before setting out on a gain's analysis and risk management as it provided a (too large) overview over the values at stake for the relevant stakeholders. One informant said that such work was often done more or less intuitively while the risk management and the analysis of gains had a rigorous structure. In such a use, the Matrix could be applied at an early stage in order to filter and select desired effects and to concentrate on some specific gains.

Even though several informants drew a picture where politicians set unrealistic goals or goals that would lead to a near-future impasse because of obsolete technological products, they did not mention

that the Matrix held a potential to be applied at a political level or as a dialogue instrument between themselves as experts and politicians.

3.4. The Processes of Filling in the Matrix

As will be further developed in the next section, the systematic approach to the documentation of knowledge triggered interest for all informants except one. As mentioned above, there clearly exists sources of knowledge concerning the assistive technologies internally in companies and in municipalities to which outsiders do not have access. Questions are related to the creation of the presented matrix related to the literature searches, the amount of sources, the validation process, the workload, and the possible validity of the findings. However, some informants said that the main challenge in assistive technologies is not so much how to systematize what is known, but rather to bring the practical experiences with assistive technologies from the care workers to the decision-makers, and then to act on this knowledge in order to create improved services.

I emphasized that the content in the Matrix built substantively upon the Socratic approach [22,46, 103], and that these were the questions guiding the search for the central value topics. However, this step was not commented upon by any of the informants. Not even those who saw it as a useful way of structuring information in planning and implementation processes.

When I presented the validation phase—obtaining knowledge from the different stakeholders of how they rated the different values—there was surprisingly little reaction to the process, but as accounted for above, the results with font sizes and positive or negative impacts triggered discussions.

4. Discussion

4.1. A Tool for Decision-Makers?

The main reaction to the matrix as containing an abundance of information might depend upon my presentation of it and the fact that I did little to structure the content beyond that of what the Socratic approach provided. However, as has been mentioned by Kaiser, Millar, Thorstensen and Tomkins [24], the Matrix is not specifically user-friendly, but it is rather its structuration approach that might provide clarity. In addition, it also raises the issue of what kind of expertise is needed for applying it. Some of the informants found some parts of the Matrix easy to understand and illuminating while others found that it had little relevance or that it was difficult to grasp. It might be necessary to have some training or knowledge of applied ethics in order to perform an analysis according to the Socratic approach and systemize the findings according to a Matrix. However, as one informant said, all forms of discussion that are intended to lead to an improvement require a form of moderating that is based on skills. What remains as a challenge is that the required skills might not be well or evenly distributed.

The degree to which one can conclude whether or not the Matrix is a valuable tool for decision-makers depends on what one perceives the decision-making problem to be. Traditionally in HTAs, the problem is framed as presenting the correct information in a relevant format to decision-makers.

Garrido and colleagues describe the rationale behind HTAs as "to optimize care using the available resources" [104]. There are several possible interpretations of what such a phrase might mean since both "care" and "resources" are terms that can be described with different meanings in different settings. In a later chapter, Røttingen, et al. [105] posed relevance as a primary quality in HTAs for decision-makers and policy-makers. An overarching question then becomes how one can provide information as to the optimization of care using the available resources in the most relevant manner. Undoubtedly, relevance is a difficult criterion as well. If one stays solidly inside a bio-medical and cost-effectiveness frame of mind, it is possible to analyze a procedure on how well it reduces or enhances a certain bio-medical process and assess the cost of the procedure and the assumed economic benefits for the health delivery system in short, mid and long range. However, in such a frameset, the ethics, values and social implications seemingly disappear, and when we open up for ethics and

social dimensions of medicine, things tend to become more complicated. In a much cited paper, Porter argues for a high value for patients as the highest goal of the health delivery system, with "value defined as the health outcomes achieved per dollar spent" [106]. This definition seems blind to the different usages of value that exist in current political debate and to the use of the health system as a means of political structuration of goods whereby disadvantaged groups should receive more aid than privileged groups—as well as alternate axiologies included in that of the HTA itself [103,107,108].

There are different epistemological cultures governing the ethical and the medical where the onus placed on evidence seems to prevail [51]. May, Mort, Williams, Mair and Gask [101] presented a sociological understanding of HTAs as a form of normative evaluation that connects to the ever-increasing emphasis laid on evidence for changes in practice. However, in addition to the epistemological point, Mol [109] sees a different and more fundamental divide in the ontologies of the objects of health research and the human body. Mol contrasts between "disease", which is what is inside the body, and "illness", which is the way we talk about, value and give meaning to "disease", and posits that these two might coexist in the same space and time, just as social values, ethics and clinical effectiveness in HTAs. May, Mort, Williams, Mair and Gask [101] emphasized that HTAs are not only about evidence, but also represent an inherent thought of modernization of treatments through research and innovation.

One of the strengths identified by some of the informants, though not all, was the Matrix's ability to provide an overview of both "illness" and "disease". In addition, other respondents saw the Matrix as providing an important first step in systematizing the different values or issues and their possible effects on different stakeholders. This first step would then provide the foundation for a form of governance mechanism with which they are more accustomed, such as risk management or value realizations' tools.

4.2. Where in the Processes

What emerged through the interviews on the innovation processes in the municipal health sector might improve the understanding of where one might open up for mutual learning, anticipation of problems, identification of alternatives, and discussions underlying outcomes with multiple values [31]. In the literature on RRI, a view on innovation as the creation of novel technological artifacts is very often presupposed [110]. However, in the health services, an important aspect of innovation is novel ways of working. As Wouters, Weijers and Nieboer [97] among others point out, technology implementation changes the working processes and thus might also affect nurses and care workers' values. Studies of Norwegian innovation strategies for ageing at home further indicate that there is a lack of structured approaches or tools to manage and include workers in the innovation processes [111]. Creating a space for organizing discussions around central values and their conceptualizations among health professionals seems to be a very relevant place for intervening in the innovation process. According to Blok and Lemmens [55], it is highly likely that different stakeholders have different priorities or interests, and they point out that this form of reluctance to cooperation based on strategic motives is not well discussed in RRI. In providing a structure that could open up for identifying the values and interests either as a tool for dialogue or as a tool for structuring experiences, the Matrix might also fill a space central to the innovation processes in healthcare.

Reijers, Wright, Brey, Weber, Rodrigues, O'Sullivan, and Gordijn [15] separate between ex-ante methods, intra methods and ex-post methods for distinguishing between ethics or value inclusion before, during and after product launches in research and innovation. What I understood from the interviews, was that there could be a place for the Matrix in a phase where prototypes are tested for improvement together with care workers and health professionals, which is then what Reijers et al. describe as the intra phase. Using a Matrix to structure these early experiences with a novel technology corresponds to a bottom-up version of the Ethical Matrix which leaves the participants to fill in every cell in the Matrix [35]. For such uses, they signal that the process might fall victim to partisan views or that the participants misunderstand the methodology with only open cells before them. It is precisely

in order to avoid misunderstandings and/or partisanship that I applied the themes from the Socratic approach that serve to specify what the values and issues at stake might be [22,23,46]. However, none of the interviewees expressed comfort that there was such a structured approach underlying the Matrix. In addition, the informants suggesting such a use said that it could be used for subjective experiences and as a basis for further discussions. As underlined by one informant, the Matrix allowed different views to co-exist without having to neglect one issue just because a different issue was under discussion. From the perspective of RRI, encountering and discussing different sets of values could enhance reflexivity among the actors in the health innovation system [13].

If one accepts that innovation is just as much a social activity as technological invention, then the planning and selection use mentioned by several informants would qualify it as an ex-ante method in Reijers et al.'s terminology [15]. In contrast to the bottom-up approach, this usage would qualify as top-down or desk-research-based use of the Matrix [35]. Behind the thinking on early-stage use of the Matrix, there are two different rationales, according to the informants. There were those seeing it as a mapping tool to systematize the current knowledge status in the field, and there was also the approach mentioned that the Matrix could identify central values that the municipality could aim at realizing for different stakeholders through introduction of an assistive technology. In this usage, the Matrix could become a vehicle for value-based governance if it is applied together with and validated by the relevant stakeholder groups. Such an approach would seem to be in accordance with what von Schomberg [7] sees as central to RRI with the realization of public values together with economic values. As an overall mapping tool of the distribution of potential impacts, it would be useful. However, one of the basic ideas behind the concept of ethical tools as well as structured tools is that they should lead to some type of discussion or action based on the outcomes of application of the tool [112,113]. If the Matrix with its colors and fonts becomes limited to indicating what we know and what we do not know, and striving to make every cell as close to green as possible, then it is more of an epistemic tool than a normative tool. Nevertheless, there is a possibility for reflecting upon alternative ways of achieving the relevant values.

If the difference between a strong and a weak form of RRI is how strong the links are between stakeholders and policy process, as suggested by Coenen and Grunwald [27], then the use of the Matrix for inclusion of workers' views and experiences into the decision-making context would qualify as strong, while the use of the Matrix as a mapping tool independent of stakeholder input would qualify as weak.

When it comes to the discussions during the interviews regarding knowledge and the existence of a range of unpublished local municipal studies or consultancy reports, there are some concerns. As the use of assistive technologies tends to understand life conditions within a biomedical rather than social frame [109], there seems to be a peril of conducting too-narrowly defined studies. In addition, implementation of assistive technologies depends on local features and the transfer from one context to another could be problematic. Obviously, there is a risk for ignoring unpublished studies when making knowledge reviews. Many technology developers are also reluctant to put their studies into the public domain while sharing these with decision-makers as they are aiming for patents or other forms of intellectual property rights. This situation makes it highly difficult to conduct independent audits or assessments of these solutions.

4.3. Experiences with the GPS System as Case

I have struggled with the reasons why the respondents did not discuss the proposed case of the GPS system more and the different findings from the literature. One obvious element is that I intended to discuss the methodology and not the case specifically since it is the Matrix that is the object for research. Furthermore, as one informant said, GPS localization is not an issue any longer in the public debate as was the case up until 5 years ago. Two of the informants would qualify as "issue advocates" in taking a very firm stance that safety for users was the central social and political question and GPS systems could and would deliver such safety (see Pielke [114]). However, several

of the informants wished to know what was behind the red colors, i.e., what is not known or are just hypotheses concerning GPS localization systems. This type of epistemic use of the Matrix points toward the possible uses for other tools or instruments that might provide insights into uncertainties and risks. As narrated above, several informants raised very specific points on which they disagreed or did not understand properly. By using these questions and queries as indicators, the proposal by Fitzgerald and Adam [9] to introduce forms of decision-support systems as a means to enhancing responsibility in planning, procurement and implementation of assistive technologies seems promising since it could contribute to steering decision-making towards addressing good aging at home with a higher epistemic quality.

4.4. A Brick in the Bridge

Demers-Payette, Lehoux and Daudelin [13] point to the different logics in health and industry where the former is stability seeking and the latter is risk- or gain-seeking. They recommend to address the differences in the value systems and the social practices in the health care system and the innovation chains where health care is strongly resistant to change with a focus on medical needs while industry turns around rapidly with a focus on lucrative opportunities. The expression of frugality as an ideal would qualify as typical of the health care system in this respect, while the view on the business case could illustrate the industry. Accordingly, there seems to be a gulf between these logics that could be bridged. The question is then to what extent the Matrix could be successful in contributing to making such a bridge. As mentioned above, respondents identify the Matrix as a tool for intra-stakeholder deliberation. A different question is how it could work as an inter-stakeholder tool for addressing value differences. The Matrix has already been applied in inter-stakeholder workshops [24,34]. What was most indicative of the potential for inter-stakeholder utility, I believe, is the amount of time and interest the respondents paid to the different stakeholder groups and if they saw the other groups as relevant. In the interviews, most respondents acknowledged the other stakeholders as relevant, and the representatives from the municipalities expressed concern over stifling innovation through an increasingly hierarchical market with a few central providers using the smaller firms as subcontractors. On the other hand, the technology developers expressed concern over instances of too strong-handed use of procurement power. These two latter instances could well be understood as conflicts based on differences in power that supersede the analysis by Demers-Payette, Lehoux and Daudelin [13], who investigated internal logics as well as Chatfield, et al. [115] who described an industry very eager to cooperate with the stakeholders. According to Blok and Lemmens [55], such differences in power are inherent to innovation processes and "[i]t is presumable that power imbalances are especially at stake in the case of grand challenges, exactly because of the different problem definitions and different value frames of the stakeholders involved" [55]. The challenge is consequently to find some domain where the parties might become responsive to each other. Here, it is noteworthy that some informants saw dignity as an essential category to which they seemed to attach large significance. Dignity constitutes both a central business case for suppliers and developers of assistive technologies and a central mandate for the health care system. However, as Sontag [116] accentuates, our perceptions of pain and dignity are phenomena determined by their surrounding narratives and frames. This background dependency would then presuppose a discussion of the frames, visions and rationales behind engaging in and showing concern for dignity rather than approaching dignity as a discrete entity that might be addressed directly. A central ambition within RRI is to discuss such framing effects. However, these effects seem difficult to address through standardized tools such as the Matrix alone (see Zwart, Landeweerd and Rooij [93]). In my combined approach here, one could investigate such framing effects through an increased attention to the theme "Is the symbolic value of the technology of any moral relevance?" raised in the Socratic approach (see Appendix A) [22].

4.5. Methodological Considerations and Limitations

The main limitation in this study is the number of interviewees and their selection. Thirteen respondents might not provide an exhaustive presentation of the possibilities for intervening in health innovation processes nor for the possible uses of the current Matrix. In addition, I selected respondents from the area surrounding the country's capital, which has a much higher population density than other parts of Norway, but then again it is lower than many other parts of the world. Furthermore, no respondents expressed concerns over lack of funding for assistive technologies—a situation I could imagine might be different in other places. These considerations might affect the transferability of the findings.

Since I approached the interviewed experts in a co-constructivist mode with open questions and some overarching themes to discuss, with the assessment methodology and its possible uses at the center of attention, other aspects suffered from lack of time and attention (see above). I could have used a different approach with a clearer focus on the case, but that would affected the attention to the methodology. In addition, the literature searches underlying the Matrix and its completion were based on GPS systems in general and some GPS systems with next of kin as first responders. I want to signal that there is no such thing as a generic GPS system, but a range of different solutions with their own composition and designs implemented in individual health care systems with unique organizational features. Furthermore, the case and validation process for the case was limited to one town and within only one health care system. This limited scope might have affected the validated Matrix (Appendix B) and consequently the informants' view on the content of the Matrix. A more thorough validation process would have placed additional strain on health professionals and care workers, as well as on persons with dementia, and I decided not to burden already strained or fragile persons.

5. Conclusions

Seen from the perspective of RRI, the current contribution finds that there is support among central stakeholders in assistive technologies for structured approaches that might secure the realization of economic and public values. Explorations into the configuration of responsibility in innovation process are still in their infancy, and this is particularly so in the public sector where the conditions for innovation are radically different from the private sector. The main differences are on the one side that citizens cannot just opt for a different country or a different municipality as they can with respect to the acquisition of private goods and services, and on the other side that authorities are legally mandated to provide some goods or services to its citizens regardless of their ability to pay, give feedback or even desire these services. Nevertheless, innovation also takes place in the public sector, and in this contribution, I have shown that there seems to be a place for responsibility in the innovation pathways in the health sector. The main place for normative considerations and reflexivity is in the interaction with health professionals and care workers during the implementation of novel assistive technologies. A strength of the Matrix in this respect is that it might pay attention to both the physiological and socio-cultural aspects of disease or illness simultaneously, whereas more epistemic dimensions of responsibility and knowledge or uncertainty management concerning the affected values might in addition benefit from more systematized approaches, such as a Matrix.

An additional factor for RRI could be to study the effect of different concepts in the health care system. For example, the introduction of *frugality* as an ideal could well open up novel avenues for understanding how decision-makers understand their mandate and how private values affect public actions.

Even though the integration of the Socratic approach into the Matrix did not receive any response from the informants, this feature remediated to some extent the concern expressed by Mepham, Kaiser, Thorstensen, Tomkins and Millar [35] over partisanship and misunderstanding since it directs the users to what are the relevant concerns.

Concerning the ability of the Matrix to build bridges between health and industry, I remain a bit skeptical due to the power struggles that seem to be present. If these power aspects could be addressed

and the discussion would revolve around the different rationales or frames for intervening in dementia care, one might be somewhat more optimistic. However, if this transformation first takes place, there would be little need for a tool such as the Matrix because then the different parties would already have acknowledged each other's values.

Some changes are however necessary to apply a structure such as the Matrix in the innovation systems in assistive technologies. When it comes to the display of information, some findings are relevant such as a limited color range and a limited number of facts and values. The issue of critical factors is specifically a central one in assistive technologies due to the large room for maneuvering for local authorities in adapting service structures to these solutions. On a substantive level, the requirements for introducing such structured frameworks would demand several experiments at the municipal level in terms of opening up deliberative structures together with the care workers and health professionals—as well as challenging existing cognitive, epistemic and normative divisions of labor between these and the workers and the employer.

Testing such a modified approach then remains. In addition, in testing approaches such as the Matrix in healthcare, one should proceed with some caution for (at least) two reasons. The first reason is that this is a system under constant pressure both to deliver quality services and to adapt to the changing nature of service delivery. Consequently, one should refrain from placing burdens on the services and the personnel. The second reason for caution is that even though the Matrix might function as a transparent tool concerning the steps, it follows the outcomes of a matrix-process into the decision-making process, which also needs to be clear and transparent. Without structures in place for such an outcome transparency (see e.g., Rowe and Frewer [100]), the whole process (and the products) might lose legitimacy.

Conflicts of Interest: The author declares no conflict of interest.

Appendix A. The Ethical HTA Matrix

	Well-Being	Dignity	Fairness
Primary user	What are the effects according to purpose? What resources are needed? Q1 What is the severity of the condition to be addressed? May this change? Q8 What other benefits or harms are there to the primary user? Please consider the implementation, use or withdrawal of the technology Q4 Does the technology involve disease prediction? How are false test results, overdiagnosis, futile or harmful treatment addressed?	Q15 Is the symbolic value of the technology of any moral relevance for the primary user? (Prestige, status?) Q16 Are there moral challenges related to components of a technology for the primary user? Q17 Are there any related technologies that have turned out to be morally challenging with respect to the direct user? Q12 Does the technology in any way challenge or change the relationship between patients and health care professionals or between health professionals? Q10 Will there be a moral obligation related to the implementation, use, or withdrawal use of a technology? (e.g., consent) Q6 Does the technology challenge a user's values or social relations—or might it affect a user's religious convictions? Q5 Does the implementation, use, or withdrawal of the technology challenge a user's autonomy, integrity, privacy, dignity or interfere with basic human rights? Q3 Might the widespread use of this technology change user's social roles? (Does it change the prestige or status, the conceptions, prejudice or status of persons with certain characteristics [e.g., old age]?)	Q9 Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered legislation? Q7 How does the implementation, use, or withdrawal of the technology affect the distribution of health care regarding the users? (Justice in allocation, access, and distribution). Q2 What patient group is the beneficiary of the technology? (Are they particularly vulnerable, have low socioeconomic status or priority, or are they subject to prejudice?
Health professionals (or care workers)	What are the effects according to purpose? What are the resources needed? Q8 What other benefits or harms are there to the health professionals? Please consider the implementation, use or withdrawal of the technology.	Q20 How does the technology contribute to or challenge or alter health professional's autonomy? Q15 Is the symbolic value of the technology of any moral relevance for health professionals? Q12 Does the technology in any way challenge or change the relationship between patients and health care professionals or between health professionals? Q6 Does the technology challenge health professionals' social or cultural values, institutions, or arrangements or does it affect their religious convictions? Q3 Does the widespread use of this technology change the role of health professionals? (Does it change the prestige or status of the disease, the conceptions, prejudice or status of persons with certain diseases?)	Q9 Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered legislation? Q2 What professional group will work with the technology? (Are they particularly vulnerable, have low socioeconomic status or priority, or are they subject to prejudice?)

	Well-Being	Dignity	Fairness
Health delivery system	What are the effects according to purpose? What are the resources needed? Q8 What other benefits or harms are there to the health delivery system? Please consider the implementation, use or withdrawal of the technology Frugality: Does the technology deliver greater value to more people using fewer resources? Does the technology presuppose a larger technological infrastructure?	Q11 How does the assessed technology relate to more general challenges of modern medicine? (Underdiagnosis, undertreatment, medicalization, overdiagnosis, overtreatment, reduced trust) Q20 How does the technology contribute to or challenge or alter health professional's autonomy?	Q9 Can the implementation, use, or withdrawal of the technology in any way conflict with existing law or regulations or pose a need for altered legislation? Q7 How does the implementation, use, or withdrawal of the technology affect the distribution of health care? (Justice in allocation, access, and distribution).
Technology providers	? Q8 What other benefits or harms are there to the technology providers? Please consider the implementation, use or withdrawal of the technology	?	Q21 What are the interests of the producers of technology (industry, universities)?
Next-of-kin	What are the effects according to purpose? What are the resources needed? Q8 What other benefits or harms are there to the next-of-kin? Please consider the implementation, use or withdrawal of the technology	Q12 Does the technology in any way challenge or change the relationship between users and next-of-kin or between next-of-kin?	Q7 How does the implementation, use, or withdrawal of the technology affect the distribution of health care? (Justice in allocation, access, and distribution).
Society as a whole	What are the effects according to purpose? What are the resources needed? Q8 What other benefits or harms are there to society as a whole? Please consider the implementation, use or withdrawal of the technology.	Q16 Are there moral challenges related to components of a technology that are relevant to the technology as such? Business model: Does the organisation that produces the innovation seek to provide more value to users, purchasers and society?	Q7 How does the implementation, use, or withdrawal of the technology affect the distribution of health care? (Justice in allocation, access, and distribution).
Climate	Decrease of greenhouse gas emissions through product lifecycle; Increase of greenhouse gas sinks		
Ecology	No parts of the product lifecycle cause unnecessary harm to the environment; A maximum of ecosystems to be protected through product lifecycle	Product lifecycle limits harm to nature to a minimum	No ecosystems suffer disproportionally more than others
Other stakeholders			

The Ethical HTA Matrix with structure from Mepham, Kaiser, Thorstensen, Tomkins, and Millar [36] and content decided by Hofmann, Droste, Oortwijn, Cleemput, and Sacchini [22], andHofmann [23] and supplemented with aspects from Responsible Innovation in Health Pacifico Silva, Lehoux, Miller, and Denis [18].

Appendix B. The Validated Matrix

Primary user	Welfare		Dignity		Justice	
Critical factors: Studies indicate that an average person with dementia might live at home up to one year though GPS	Live at home (+)	Some users might reside at home for a longer time	Able to ask for assistance (+)	Most find it easier to request assistance	Everyone with the same needs get proportionally equal access to the same services (?)	Without family living nearby, there is a need for public solutions
Critical factors User ability to benefit from GPS Abilities and habits: understanding traffic; going for walks Family living nearby	Mail, shopping, waste disposal (+)	Most experience increased mastery of daily tasks	Trusting the services (?)	It is uncertain how GPS increases trust in the services	Consent to use (+)	Ability to consent GPS tracking legally sanctioned
	Outdoor movement (+)	Most get around more	Decide what activities to partake in (+)	Several seem to partake in more activities		
Social connections nearby Understanding the design of the GPS tracker Ability to consent Personal convictions	Going for walks (+)	Those with the habit report more walking	Decide on the service measure (+)	GPS is a service measure where consent is central		
Functioning GPS system	Vacations (+)	It seems possible for more people to go on holiday	Decide where to go (+)	Increased opportunities for all to decide on where to go		
GPS accuracy and updating frequency	Be found (+)	Users are located and found	Contact with family (+)	Increased contact with family		
Organisation of health services Solutions for those without family living nearby	Affordable services (?) Experience that the service is worth the cost (+)	Many experience the service as good, but the quality seems variable	Contact with friends (+)	Most can maintain contact with friends		

Next of kin	Welfare		Dignity		Justice	
Critical factors: User's ability to benefit from GPS Well-functioning GPS system GPS accuracy and updating frequency Adequate training	Own safety (+)	Everyone experience increased safety	Safety for next of kin (+)	Everyone experiences increased safety	Adequate sharing of care burden (?)	Most experience less relief but little is known about the fairness of the arrangement
	Relief in caring (÷)	Most experience less relief	Freedom for next of kin (+)	Everyone experiences increased freedom		
Solutions for those without family living nearbyOrganization of health services	Own job / career (+)	Some find more time for work / career	Freedom (+)	Most experience more freedom		
	Time to remaining family (?)	Uncertain how many find time for remaining family	Peace of mind (+)	Peace of mind is the largest effect		
	Time to maintenance of GPS equipment (÷)	Several use time for maintenance and charging	Role changes in family (?)	Next of kin become carers–uncertain if it is negative or positive; it is a change		
			Knowing where next of kin is (+)	One has always the possibility to track		
			Understanding the services (+)	Most seem to understand the services better		
			Understanding the technology (+)	Most seem to understand the technology better		

Employees	Welfare		Dignity		Justice	
Critical factors: Employees Critical factors	Feeling safe at work (+)	Most feel safer at work	Freedom to provide healthcare (+)	Most experience increased time for healthcare	Users understand the legal grounds for the service (+)	Seems to be increased attention to consent with GPS
Well-functioning GPS system Configuration of GPS system to electronic patient register	Understanding the seriousness of alarms (÷)	With less knowledge of the user, the seriousness of alarms might become difficult to estimate	Understanding the technology (?)	Uncertain if the health workers increase their understanding	Next of kin understand the legal grounds for the service (?)	Uncertain whether next of kin become more informed about the legal aspects
Quality and structure of the control panel for the GPS system	Correct user location information (+)	Everyone can get a precise location	Adequate training in technology (?)	Uncertain what kind of training that is given	Next of kin understand the privacy regulations (?)	Uncertain if next of kin understand or maintain privacy rules
Organization of health services Financing of health services	Understandable technical infrastructure (?)	Uncertain if the infrastructure is understood	Recognising users' ability to benefit from the technology (?)	Very uncertain what happens with the match between user and solution	Agreement between service and next of kin on measure (÷)	Uncertain, but clear potentials for disagreements over the service
Ability to consent User contact	Competent colleagues (÷)	Can become difficult to find adequate personnel	Knowing the users' cognitive condition (÷)	There is a danger for lower understanding of users (if less contact)	Knowing who is responsible for control of the GPS (+)	Difficult to estimate, but work sharing seems to become clearer
Increased research Personal convictions regarding health services Adequate training	Vulnerability to technological errors (÷)	Increased vulnerability to errors Wrong location might be critical	Knowing the users' general condition (÷)	There is a danger for lower understanding of users (if less contact)	Routines for who is responsible for locating users (+)	The routines for responsibility sharing become clear
	Vulnerability to inherent limitations in technology (÷)	Increased vulnerability if GSM/GPS does not work indoors	Having adequate info on the user in case of alarms (÷)	Novel challenges seem to arise when workers know where a user is but not what s/he does	Routines for vacation and travels (÷)	It seems that changing routines might be a challenge
	Resources for rescue (+)	Less time is spent on rescues	More time to provide healthcare (+)	Most experience more time to provide healthcare		
	Next of kin assisting in finding users (+)	Next of kin will find users in most cases	Conflicts with users (+)	Less conflicts arise when users can move freely		
	No. of alarms (÷)	More devices with alarms = more alarms	Confidence with modernization of healthcare (+)	Work changes character with more attention to maintenance of devices		
	No. of false alarms (÷)	Most alarms are false alarms				
	Relaying on next of kin's knowledge (?)	Difficult to assess next of kin's knowledge				
	Adapt services to user (+)	Valuable tool for personal adaptation in most cases				
	Next of kin responding to alarms (+)	Next of kin participate to a large extent				
	Next of kin locating users (+)	Next of kin participate to a large extent				
	Cooperation with next of kin (?)	Next of kin participate to a large extent, but unclear if it improves to cooperation				
	Early intervention (+)	Early intervention is assumed to have positive effects				

Health system	Welfare		Dignity		Justice	
Critical factors: Organisation of health services Quality and struc-ture of the control panel for the GPS system	Efficient organization (?)	Not clear how GPS affects organization	Increased user quality of life (+)	Most users report increased QoL	Equal access to services for all citizens regardless of social situation (?)	Without family living nearby, there is a need for public solutions
Pricing mechanism with tech supplier Adequate training Early interventions Functioning GPS system Solutions for those without family living nearby	Efficient service (+)	Services seem to become more efficient if differentiated	Postponed need for adapted home (+)	A minority of users seems to reside at home for some time	User consent (+)	Increased attention to consent through tracking technologies
User ability to bene-fit from GPS User's abilities and habits	Efficient cooperation in the service (?)	The service cooperation is unclear	Postponed need for assistive living facility (+)	A minority of users seem to have postponed use for different housing		
	Robust technical infrastructure(	Vulnerability increases through multiple systems, but SafeMate Pro seems robust	Active users (+)	Most users become more active, but efforts are needed for those without the habit		
	Easy upscaling of users (+)	The system seems flexible when it comes to upscaling, but little research	Less practical assistance (+)	Flere klarere hverdagsgjøremål, men er avhengige av tjenester for å opprettholde aktivitet		
	Economic savings (+)	Uncertain, but there are indications of savings–related to home residency	Longer user residency at home (+)	A minority seems to be able to reside at home for some time		
	Affordable upscaling of users (÷)	Uncertain, but there does not seem to be any savings related to upscaling as such	Early intervention (+)	Early intervention is expected to increase positive effects		
	Staff reduction (÷?)	Very unsure, but little indicates fewer employees	Finding persons faster (+)	Users are located faster		
	Certainty regarding expenses (?)	Very uncertain, and especially due to rapid technological changes	Quality control of services (?)	GPS increases the need for the control of services. Little research on the quality control.		
	Certainty regarding future savings (?)	Very uncertain, also affected by social and technological changes	Creating new services (+)	Re-organisation of health services seems to be a recurring consequence		
	User payment for services (?)	Very uncertain how user payment is decided; local variations	Coordinating services with technology (?)	GPS increases the need for the coordination of services, but little research on the actual practice,		
			Employees mastering technologies (?)	GPS demands increased tech mastery, but unclear if mastery takes place		
			Cooperation with next of kin (+?)	Clearly increased cooperation, but there remains challenges of coordination and quality control.		

Tech supplier	Welfare		Dignity		Justice	
Critical factors Procurement policies	Assured income (?)	Uncertain, but most agreements are over 3 years or longer	Recognition for suppling important solutions (?)	Uncertain, depends on the dialogue with procurer	Competitive rules independent of products (?)	Uncertain as many municipalities already have specific systems
	Avoid larger uncertainties (?)	Very uncertain, but the terms of agreement tend to be clear–however novel challenges often arise	Proximity to users (?)	Uncertain, depends on follow up by both parties	Fair use of procurement power (?)	Uncertain, large procurer might set demanding terms
	Avoid long-term expenses (?)	Very uncertain since it depends on both agreements for development and unforeseen events	Proximity to procurers (?)	Uncertain, depends–in addition to business culture–on personal factors	Fair contracts (?)	Uncertain, but long-term agreements would indicate some fairness
			Call for tender expressed in terms of desired functions and not solutions (?)	Uncertain, presumes that procurer leaves a large amount of discretion to the tech supplier		

Climate	Welfare/dignity/justice	
Critical factors Life cycle analysis Procurement policies	Lower emission of greenhouse gases (÷?)	Fairly certain increased emissions through plastic material Uncertain, but could reasonably lead to less driving Very likely less search operations Very likely increased usage of electric power
	Increased uptake of greenhouse gases(÷)	Fairley certain that there will not be any significant uptake of greenhouse gases

Ecosystems	Welfare		Dignity		Justice	
Critical factors Life cycle analysis Procurement policies	Avoid unnecessary harms to ecosystems (÷?)	Uncertain what recycling arrangements there are Spread of heavy metals	Limit harms to the environment to a minimum (÷?)	Reasonably certain that the heavy metals in phones and tracking devices will increase pollution	No ecosystems to suffer disproportionally to others (÷)	Reasonably certain that places where central metals are mined will suffer more than others
	Protect as many ecosystems as possible (?)	Uncertain how the pollution is distributed				

Certainty of effect	Hypothesis	<25 % certain	Ca 50 % certain	>75 % certain	Broad consensus
	236, 112, 99	230, 126, 34	247, 220, 111	130, 224, 170	82, 190, 128
Large variation in validation	236, 112, 99	230, 126, 34	247, 220, 111	130, 224, 170	82, 190, 128

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